



Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation

Annex VI



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Erratum

RPA has undertaken minor editing on page 33 of Case Study 11 (Annex VI) and removed original Table 3-4, which provided incomplete details.

Annex VI Glossary

ADI	Acceptable Daily Intake
ADR	European Agreement on the international transport of Dangerous Goods by Road [note: acronym derives from the French]
AEL	Adverse Effect Level
AISE	International Association for Soaps, Detergents and Maintenance Products
AOEL	Acceptable Operator Exposure Level
AOP	Adverse Outcome Pathway
ARfD	Acute Reference Dose
ASO	Accredited Stakeholder Organisations
ATE	Acute Toxic Estimates
ATP	Adaptation to Technical Progress
BAF	Bioaccumulation Factor
BAT	Best Available Technique
BAuA	Federal Institute for Occupational Safety and Health (Germany)
BCF	Bioconcentration Factor
BCOP	Bovine Corneal Opacity & Permeability Assay
BEUC	The European Consumer Association
BIS	UK's Department for Business, Innovation and Skills
BLM	Biotic Ligand Model
BPR	Biocidal Products Regulation
BMF	Biomagnification Factor
BOELVs	Binding Occupational Exposure Limit Values
BPC	Biocidal Products Committee
BREF	Best Available Techniques Reference Documents
BRIC	Brazil, Russia, India, China
CA	Competent Authority
CAD	Chemical Agents Directive
CAR	Competent Authority Report
CARACAL	Competent Authorities for REACH and CLP
Carc.	Carcinogen
Cat	Category
CCA	Cumulative cost assessment study
CEEMET	European Employers Association representing Metals, Engineering and Technology based industry
Cefic	European Chemical Industry Council
CEPA	European Council of Paint, Printing Inks, Artist's Colours Industry
CIFs	Child impeding fastenings
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CLH	Harmonised Classification and Labelling
CLI	Classification and Labelling inventory
CLP	Classification, Labelling and Packaging
CMD	Carcinogen and Mutagen Directive
CMR	Carcinogenic, Mutagenic or Toxic for Reproduction
COM	Commission
Concawe	Conservation of Clean Air and Water in Europe
CoRAP	Community Rolling Action Plan
Corr.	Corrosive
COSME	Competitiveness of Small and Medium-sized Enterprises
CP	Cosmetic Products Regulation
CRC	Child Resistant Closures

CRED	Criteria for Reporting and Evaluating Ecotoxicity Data
CRF	Child Resistant Fastenings
CSR	Chemical Safety Report
D4/D5	Siloxane compounds
Dam.	Damage
DAR	Draft Assessment Report
DB-ALM	DataBase Service on ALternative Methods
DecaBDE	Decabromodiphenyl Ether
DGUV	German Social Accident Insurance
DNEL	Derived No Effect Level
DOT	Department of Transportation
DPD	Dangerous Preparations Directive
DR	Detergents Regulation
DSD	Dangerous Substances Directive
E(L)C ₅₀	Effect (Lethal) Concentration showing effects on 50% of the test individuals
EC	European Commission
eCA	evaluating Member State Competent Authority
ECHA	European Chemicals Agency
ECJ	European Court of Justice
ECPA	European Crop Protection Association
EEA	European Environment Agency
EEB	European Environmental Bureau
EEE	Electrical and Electronic Equipment
EEN	Enterprise Europe Network
EFSA	European Food Safety Agency
EMA	European Medicines Agency
EoW	End of Waste
EQS	Environmental Quality Service/Standard
ETUI	European Trade Union Institute
EU RAR	European Union Risk Assessment Report
EU	European Union
EUH	European Union Hazard
EURL-ECVAM	European Union Reference Laboratory for Alternatives to Animal Testing
Eurometaux	Association Européenne des Métaux
EU-TGD	EU Technical Guidance Document for Risk Assessment
FCM	Food Contact Materials
FECC	European Association of Chemical Distributors
Flam.	Flammable
GaAs	Gallium arsenide
GCL	Generic Concentration Limit
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
GLP	Good Laboratory Practice
HBCDD	Hexabromocyclododecane
HCB	Hexachlorobenzene
HCH	Hexachlorocyclohexane
H-criteria	Hazard Criteria
HEAL	Health and Environment Alliance
HELCOM	Helsinki Commission
HMP	Human Medicinal Products
HP	Hazardous Properties
HSE	Health & Safety Executive
H-statements	Hazard statements

IA	Impact Assessment
IARC	International Agency for Research on Cancer
IATA	Integrated Approach to Testing and Assessment
ICE	Isolated Chicken Eye test
IED	Industrial Emissions Directive
ILA	International Lead Association
IOELVs	Indicative Occupational Exposure Limit Values
ISO	International Organisation for Standardisation
JRC	Joint Research Centre
LC50	Lethal Concentration, concentration at which 50% of the test organisms die
LD50	Lethal Dose; dose at which 50% of the test organisms die
LEV	Local Exhaust Ventilation
Liq.	Liquid
LoW	List of Waste
MAPP	Major Accident Prevention Policy
MARS	Major Accident Reporting System
MBM	N,N-Methylenebismorpholine
Me	Metal ion
MoS	Margin of Safety
MPa	Mega Pascal
MRL	Maximum Residue Level
MS CA	Member State Competent Authority
MS	Member State(s)
MSC	Member State Committee
Mut.	Mutagenic
NAMs	New Assessment Methods
NGO	Non-Governmental Organisation
NHL	non-Hodgkin's lymphoma
Ni	Nickel
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NTB	Non-Tariff Barrier
NTM	Non-Tariff Measures to Trade
NVWA	Netherlands Food and Consumer Product Safety Authority
OECD	Organisation for Economic Cooperation and Development
OEL	Occupational Exposure Limit
OPC	Open Public Consultation
OSH	Occupational Safety and Health
OSPAR	Oslo Paris Convention
Ox.	Oxidative
P and H	Precautionary and Hazard
PAN	Pesticide Action Network
PAR	Product Assessment Report
PBT	Persistent, Bioaccumulative and Toxic
PBTs	Persistent, Bioaccumulative and Toxic substances
PCB	Polychlorinated biphenyl
PCCs	Poison control centres
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanesulfonic acid
PHS	Priority Hazardous Substance
PIC	Prior Informed Consent Regulation
PNEC	Predicted No Effect Concentration
POPs	Persistent Organic Pollutants
PPAMS	Plant Protection Products Application Management System
PPE	Personal Protective Equipment

PPPR	Plant Protection Products Regulation
PPPs	Plant Protection Products
P-statements	Precautionary statements
PT	Product Type
QQs	Qualifying Quantities
QR code	Quick Response code
QSAR	Qualitative Structure Activity Relationship
R&D	Research & Development
RAC	Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation & Restriction of Chemicals
Rep. Exp.	Repeated Exposure
Repro.	Reproductive
RIVM	National Institute for Public Health and the Environment (Netherlands)
RMM	Risk management measure
RMOA	Risk Management Options Analysis
RMS	Rapporteur Member State
RoHS	Restriction of Hazardous Substances in Electrical and Electronic Equipment
ROI	Registry of intentions
RPA	Risk & Policy Analysts
SACKI	Solvent Abuse Can Kill Instantly
SCCS	Scientific Committee for Consumer Safety
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCHER	Scientific Committee on Health and Environmental Risks
SCL	Specific Concentration Limit
SCOEL	Scientific Committee on Occupational Exposure Limits
SDS	Safety Data Sheet
SECR	ECHA secretariat
SED	Systemic Exposure Dosage
SKUs	Stock Keeping Units
SMEs	Small and Medium Sized Enterprises
SPC	Summary of Product Characteristics
STOT RE	Specific Target Organ Toxicity – Repeated Exposure
STOT SE	Specific Target Organ Toxicity – Single Exposure
STOT	Specific Target Organ Toxicity
SVHC	Substance of Very High Concern
T/D	Transformation Dissolution protocol
TCEP	Tris(2-chloroethyl)phosphate
TCPP	Tris(2-chloro-1-methylethyl)phosphate
TDCP	Tris[2-chloro-1(chloromethyl)ethyl]phosphate
TDG	Transport of Dangerous Goods
Tox.	Toxicity
TSD	Toy Safety Directive
TTIP	Transatlantic Trade and Investment Partnership
TWD	Tactile Warnings of Danger
UBA	German Environment Agency
UEAPME	European Association of Craft, Small and Medium-sized Enterprises
UK	United Kingdom
UN GHS	United Nations Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
UN	United Nations
UNCTAD	United Nations Conference on Trade & Development
US EPA	Environmental Protection Agency of the United States
US OSHA	United States Occupational Safety & Health Administration

US	United States
VCI	Verband der Chemischen Industrie e.V.
VMP	Veterinary Medicinal Products
vPvBs	Very Persistent and Very Bioaccumulative substances
VSA	Volatile Substance Abuse
WEEE	Waste Electrical and Electronic Equipment
WEN	Women's Environment Network
WFD	Water Framework Directive/ Waste Framework Directive
WG	Working Group
WHO	World Health Organisation
WHO/IPCS	World Health Organisation / International Programme on Chemical Safety
WoE	Weight of Evidence
ZnO	Zinc oxide
zRMS	zonal Rapporteur Member State

Case Study 1:
Comparison of implementation of
UN GHS in the EU and other key economies

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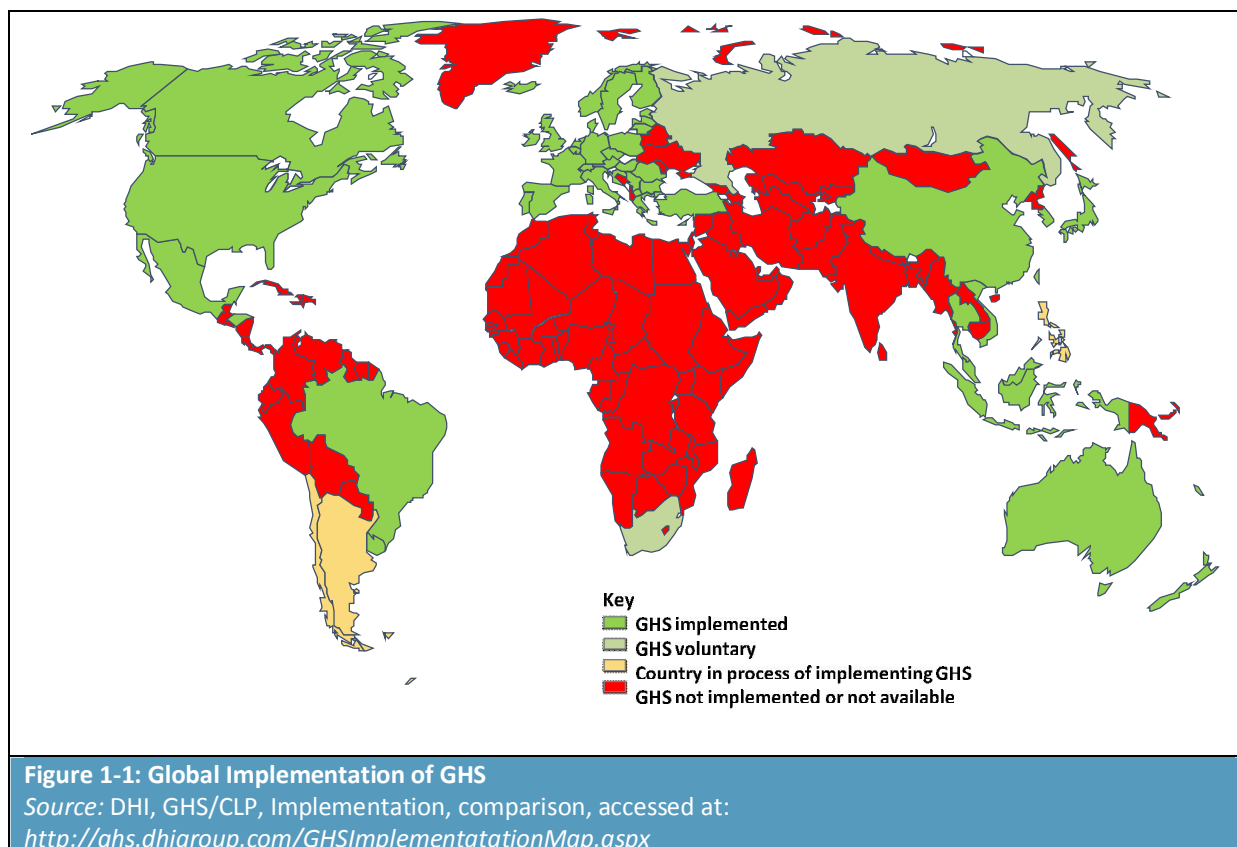
1 Introduction to Case Study

1.1 Overview of GHS

The UN GHS (Globally Harmonized System of Classification and Labelling of Chemicals) was adopted in 2002 (and published in 2003) in recognition of the need for a more globally harmonised approach to chemical risk and hazard management due to the increasingly globalised trade of chemicals. GHS is intended to promote a more uniform way of managing the risks and hazards of chemicals, whilst also encouraging trade and competitiveness and improving human health and protection of the environment. However, the GHS, through its building blocks approach, offers significant flexibility. The 'GHS building blocks approach' is so-called because it allows countries and regions to choose the GHS hazard categories which best serve their domestic needs, whilst also meeting the requirements of the GHS in terms of cut-off values, concentration limits and label elements.

The map presented in Figure 1-1 illustrates global implementation of GHS. It is evident that implementation of GHS is concentrated in North America, Europe and East/South East Asia which are the main chemicals importers and exporters in the global economy.

For the full list of building blocks which have been adopted by different countries, please see Annex 1. As discussed further below, there are some key differences in the adoption of hazard categories (or building blocks) across the countries or regions that have implemented GHS (see for example Table 2-2).



1.2 Overview of case study

This case study is part of the work carried out to inform the evaluation of GHS implementation as part of Task 1 to the study. It looks at the following four aspects of implementation individually and then together to provide a more comprehensive assessment of their impact on international trade of chemicals and the competitiveness of the EU chemicals industry:

1. Differences in adoption of GHS building blocks;
2. Differences in transition times for adopting GHS and revisions to GHS;
3. Differences in labelling and packaging requirements; and
4. Differences in classification requirements.

Impacts of differences in the take-up of building blocks

The GHS permits countries and regions to choose which hazard classes or hazard categories to implement and include within their system, in order to serve domestic needs. It is thus not necessary to adopt all 'building blocks', but those adopted should be consistent with the requirements of GHS (cut-off values, concentration limits and label elements). This case study focuses on the differences in impacts stemming from the EU's take-up of building blocks related to transport, workers, environment and consumers compared to the more limited take-up of only transport and workers by the US and Canada, for example.

Impacts of differences in transition times

The GHS is continually discussed within a sub-committee responsible for considering further amendments as part of two-yearly revisions and up-dates which may include the introduction of new building blocks or other changes to specific requirements (i.e. cut-off values, etc.). These revisions are adopted within the EU through Adaptations to Technical Progress and, at the EU level, decisions are made as to whether or not to adopt all (or any) of the revisions proposed by the GHS sub-committee. This element of the case study will consider the following issues:

- The appropriateness (effectiveness and efficiency) of having ATPs every two years, rather than more often or less often; and
- The transition times allowed for implementation of changes in wording of hazard and precautionary phrases, new hazard category building blocks (in the future) and the practical implication of these, as well as the costs and benefits of their adoption in relation to human health, the environment and international trade.

International variations in labelling and packaging requirements

There are also some significant differences in labelling requirements across countries. Some countries have set minimum GHS label size requirements for packages with different packaging capacities. This includes setting additional requirements on GHS label pictogram size and font size. In addition, because the take-up of options varies across countries, the information requirements for labels on the same product can vary considerably. Such differences in labelling information and size requirements may act as a non-tariff barrier to trade, or result in significant additional cost burdens for suppliers of small packages.

International variations in classification requirements

The UN GHS “Purple Book” allows countries to choose from a range of cut-off limits and concentration limits. This means that some countries classify mixtures more stringently than others which can have consequences for labelling and packaging as well as potentially leading to differences in the protection of human health and the environment.

1.3 Aims of the case study

The aim of this case study is to support the analysis of CLP in terms of the following evaluation questions:

- To what extent does the EU legislative framework meet its objectives in relation to the functioning of the single market?
- To what extent has the chemicals legislative framework been effective in facilitating international trade of chemicals?
- To what extent has the chemicals legislative framework contributed to international competitiveness of the chemicals industry?
- To what extent has the chemicals legislative framework contributed to innovation in the chemicals industry?
- Are there unnecessary regulatory burdens?
- What are the costs and benefits associated with the implementation of the legislative framework for chemicals? To what extent are the costs proportionate to the benefits? What are the key drivers for those costs and benefits?

2 Methodology

2.1 Countries considered in case study

The countries considered in this case study for comparison with the EU are: Australia, Brazil, Canada, China, Japan, Russia and the USA. These countries were chosen on the basis of their position on the global market for chemicals as well as their importance to the EU chemicals industry as trading partners. Switzerland and Turkey were considered but Switzerland has adopted the same building blocks as the EU, as has Turkey, with the exception of two physical hazards (Chemically unstable gases, Categories A and B).

2.2 Approach

2.2.1 Key differences

The first part of this case study is to map the key differences in the way GHS has been implemented by the countries of interest to this case study. This entails:

1. **Mapping the key differences in the take-up of GHS building blocks:** this includes mapping the sectors for which GHS applies in each country;
2. **Mapping the timing of GHS implementation:** we consider both the initial adoption of GHS in each country and then look at the latest revisions to GHS adopted in each country and the transition periods for adopting these changes;
3. **Outlining differences in labelling requirements:** differences have been established in terms of the mandatory label contents, P and H statements and label dimensions; and
4. **Outlining differences in classification requirements:** we look at the aspects of chemicals classification which differ across countries including the way in which mixtures are classified (in terms of cut-off values and concentration limits).

2.2.2 Non-tariff measures applied to chemicals and chemical products

After establishing and presenting the key differences in various aspects of GHS implementation, we then present data for the number of non-tariff measures to trade (NTMs) which are enforced on chemicals and chemical products and how many of these are linked to labelling and packaging. This is inspired by the methodology used in the 2006 GHS Impact Assessment (hereafter referred to as the 2006 IA) to estimate the impacts of GHS on international trade. Data on NTMs is taken from the UNCTAD/WITS database for each country of interest. This data also allows us to examine which country imposes the greatest number of NTMs on chemicals. By detailing data on the number of NTMs, we quantify the importance differences in labelling requirements for international trade.

2.3 Information requirements

This case study has been carried out through a mixture of desk-based research, interviews and targeted consultation. A combination of qualitative and quantitative data is needed to conduct a thorough assessment under this case study. Desk-based research entails the collection of available data and a review of existing literature relating to this topic. Sources of such data which have been reviewed include, but are not limited to, the information collection exercise/data requests sent out

to stakeholders; impact assessments conducted by individual countries/regions; national and international databanks such as World Bank, IMF, Eurostat; literature review.

2.3.1 Stakeholder Consultation

As part of this case study, interviews and discussions (either in person, by phone or by email) were held with the following stakeholders to provide further insight into the issues uncovered from the desk-based literature review and the responses from the targeted questionnaires:

- AISE
- Cefic
- CEPE
- Concawe
- Cosmetics Europe
- FECC
- ECPA
- UEAPME
- UN GHS
- US OSHA

The UN GHS Secretariat within the UN Economic Commission for Europe (UNECE) was asked to participate in consultation for this case study. Their preferred method for conducting this consultation was to provide written answers to the consultation questions. These responses are reproduced verbatim in blue boxes (as this was preferred) in relevant sections and are a pivotal foundation for the analysis drawn in this case study.

Similarly, the United States Occupational Safety and Health Administration (OSHA) was also approached for consultation. They provided us with written answers to our questions, as well as participating in a telephone interview to follow up on their responses. Where relevant, their responses have also been reproduced verbatim in blue boxes.

2.4 Limitations

In order to understand the true effect of CLP and GHS on the competitiveness of the European chemicals industry, we would require detailed data on the costs incurred by EU and non-EU companies pre-GHS in relation to classification, labelling and packaging obligations with regards chemical products placed in both domestic and foreign markets, and how those have changed post-GHS implementation. This data would enable comparison on two vectors: firstly, one would compare the costs incurred by industry before and after GHS. Secondly, one would compare the differences in pre- and post-GHS costs between EU and non-EU companies.

EU companies contacted during consultation were unable to provide such data as mechanisms are not in place to collect such information, in addition, implementation deadlines have not been reached in all countries. Furthermore, although a questionnaire was sent to non-EU companies involved in the manufacture and import of chemicals, an insufficient number of responses were collected, so the analysis of those received cannot be considered representative of the experiences of the chemical industry in other countries. In addition, the impact of GHS on international trade of chemicals is difficult to analyse given that trade flows of chemicals are dependent on many different factors, many of which are more influential than the implementation of GHS, thus making it difficult to isolate the impact of GHS on trade.

3 Differences in Adoption of GHS Building Blocks

3.1 Overview

A key premise underlying the adoption of the GHS through the CLP Regulation was that differences in global classification, labelling and packaging requirements led to non-tariff barriers to trade. A key question for this evaluation then is whether or not such non-tariff barriers to trade have been reduced as a result of the EUs move to the GHS. One fact that may have impacted on this is the degree to which different countries have adopted different building blocks.

The UN Secretariat provides the following reasoning for the ways in which GHS has been adopted in different countries, indicating that countries often implement GHS in a similar way to their trading partners.

UN GHS Secretariat

Experience with the implementation so far indicates that, generally speaking, implementation of the GHS in a major trading partner country or region often triggers implementation in its trading partners in a similar way. In other words, once the GHS is implemented in a given country or region (in particular if the country or region has a significant weight as regards chemicals manufacturing and trading), its trading partners start considering implementation in a similar way.

Countries which did not have a system in place for chemicals management, usually implement the GHS in full, adopting all hazard classes and categories.

Countries which already had a classification and labelling system before the GHS, try to accommodate its implementation to the systems they had previously, to minimise under or over-regulation of chemicals to the extent possible.

3.2 Mapping take-up of GHS building blocks

Mapping of different countries' adoption of GHS makes clear the differences in take-up of particular building blocks, allowing for easier identification of the potential variations in costs and benefits arising from variations in hazard classes adopted. As Switzerland and Turkey have adopted the same building blocks as the EU, they have not been mapped below. As Australia, the US and Canada have yet to adopt any of the environmental hazard classes of GHS, it is likely that companies from these countries will face additional classification, labelling and SDS requirements when trading with the EU and other countries which have adopted these classes. This also means that EU companies will need to modify their labelling information (as well as any safety data sheet) to reflect this difference in classification and labelling.

Table 3-1 shows that the following hazard categories have not been equally adopted across countries adopting GHS¹. A full list of GHS implementation can be found in Annex 1. Of note is that

¹ It ought to be noted that no country has adopted the GHS hazard classes *Desensitized explosives, Cat.1 to Cat.4*.

the EU is the only one of these regions/countries to not adopt the physical hazard 'Flammable liquids, Cat.4' and the health hazard 'Serious Eye damage/Eye Irritation, Cat. 2'.

Table 3-1: Differences in building block adoption								
Building Blocks	EU	RU	US	CA	CN	JP	BR	AU
Physical Hazard								
Chemically unstable gases, Cat. A								
Chemically unstable gases, Cat. B								
Aerosol, Cat. 3								
Flammable liquids, Cat. 4								
Health Hazard								
Acute toxicity, Cat. 5								
Skin corrosion/irritation, Cat. 1								
Skin corrosion/irritation, Cat. 3								
Serious Eye damage/Eye Irritation, Cat. 2								
Serious Eye damage/Eye Irritation, Cat. 2A								
Serious Eye damage/Eye Irritation, Cat. 2B								
Aspiration hazard, Cat. 2								
Environmental Hazard								
Acute hazards to aquatic environment, Cat. 1								
Acute hazards to aquatic environment, Cat. 2								
Acute hazards to aquatic environment, Cat. 3								
Long-term hazards to the aquatic environment, Cat. 1								
Long-term hazards to the aquatic environment, Cat. 2								
Long-term hazards to the aquatic environment, Cat. 3								
Long-term hazards to the aquatic environment, Cat. 4								
Hazard to the ozone layer								
<div></div> Building block adopted <div></div> Building block not adopted								

When asked about the reasons for choosing which building blocks to adopt, US OSHA indicated that they adopted those building blocks that reflected the scope of existing requirements with the aim of ensuring that there was no reduction in the level of protection provided to workers.

US OSHA
<p>Did the US carry out an impact assessment covering both costs and benefits of the adoption of GHS and did this consider different options regarding the adoption of GHS building blocks (e.g. were the relative costs and benefits of adopting the environmental building blocks assessed)?</p> <p><i>Yes, the U.S. conducted a cost assessment when it aligned the GHS with OSHA's Hazard Communication Standard. In the U.S. regulatory process, this assessment is called an Economic Analysis; it evaluates both costs and benefits of the rule. You can find the full analysis in Section VI of the preamble to the 2012 final rule, which begins on page 17605. You can view the preamble to the final rule at: http://www.osha.gov/FedReg_osha_pdf/FED20120326.pdf</i></p> <p><i>Yes, OSHA considered different options for the building blocks. However, one of the premises of the rulemaking was that OSHA would not reduce protections – therefore OSHA chose the building blocks that would encompass the scope of OSHA existing rule. The regulation of environmental hazards is done by our sister agency, the U.S. Environmental Protection Agency [EPA]. Since OSHA regulates workplace hazards, the assessment did not include the impact of adopting the environmental building blocks.</i></p>

3.3 Differences in sectors within the scope of the GHS

As the GHS covers all hazardous chemicals (i.e. chemicals meeting the criteria for classification against a hazard class in the GHS), there are four broad sectors to which it is relevant. Some countries have adopted the GHS across all four sectors, whilst in others the GHS has been adopted for only a few sectors – see Table 3-2. It should be noted that certain consumer products that have specific sectoral legislation (toys, textiles, cosmetics, food, pharmaceuticals, medical devices) are not covered by the GHS at the point of consumption. They will only be covered where workers may be exposed (workplaces) and during transport.

Table 3-2: Scope of the UNGHS and applicable industry sectors	
Sector	Comment
Transport	<ul style="list-style-type: none"> The UN Recommendations on the Transport of Dangerous Goods - Model Regulations takes precedence GHS parts expected to be adopted: GHS hazard classification criteria, GHS hazard pictogram
Workplace	<ul style="list-style-type: none"> Some authorities may not have jurisdictions over environmental hazards GHS parts expected to be adopted: GHS hazard classification criteria, GHS label elements
Consumer	<ul style="list-style-type: none"> Labels may include the core elements of GHS labels subject to some sector-specific considerations (i.e., instructions for use, expiration date) Risk-based labelling may be applied GHS parts expected to be adopted: GHS hazard classification criteria, GHS label elements
Pesticides	<ul style="list-style-type: none"> Pesticides labels may include the core elements of GHS labels subject to some sector-specific considerations (i.e. instructions for use, crops, expiration date) GHS parts to be adopted: GHS hazard classification criteria, GHS label elements, GHS safety data sheets required in workplace
Source: ChemSafetyPro, Introduction to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), accessed at http://www.chemsafetypro.com/UN_GHS_Chemicals_GHS_for_Dummies.html	

Table 3-3 below shows the sectors for which countries/regions have adopted GHS.

Table 3-3: Scope of the UNGHS and applicable industry sectors								
Sector	EU	RU	CA	US	CN	JP	BR	AU
Transport								
Workplace								
Consumer								
Pesticides								
	Building blocks implemented or can be used							
	Building blocks not implemented							
	Considering implementation							
<i>UNECE, GHS Implementation, accessed at</i> http://www.unece.org/trans/danger/publi/ghs/implementation_e.html <i>Canadian Centre for Occupational Health and Safety</i> <i>OSHA fact sheet, Hazard communication standard final rule, accessed at</i> https://www.osha.gov/dsg/hazcom/HCSFactsheet.html								

When asked why GHS was not adopted for consumer products, US OSHA noted that its regulatory framework is different from that which exists in the EU and that decisions regarding the adoption of GHS rely with different government bodies, as indicated below.

US OSHA

As you will know, the EU adopted the GHS across all building blocks with the aim of ensuring consistency in hazard communication. Do you know what the reasons were for the US not also adopting GHS labelling requirements for consumer products? Do you have any views on advantages of the US approach as opposed to the EU approach?

The U.S. regulatory process is different from that of Europe and other countries. Different agencies regulate different segments and not all agencies have adopted the UN GHS to date. The U.S. Department of Transportation regulates hazard in transport; the U.S. Occupational Safety and Health Administration regulates workplace hazards; the U.S. Environmental Protection agency regulate environmental hazards; and the Consumer Product Safety Commission regulates hazards to consumers. Although involved in the development of the GHS, the Consumer Product Safety Commission has not adopted the GHS at this time.

If global adoption of GHS building blocks became increasingly harmonised, do you think this would influence the US's adoption of building blocks into the future?

It may, but OSHA intends to maintain its current scope of the Hazard Communication Standard. Any change that OSHA would consider would include an analysis of the impact on the American worker and would go through the normal "notice and comment" rulemaking procedure. As for other sectors which adopted GHS, OSHA cannot speak for other Agencies.

As part of case study research, the study team looked at what type of analysis could be carried out in terms of differences in treatment of different product groups due to variations in the take-up of GHS globally. In order to establish whether differences in the adoption of GHS building blocks in, say, the US compared to the EU would lead to a higher or lower level of protection in one jurisdiction than the other would require extensive and detailed research into the structure of, in this example, US regulation, US risk assessment processes, US use of precautionary versus non precautionary approaches, etc. Against this background, it was not feasible to do anything robust on this within the available resources for this study.

3.4 Impact of differences in building block adoption

Differences in the take-up of the consumer building blocks in GHS may mean that EU suppliers of certain products may face very different packaging and labelling requirements than US suppliers of the same goods. As part of international trade, the requirements of the importing country would have to be met. This disparity in requirements may add to the costs of EU exporters or act as a non-tariff barrier to trade to importers of substances and mixtures (and goods) into the EU.

For example, suppliers may need to (or choose to) have multiple packaging or labelling production lines. With respect to packaging, this may be a particular problem for suppliers of products who must meet requirements concerning the use of child-resistant fastenings² or closures (CRF/CRC) and

² Sometimes also referred to as child-impeding fastenings - CIFs

the use of tactile warnings of danger (TWD). These are triggered by specific hazard classes, such as acute toxicity, skin corrosion, respiratory sensitisation, carcinogenicity cat. 2, flammable gases and liquids, etc. In such cases, suppliers must be able to demonstrate conformity with the standards set out in Annex II to CLP, with this requiring certification by a laboratory. If similar requirements do not apply outside the EU, then there may be market reasons for suppliers to package and label their export products differently from those placed on the EU market.

Differences in adoption of building blocks may also lead to differences in the benefits received by different countries in terms of the protection of human health and the environment. Time series analysis of the number of chemical-related illnesses or accidents occurring or concentration levels of chemicals in the environment in each country since GHS was adopted would contribute to the evaluation of whether adopting more of the building blocks leads to greater benefits. However, such an analysis could only be carried out at a point in time further away from final implementation dates so is not possible here. Furthermore, in terms of quantifying the human health and environmental benefits of GHS, it would be difficult to distinguish between the impacts of GHS and the impacts of other legislation, such as classification and labelling requirements under international transport regulation and risk management measures under national downstream legislation.

We asked the Secretariat, however, whether differences in building block adoption have led to differences in benefits associated with implementing GHS. The Secretariat's response is provided below.

UN GHS Secretariat

Do you believe significant trade, human health or environmental benefits are foregone by the EU in not adopting the following GHS building blocks?

- a. Flammable liquids, cat.4
- b. Acute toxicity, cat.5
- c. Skin corrosion/irritation, cat.1 (cat.1A, 1B and 1C were adopted)
- d. Skin corrosion/irritation, cat.3
- e. Serious Eye damage/Eye Irritation, cat.2A
- f. Serious Eye damage/Eye Irritation, cat.2B
- g. Aspiration hazard, cat.2
- h. Acute hazards to aquatic environment, cat.2
- i. Acute hazards to aquatic environment, cat.3
- j. Desensitized explosives, cat.1 to cat.4

The choice of the GHS building blocks to be implemented in a country or region is the responsibility of the relevant competent authority. We understand that the hazard classes/categories above were not implemented because the EU decided to keep the same level of protection offered by the substance and preparations directives previous to the CLP regulation.

As long as the hazards classes/categories implemented are covered consistently with the GHS criteria and requirements, this is considered appropriate implementation of the GHS.

We note also that even in the EU, implementation of the GHS is sector related, which is logical. For transport in the EU, Acute 2 and Acute 3 are regulated for transport in tank-vessels.

We do not have comments or specific information on the impact in trade, human health or environmental benefits or short-comings derived from the adoption or non-adoption of a particular set of hazard classes or criteria.

4 Differences in Transition Times

4.1 Deadlines for implementing GHS

Table 4-1 below outlines the transition periods and deadlines set in place in each country of interest to this study for the implementation of GHS.

Table 4-1: Transition periods and deadlines for implementing GHS ³		
Country/Region	Transition period	Scope of implementation
EU	20/01/09 – 30/11/10	Substances
	20/01/09 – 31/05/15	Mixtures
Australia	01/01/12 – 31/12/16	Not specified
Brazil	26/09/09 – 26/02/11	Substances
	26/09/09 – 31/05/15	Mixtures
Canada	11/02/15 – 31/05/17	Manufacturers and importers
	11/02/15 – 31/05/18	Manufacturers, importers and distributors
	11/02/15 – 30/11/18	Suppliers and employers
China	01/05/10 – 30/04/11	Not specified
Japan	01/12/06 – 31/12/10	640 designated substances
Russia	01/01/09 - (no deadline set)	Labelling
	01/01/11 – (no deadline set)	Classification
USA	25/05/12 – 31/05/15	Not specified

The earliest adopter of GHS was Japan, where the transition period for implementing GHS began in December 2006 although it was only applicable to 640 designated substances. The EU, Brazil and Russia began implementing GHS in 2009, followed by China in 2010. Australia and the USA began implementing GHS in 2012, after the deadlines in four of the other countries/regions. Deadlines for the transition period for adopting GHS are yet to pass in Australia, USA and Canada.

Different approaches to the transition period were adopted in different countries. For example, in Australia, China, Japan and the USA, a single transition period was allowed for all stakeholders and all chemicals under the scope of the legislation. In contrast, the EU and Brazil had two different deadlines for substances and mixtures, respectively. Canada implemented different deadlines for different groups of stakeholders (manufacturers, importers, distributors, suppliers and employers). Russia had two deadlines: one for meeting the labelling requirements of GHS and one for meeting the classification requirements.

4.2 Adopting revisions to GHS

Revisions to the UN GHS follow a biennial rhythm. Thus far, there have been six revisions, the latest being published in 2015. Countries and regions do not necessarily adopt the same revisions at the same time. This can have consequences for international chemicals trade. Table 4-2 below outlines for each country of interest to the case study the latest revisions to GHS which they have adopted into their implementation of GHS.

³ Information is taken from DHI Group website. Accessed 12/10/16 at: <http://ghs.dhigroup.com/GHSImplementation.aspx>

Table 4-2: Latest revision to GHS adopted in each country		
Country	GHS Revision adopted	Transition period for adoption
EU	Rev. 4 (2011)	Adopted 01/06/13 Substances - Entry into force: 01/12/14 Mixtures - Entry into force: 01/06/15
Australia	Rev. 3 (2009)	Legislation yet to be adopted is based on GHS Rev.3
Brazil	Rev. 4 (2011)	Entry into force: 01/06/15
Canada	Rev. 5 (2013)	Legislation yet to be adopted is based on GHS Rev. 5
China	Rev. 4 (2011)	Adopted 2013 Entry into force: 01/11/14
Japan	Rev. 4 (2011)	Entry into force: 01/01/17
Russia	Rev. 4 (2011)	Entry into force expected to be 01/01/17
USA	Rev. 3 (2009)	Adopted: 26/05/12 Entry into force: 01/06/15

Possible reasons for these differences in adoption (as explained by the Secretariat) include differences in resources available and national law-making procedures - see the box below.

It was noted in the targeted consultation by several EU industry associations that it is important that CLP remains aligned with the revisions to the GHS. It is unclear whether these views relate more to a desire to adhere to the commitments that have been made or due to concerns over a loss of global harmonisation benefits. Given the fact that other regions are not adapting their systems at the same pace as the revisions are being made at the UN level, it is hard to argue strongly that there would be a significant impact on global harmonisation benefits should the EU adopt a slower pace of adaptation (particularly given that most manufacturers and importers have not yet seemed to experience such benefits).

UN GHS Secretariat
<p>It is our understanding that the GHS is formally revised on a two yearly basis. These revisions have been regularly adopted in the EU. Do most countries adopt the changes made through the revisions within a reasonable timeframe after they have been introduced, or are there significant differences in the speed of adoption?</p> <p><i>Updating of national GHS implementing legislation varies depending on availability of resources and on national law making process requirements.</i></p> <p><i>Some countries/regions base their GHS implementation legislation on a specific revised edition of the GHS and then publish the relevant amendments every two years following the biennial cycle of adoption of amendments at UN level.</i></p> <p><i>Others on the contrary follow their own pace. Reasons may vary: e.g. availability of resources (both human and economic) needed for drafting, reviewing and adopting a new revision: time needed for public consultation and discussion as well as for passing and enacting the revised legislation; waiting for major revisions of the whole legislative framework, etc. Unfortunately, this is an obstacle to effective international harmonization.</i></p> <p><i>Others adopt the GHS by incorporating into their legal instruments a reference to “the latest revised edition of the GHS published”, thus avoiding going for the whole legislative process every two years, but this is usually possible only when the official language of the country is one of the UN official languages.</i></p>

5 Differences in Labelling and Packaging Requirements

5.1 Overview

Targeted stakeholder consultation revealed that the most prominent non-tariff barriers to trade in the context of international chemicals trade are the differences in labelling requirements across countries, including those who have adopted GHS. These differences pertain to the mandatory requirements for label content as well as requirements for the dimensions of labels.

5.2 Mandatory Label Content

All countries implementing GHS are required to include the following elements on their labels:

- product identifier;
- signal word;
- pictograms;
- hazard statements;
- precautionary statements; and
- supplier identification.

However, there are additional elements under CLP that were taken from the previous legislation and must be included in the supplemental information section. These elements are not always included on labels for imports into Europe; in some cases the information is listed in the SDS as additional information.

China imposes an additional format requirement for its labels: a black border must be placed around the label inside which the following must be present:

- the percentage/percentage range of ingredients which contribute to the hazards of a mixture, usually for up to five components;
- an emergency telephone number of a company located in China; and
- a reminder to the user to “Please refer to the Safety Data Sheet”.

In Japan there are additional labelling requirements which are quite complex as they pertain to other pieces of national legislation⁴, including:

- Poisonous and Deleterious Substances Control Law;
- Fire Service Law;
- Chemical Substances Control Law;
- High Pressure Gas Control Law;
- Explosives Control Law;
- Ship Safety Law; and
- Civil Aeronautics Law.

⁴ https://www.chemicalsafetyconsulting.com/sites/www.chemicalsafetyconsulting.com/files/global-ghs-labeling_csc.pdf

Those exporting to Japan must take care to list the hazardous ingredients in compliance with these other laws as well as following the specific labelling requirements of these other laws.

In the GHS guidance, it is stipulated that if the skull and crossbones pictogram is used, the exclamation mark pictogram does not need to be displayed on the label and so only a maximum of three pictograms would appear on a label. However, under US OSHA, this stipulation is not made; so it could be the case that four pictograms appear on one label. Furthermore, OSHA allows for both the GHS physical hazard pictogram and the Department of Transportation (DOT) diamond transport label of the same class to appear on the same label, though this is not generally supported by 1.4.10.5.1 of the UN GHS standard.

5.3 P and H statements

Another difference in labelling requirements in the EU is that CLP states that a maximum of 6 precautionary statements can be printed on the label, unless more are required to “reflect the nature and the severity of the hazards.” Yet many other countries do not stipulate a maximum number of precautionary statements and often labels in these countries will have a long list of them. A problem then occurs when these countries have to cut this list of statements down to six ready for import into Europe: which statements should be excluded and included on the EU labels is a decision usually made at the manufacturers’ discretion. This is a potential source of inconsistent hazard communication, which may hinder the downstream user’s understanding of the risks of the chemicals.

Additionally, it has been suggested by some stakeholders that greater flexibility is required in terms of accounting for regional differences in the use of language. However, the Secretariat believes that allowing such regional differences, would be contrary to what is currently stated in the GHS (paragraph 1.4.6.2), as well as causing linguistic problems, as has been the case for other international regulation (e.g. international transport). They concede, nonetheless, that some flexibility is required but that this should be limited so that the overall goal of GHS (i.e. harmonisation) is not undermined.

However, US OSHA exhibits more flexibility in this regard and finds that there are no issues relating to regional differences in language.

UN GHS Secretariat

Stakeholders have also indicated that there should be greater flexibility in the P and H phrases to account for regional differences in the use of language (e.g. French in Canada and in France). Do you have any views on this?

There are several references in the GHS as regards implementation of the GHS labelling elements. In particular, paragraph 1.4.6.2 clearly states: “For labels, the hazard symbols, signal words and hazard statements have all been standardized and assigned to each of the hazard categories. These standardized elements should not be subject to variation, and should appear in the GHS label as indicated in the Chapters for each hazard class in this document.”

In view of the above, the secretariat believes that allowing “regional differences” in the use of any of the harmonized elements of the GHS at this point would be against its main goal (i.e. achieving worldwide harmonisation in hazard classification and labelling), would be contrary to what is currently stated in the GHS (e.g. in paragraph 1.4.6.2) and could be perceived as a step-back towards global harmonisation, with the consequent loss of credibility in the system and in the work of the GHS

Sub-Committee.

As regards P statements, the same paragraph 1.4.6.2 states: “Although precautionary statements have not yet been fully harmonized in the current GHS, Annex 3 provides guidance to aid in the selection of appropriate statements. Additional work to achieve greater standardization in this area may be undertaken in the future, once countries have gained experience with the system.” Therefore, it seems clear that although the GHS allows some flexibility in the use of P statements, it also encourages achievement of greater harmonisation and the secretariat is of the opinion that the work currently being done at sub-committee level on further improvement of precautionary statements has to be understood as going in that direction.

It is also worth noting that the GHS, even when addressing the use of non-standardized or supplemental information (see 1.4.6.3), establishes some limits to ensure that the use of this information “does not lead to unnecessarily wide variation in information or undermine GHS information”. So again, it seems clear to us that all efforts should be made to minimise regional differences to the extent possible.

This being said, our experience in the transport sector shows clearly that any written information required in an internationally regulatory context (e.g. information in transport documents, instructions in writing for drivers of vehicles carrying dangerous goods) leads to linguistic problems because of regional language differences (not only French in Canada/France, but also Spanish in Spain/Latin America, German in Germany/Austria/Switzerland, Dutch in Belgium/Netherlands, Arabic in the Middle East/North Africa, etc.). Therefore, some flexibility might be needed but we think that when countries want to allow variation, they should nevertheless accept P statements when drafted in accordance with the UN official editions of the GHS if their national language is one of the six UN official languages.

US OSHA

Stakeholders have also indicated that there should be greater flexibility in the P and H phrases to account for regional differences in the use of language (e.g. French in Canada and in France). Do you have any views on this?

In the U.S., English is required to communicate the hazards of chemicals. However, we permit the use of other languages on labels and SDSs. Flexibility of these phrases to account for regional differences in language does not have an impact on the labels and SDSs required by U.S. OSHA.

5.4 Label Dimensions

Different countries implement minimum label sizes for their chemical products. Some of these are outlined in Table 5-1 below to illustrate such differences. There is considerable disparity across the different regions in terms of their packaging and labelling size requirements. For example, Japan and the US do not have specific minimum size requirements, whereas the EU stipulates specific dimensions for different package capacity in terms of label size and pictogram size. China has two extra dimension requirements for label size compared to the EU, one for packaging capacity <3L and one for >1,000L. Comparing the dimensions listed for the package capacity bands shows small but important differences in the label size requirements. For example, for the packaging capacity band “>3 to <=50L”, the EU sets minimum dimensions of 74 x 104mm. China sets a minimum of 75 x 100mm. Even though these are given as minimums, thus allowing some leeway, it still represents an arguably unnecessary burden to companies trading with either or both of these countries, especially as one label is not smaller than the other for both height and width.

Table 5-1: Differences in label size requirements			
Country/Region	Package capacity	Label size (mm)	Pictogram size(mm)
EU	<= 3L	52 x 74 if possible	10 x 10 min, 16 x 16 if possible
	>3 to <=50L	74 x 105 min	23 x 23 min
	>50 to <=500L	105 x 148 min	32 x 32 min
	>500L	148 x 210 min	46 x 46 min
China	<=0.1L	Use simplified label	Visible from a distance, even in mist conditions
	>0.1 to <=3L	50 x 75 min	
	>3 to <=50L	75 x 100 min	
	>50 to <=500L	100 x 150 min	
	>500L to <=1,000L	150 x 200 min	
	>1,000L	200 x 300 min	
Japan		No minimum label sizes defined	No minimum pictogram sizes defined
US		No minimum label sizes defined under HCS but DOT diamond transport label size requirement is referenced	No minimum pictogram sizes defined
Source: Chemical Safety Consulting (2013)			

An example of how differences in labelling requirements can lead to unwanted economic consequences relates to those chemicals for which labelling is printed straight onto the packaging. In such cases, producers have to decide in advance of packaging where a particular production lot will be sold i.e. EU, USA, etc. due to the differing labelling requirements across these different markets. This can lead to great difficulty for producers, as most products are packaged immediately and then stored, rather than the other way round. The result is a significant strain on logistics and production planning which, if not effectively managed, can impact on the downstream supply chain. This strain would be reduced with greater global harmonisation of labelling requirements.

The UN Secretariat agrees that differences in regional labelling requirements can be a constraint but believes these differences were introduced on purpose, i.e. to minimise the impact of implementing GHS in countries/regions which already had a classification and labelling system in place and did not want levels of protection to be lowered.

UN GHS Secretariat

The EU chemicals industry has suggested that the real constraint to global harmonisation related to differences in regional labelling requirements rather than classification. Is this also the perception of the UN?

We understand that differences in regional labelling requirements might be a constraint. However, we also understand that in some cases, these differences in labelling were introduced to minimise the impact of GHS implementation in countries/regions which already had a system in place and did not wish to lower their level of protection (e.g. CLP supplemental hazard information and supplemental label elements for certain mixtures).

As regards classification, we welcome all efforts to achieve harmonised classification results. We believe that differences in the classification of one substance or mixture between countries or among sectors (e.g. transport and workplace or supply and use regulations) would also be a constraint. We think that it would be desirable to agree on the GHS classification of chemicals which are most commonly internationally traded.

US OSHA explained that their labelling requirements (which require that the pictogram, signal word and hazard statements must be included together on the label) will remain the same and that these will not change to enforce a mandatory label format. They also claim that the SDS provides more detailed information for users such as workers, emergency responders and health and safety professionals, compared to labels.

US OSHA

Does OSHA have plans for establishing mandatory chemical product label formats in the future, or is the intention to continue to allow any label format provided that it contains all required information? Which is viewed as more important the label or the SDS?

OSHA does not have any plans to require mandatory chemical product label formats other than our current requirement that the pictogram, signal word and hazard statements must be together on the label. Each of these hazard communication tools, the label and the SDS, are important in providing information to the worker. The label serves as the initial and immediate information available to the worker, providing information about the chemical identity, hazard information, and protective measure. The SDS provides the more detailed information, and is used by the worker, emergency responders, and safety and health professionals.

6 Differences in Classification

6.1 Overview

The underlying concept of GHS is that standards for the classification, labelling and packaging of chemicals and chemical products should be harmonised on a global scale to allow for easier international trade whilst ensuring protection of human health and the environment is also equal globally. As has been explained, significant differences are still in place in terms of building block adoption, transition times and labelling and packaging requirements. In addition to this, there are significant differences in the way substances and mixtures are classified globally, in terms of testing data requirements, cut-off values and concentration limits.

6.2 Substance classification lists

Written into the provisions of CLP is Annex VI, which contains a list of harmonised substance classifications, deemed to be “minimum classifications” for endpoints of certain hazard classes such as acute toxicity and STOT repeated exposure. For any endpoints not specifically listed, the classifications are deemed as being “incomplete”, meaning that if there is evidence which would support a classification in an endpoint that is not classified in the Annex VI list, the manufacturer, importer or downstream user must use apply this endpoint classification as a self-classification, in addition to all listed endpoint classifications (see also discussion on this in the Task 1 report). Other countries also have their own substance classification lists, including Japan, South Korea and New Zealand.

Endpoints for a substance can be given different classifications in other jurisdictions which suggests there may be data which would support variations in classification. As self-classification by a manufacturer, importer or downstream user of a substance (or mixture) is a key principle of CLP, hazard data which is publicly available in other jurisdictions should be included when self-classifying a substance. Nonetheless, classification developed for non-EU jurisdictions may not necessarily be relevant to the EU given differences in data interpretation and use of weight of evidence. This may lead to non-EU authorities interpreting data differently and deciding on a different classification.

When asked about the possibility of a globally centralised list of substance classifications, the Secretariat responded that globally harmonised classification of chemicals ought to be the end goal for GHS but they concede that this is a long-term ambition. They credit the harmonisation of classification criteria as being a first step towards this goal. Additionally, the Secretariat suggests that a centralised list of harmonised classifications could be developed in a similar way to the UN Model Regulations on the Transport of Dangerous Goods. Currently, the GHS Sub-Committee is undertaking a pilot classification exercise to ascertain whether such a list could be actualised. The Secretariat has stated that the UN Recommendations on the Transport of Dangerous Goods contains a list of the most commonly carried dangerous substances and the GHS Sub-Committee has been made aware of this list and its potential as a starting point for a similar list for GHS, to see if their current transport classification is still consistent with the GHS criteria. They suggest that, if this is not the case, consideration could be given to amending the transport classification in line with GHS.

UN GHS Secretariat

Some EU stakeholders have suggested that the UN should oversee the development of and inclusion into the GHS of a list of substances that have internationally agreed classifications for properties such as carcinogenicity. Do you have any views on this?

We believe that a globally harmonised classification of chemicals should be the ultimate goal of the harmonisation process but we understand this is a long-term endeavour.

We also believe that the first step towards this objective was harmonisation of the classification criteria.

Inclusion of a list of chemicals classified in accordance with the GHS could be done in a similar way as for the UN Model Regulations on the Transport of Dangerous Goods. However, before this can be achieved, agreement on a number of important questions need to be reached, i.e.: mandatory versus voluntary classification results; selection of the substances/mixtures to be listed; selection of hazardous properties to be considered; body responsible for the classification; evaluation of the data to be considered for classification for each entry in the list; assessment of conflicting results; determination of the end-points to be considered (all or only a selection of them) for each substance or mixture; updating and revision of the classification results as new data become available or new hazard classes/categories are introduced in the GHS, etc.

The GHS Sub-Committee has started examining all these questions and work is being done on a few chemicals as a pilot classification exercise. The results of this exercise will help to ascertain whether the developments of an internationally agreed classification list in accordance with the GHS can be envisaged. For additional information, refer to the reports on the Sub-Committee sessions.

In this context, the secretariat has drawn the attention of the GHS Sub-Committee to the fact that the UN Recommendations on the Transport of Dangerous Goods contain the list of dangerous substances which are most commonly carried. It would be desirable to start the exercise with the substances contained in this list to check whether their current transport classification – of mandatory application worldwide – is still consistent with the GHS criteria, if not, amending the transport classification to bring it in line with the GHS and, if necessary, amending the transport conditions accordingly should be considered. This would help intersectoral harmonization at least for those specific substances which are supposed to be those produced and traded in the biggest quantities worldwide.

6.3 Mixture classification

The GHS allows countries to choose the cut-off values and concentration limits they wish to implement when classifying mixtures; these options are given in the “Purple Book” (the official UN GHS recommendation) and are part of what is known as the compromise classification scheme. For example, the different cut-off/concentration limits for classification of mixtures as reproductive toxicants are summarised in the Table 6-1 below (which replicates Table 3.7.1 of the GHS Rev.5).

This could lead to the same mixture being classified differently in different countries, with consequences for the way in which it is labelled and even packaged in different countries. It may also mean that there could be different levels of human health and environmental protection.

Table 6-1: Cut-off values/concentration limits of ingredients of a mixture classified as reproductive toxicant or for effects on or via lactation that would trigger classification of the mixtures - Table 3.7.1 of the GHS Rev. 5 Purple Book^a

	Cut-off/concentration limits triggering classification of a mixture as:			
Ingredients classified as:	Category 1 reproductive toxicant		Category 2 reproductive toxicant	Additional category for effects on or via lactation
	Category 1A	Category 1B		
Category 1A reproductive toxicant	≥ 0.1%			
	≥ 0.3%			
Category 1B reproductive toxicant		≥ 0.1%		
		≥ 0.3%		
Category 2 reproductive			≥ 0.1%	
			≥ 3.0%	
Additional category for effects on or via lactation				≥ 0.1%
				≥ 0.3%

^a This compromise classification scheme involves consideration of differences in hazard communication practices in existing systems. It is expected that the number of affected mixtures will be small; the differences will be limited to label warnings; and the situation will evolve over time to a more harmonized approach.

6.4 Impact on effective harmonisation

In terms of being effective in facilitating the international trade of chemicals, the differences in adopted classification modules/categories limits the overall harmonisation and the 'facilitation of the trade of chemicals' and can create barriers to trade. For example, the EU classification system is the only one to introduce specific concentration limits affecting mainly the classification of mixtures and impurities in substances; these specific concentration limits affect classification in a manner which may impact on recycling (see Case Study 2 and the 'lead metal' example, with another example being the establishment of a harmonised classification re the proposed SCL mainly impacts recycling and production of alloys (mixtures).

7 Non-Tariff Barriers to Trade

7.1 Overview

Significant differences in the adoption of building blocks may well have impacted on the degree to which non-tariff barriers continue to be an issue for the international trade of chemicals. This section provides an overview of the number and nature of such barriers which are placed on products falling under the scope of the GHS system.

The harmonisation of technical requirements and shared standards are similar examples of moves to reduce NTBs. This is expected to have a positive impact on trade since country pairs that share standards and harmonise technical requirements have lower trading costs than other country pairs.

However, we have seen in previous sections of this case study that not all technical requirements and standards have been harmonised for the management of chemicals which means significant technical barriers remain.

7.2 Defining non-tariff barriers

The term “non-tariff barrier” is all encompassing and is defined by the World Bank as follows:

Non-tariff barrier (NTB): A catch-all phrase describing barriers to international trade other than the tariffs for example, quotas, licensing, voluntary export restraints.

Another term used in international trade economics is “non-tariff measure” and this is defined by the world banks as:

Non-tariff measure: Any government action with a potential effect on the value, volume, or direction of trade. Also see Non-tariff Barrier.

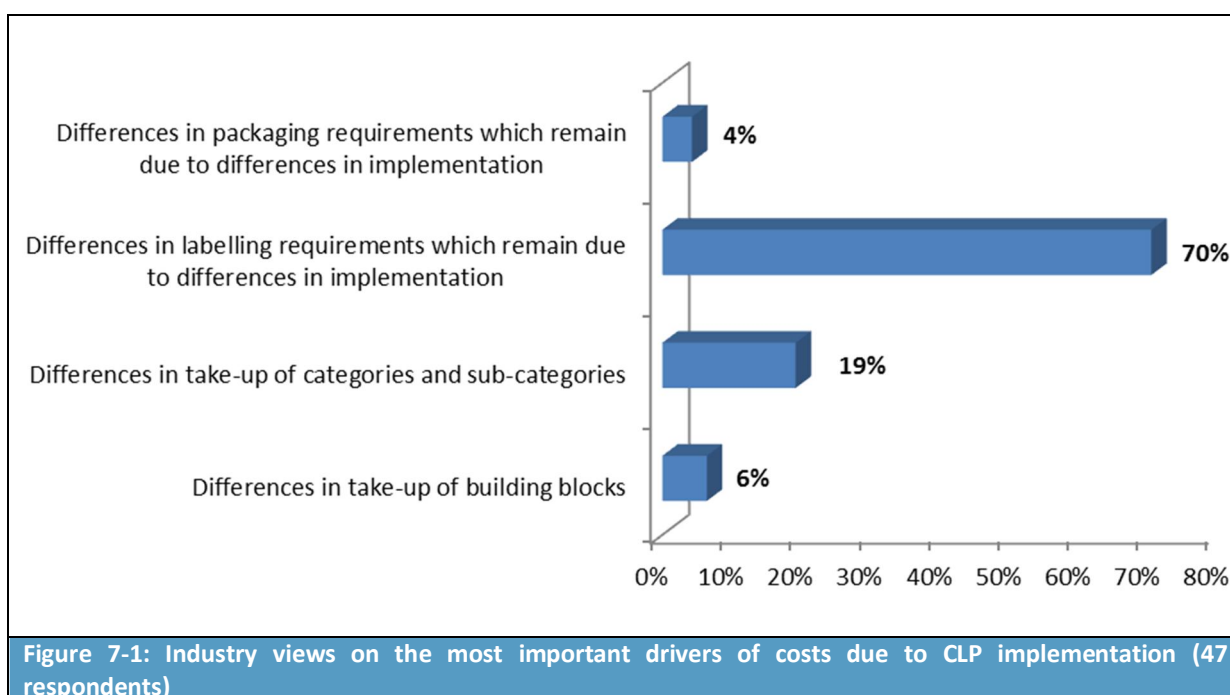
The authors of the GHS Impact Assessment note that NTBs are a useful mechanism for economies seeking trade protection without implementing tariffs, which can be easily observed and may lead to retaliation from other economies. NTBs, on the other hand, are neither easily quantifiable nor easy to monitor.

7.3 Non-tariff measures related to labelling and packaging provisions

Table 7-4 below lists data for 2014 taken from the WITS database relating to the total number of non-tariff measures (NTM) put in place in different importer countries (for which data is available) and the number of these which are linked to the labelling of products and the number which are related to the packaging of products. This is based on the UNCTAD Coding System for the classification of non-tariff measures. Classification B31 is entitled “Labelling Requirements” and pertains to measures which regulate the format and information on packages and labels. Requirements may include, amongst others, information on use, safety and security. Classification B33 is entitled “Packaging Requirements” and relates to the measures which regulate the way in which goods are packed and the packaging materials which can be used. Again, the data is given for the number of NTMs which apply to those product categories listed in Table 7-1.

Table 7-1: Number of NTMs related to labelling and packaging ⁵			
Importer	Total number of NTMs in 2014	NTMs related to labelling (B31)	NTMs related to packaging (B33)
EU	157	20	6
Australia	551	63	26
Brazil	263	25	4
Canada	325	30	7
Japan	584	39	15
USA	1046	172	30

The table above indicates that the number of barriers to trade linked to labelling account for between 7% and 16% of all NTMs. (Data is not available pertaining to the legislation to which these NTMs relate.) This is a significant proportion which supports findings from the stakeholder consultation: when asked about the drivers of costs due to CLP being implemented, 70% of industry stakeholders indicated that differences in labelling requirements across countries were key drivers of these costs.



⁵ The database managers for the UNCTAD TRAINS/WITS database system were contacted with regards to obtaining data from previous years in order to develop a time-series analysis of the NTMs relating to packaging and labelling. However, we were informed that this data is not retained by UNCTAD. Furthermore, data on NTMs is not available for China or Russia, nor is data for NTMs linked to classification requirements

8 Impacts of GHS on Global Trade in Chemicals

8.1 Overview of global trade of chemicals

As identified in the Inception Report, the main actors on the global chemicals market are: the EU, Asia and North America. Their share of global chemicals exports is given in Table 8-1 below. China and Japan make up most of Asia's share.

Table 8-1: World exports of chemicals by region (2013)		
Region	Total exports (€ billion)	Share in world exports
EU	430.6	42.5%
Asia	355.1	35.0%
NAFTA	137.5	13.6%
Rest of Europe	46.8	4.6%
Latin America	24.2	2.4%
Africa & Oceania	19.6	1.9%
World total	1014	100%

Despite continuing to lead at the global level, the EU's share in world exports of chemicals has fallen significantly in recent years. This is due to competitors from emerging markets such as China and Saudi Arabia (as well as the other BRIC countries) who enjoy the advantage of being raw energy suppliers rather than buyers. In addition, these countries reap the benefits of having access to a cheaper but equally-skilled labour force.

8.2 Impact of GHS on global trade of chemicals

One of the key objectives of GHS was to facilitate international trade by reducing non-tariff barriers and it could be expected that a failure to harmonise the implementation of GHS globally would undermine this objective. Yet the statistical data undermines these claims, as can be seen from the following graphs which illustrate EU trade balance for chemicals (Figure 9-2) and exports from and imports to the EU of chemicals (Figure 9-3). When asked whether there were specific sectors of the global chemicals industry that had benefitted more than others from the implementation of GHS, the Secretariat replied that they assume that those chemical companies which export and import chemicals benefit from not having to deal with conflicting legislation in different countries; they concede, however, that SMEs may need more time to experience the benefits of GHS implementation. Another benefactor of GHS according to the Secretariat are those countries who have less experience in chemicals management.

UN GHS Secretariat

In your view, have some sectors of the global chemicals industry gained more from implementation of the GHS than others? If so, which sectors are these? For example, we are aware that the aerosols sector has used the GHS as a vehicle for gaining global agreement on test methods. Are there other such examples?

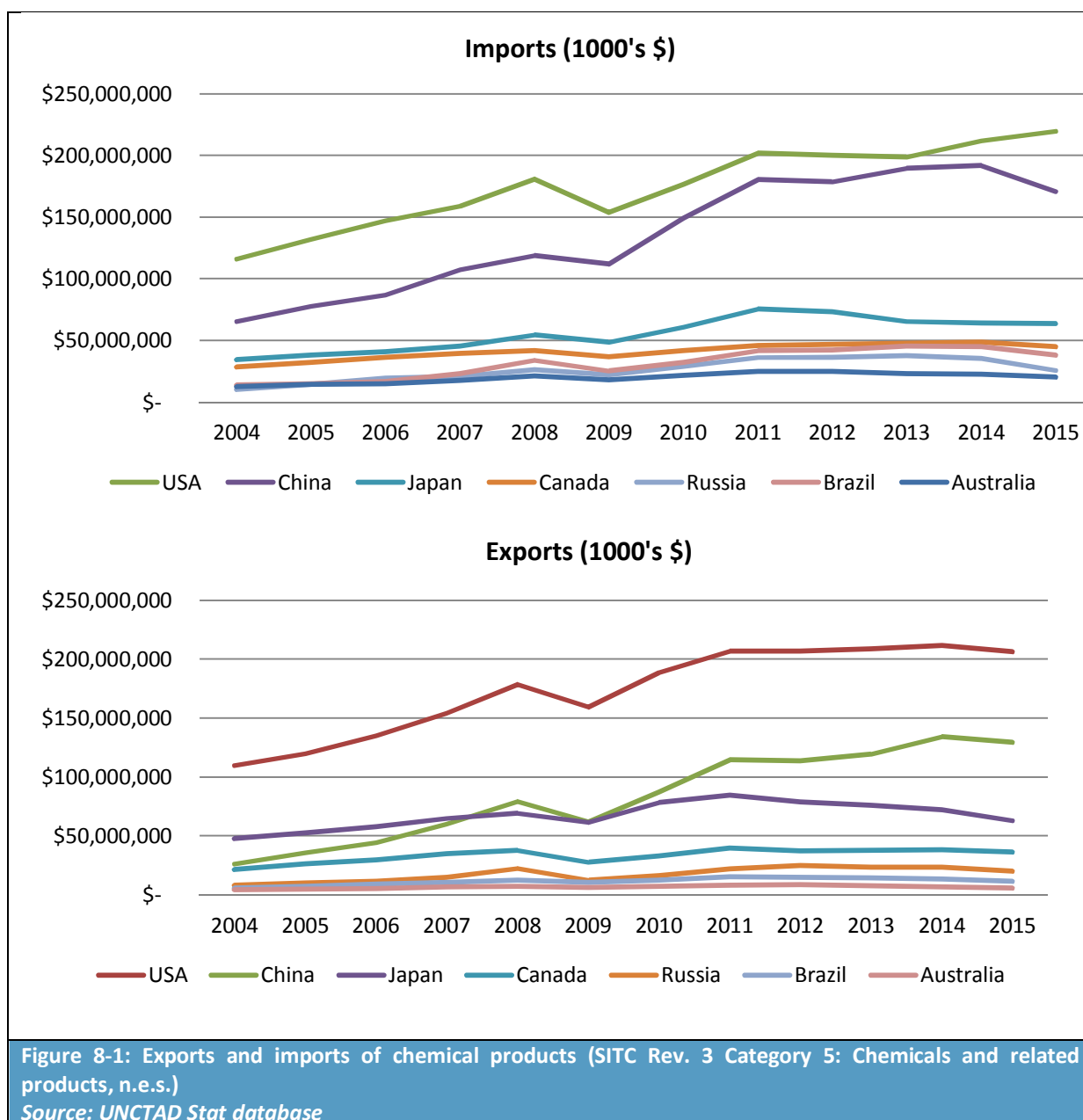
From the economic point of view, we assume that chemical companies exporting or importing chemicals into or from other countries may have already benefited from the fact of not having to conform to conflicting legislation in different countries while for medium and small enterprises the

benefits might need more time to be felt.

We also believe that countries with less experience in chemicals management have also benefited from a globally harmonised classification and labelling system, as it is now easier for them to access all the information behind a given classification result or the information provided on a GHS label.

As pointed out in the Secretariat's response, countries that did not have a well-founded chemicals management system prior to GHS will have also benefitted from a globally harmonised system, in terms of trade benefits as well as health and environmental protection benefits.

Export and import data taken from the UNCTAD database is depicted in Figure 8-1 below for all countries considered in this case study, with exception of the EU.



One could infer from this data that the global trade of chemicals has not been affected by the implementation of GHS. However, it is not anticipated that there is a causal link between the implementation of GHS and international trade of chemicals, let alone a significant one; for example, the authors of the GHS Impact Assessment modelled the econometric relationship between international trade of chemicals and a set of explanatory variables which included tariffs and NTBs, as well as accounting for fixed effects (i.e. other factors which influence international trade). Their model estimated that the elasticity of trade flows with respect to the level of NTBs is -0.025 (C.I. (90%): -0.012 to -0.038). This parameter estimate suggests that even if NTBs were removed (which is the expected upshot of implementing GHS), the impact on the international trade of chemicals would not be significant. This hypothesis is supported by the above data.

When US OSHA was asked whether the US chemicals industry had been impacted by the differences in implementation of GHS, they said that there are mixed responses from industry regarding this matter, with some industry stakeholders suggesting that there are issues relating to compliance and potential cost implications as a result of these differences, despite other industry stakeholders saying they are not experiencing problems.

Furthermore, US OSHA does not believe there is evidence to suggest that the US chemicals industry has a competitive advantage over the European chemicals industry as result of the US not adopting GHS for consumer products (relating to the US not having adopted the environmental hazards).

US OSHA

How has the US chemicals industry been affected by the global differences in GHS uptake, in terms of trade flows, trade volumes, etc.?

OSHA has received mixed messages on this. Some industries are not experiencing problems, while others are noting that the differences are causing compliance issues and potential cost implications.

Do you believe the US chemicals industry has gained a competitive advantage over its European counterpart in not having adopted as many GHS building blocks?

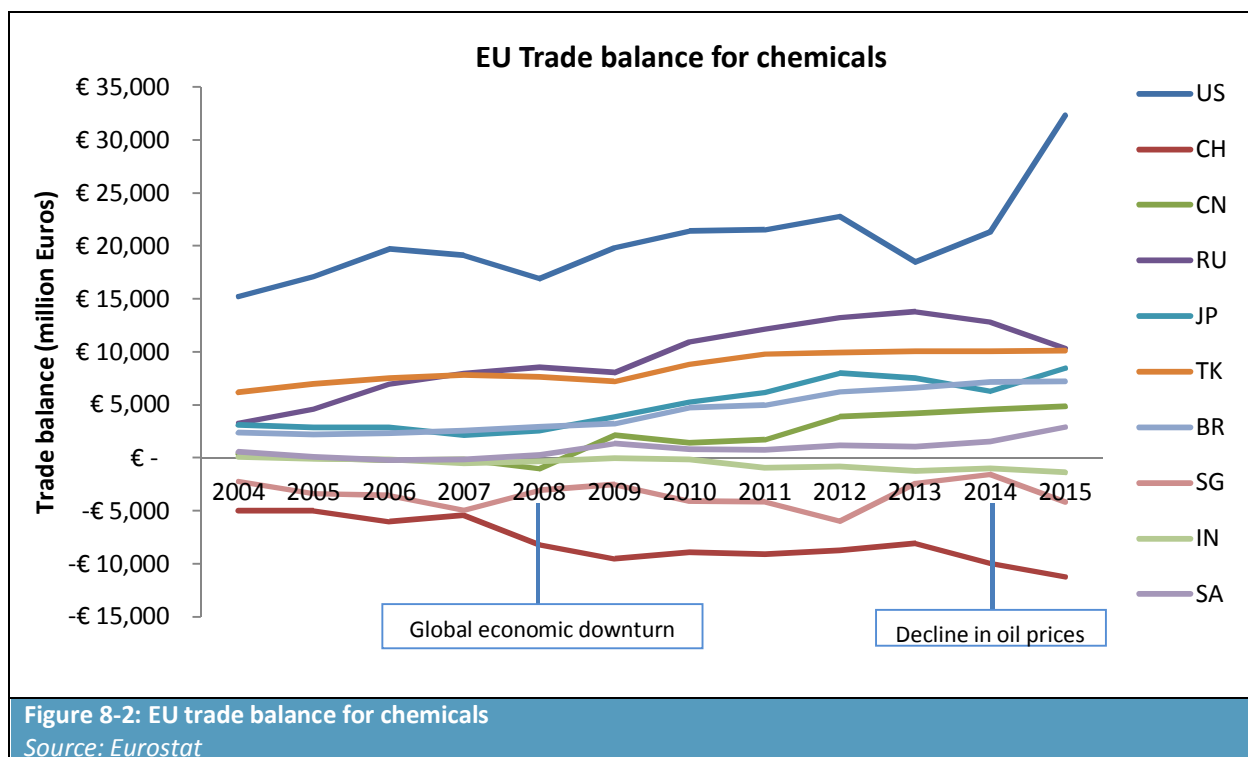
No, there is no evidence of this. We have adopted all the physical and health hazards and more categories than the EU (flammable liquid category 4 and acute toxicity category 4⁶). As mentioned earlier, we did not pick up the environmental hazard categories, as this is not within OSHA's jurisdiction. However, all EU companies need to comply with OSHA's requirements when shipping chemicals to the US and, similarly, US companies need to comply with the EU requirements under REACH.

⁶ See Annex 1: EU did not adopt 12 physical and health hazard categories whereas US did not adopt 10 of these hazard categories

8.3 GHS and the EU chemicals industry

Data from Eurostat suggests that the EU chemicals industry continues to perform strongly in the global chemicals market, experiencing increasingly positive trade balances with its closest competitors (US, China and Japan).

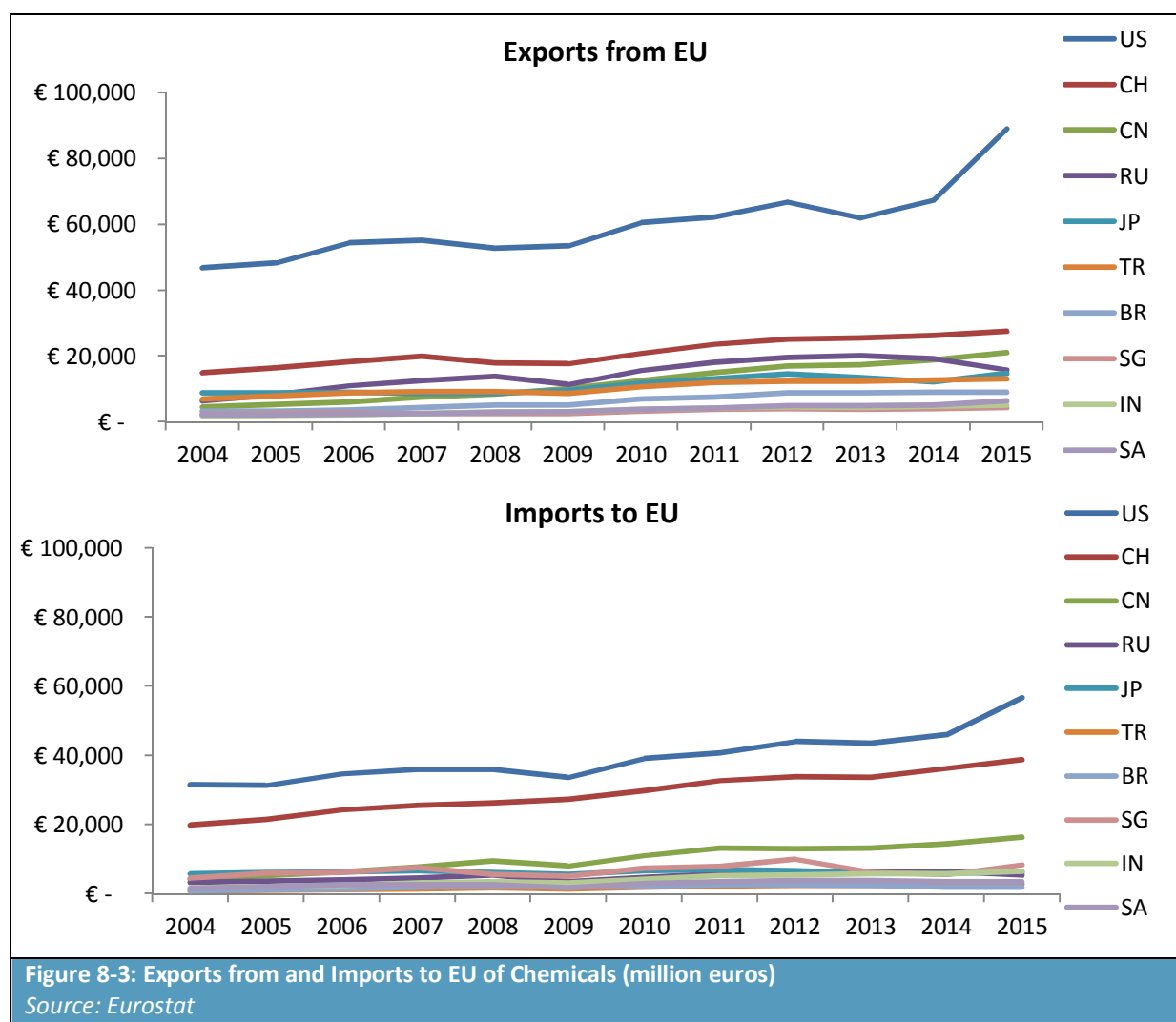
In Figure 8-2 below, the EU holds a positive trade balance for chemical products with 7 trading partners over the period; these are (in order of trade balance value in 2015): US; Russia; Turkey; Japan; Brazil; China and Saudi Arabia. The EU holds a negative trade balance for chemical products with India, Singapore and Switzerland.



The pattern of trade balance growth was similar for all those trading partners with whom the EU enjoyed a positive trade balance. The exception is the US with which the EU sees comparatively sharper fluctuations in the trade balance.

The data depicted in Figure 8-3 below shows a breakdown of EU imports and exports, providing further explanation and context to the trade balance, as depicted in Figure 4-3. From the figure below, it is evident that the US is the EU's key trading partner for chemicals, particularly in terms of EU exports.

Between 2014 and 2015 there is a steep increase in the EU's trade balance with the US. From an EU export perspective, this may be due to the dramatic decline of the oil price which would benefit EU chemicals industry, net importers of oil. Another reason for this boost in trade between the EU and the US may be that negotiations for the Transatlantic Trade and Investment Partnership (TTIP) began in 2013 and may have boosted confidence for industry on both sides.



Furthermore, the graphs depicted above indicate that the EU continues to experience a trade surplus on chemical products. Again, we reiterate that the international trade of chemicals is affected by numerous other factors and that GHS implementation is unlikely to have had a significant impact on trade.

The data gathered for this case study does not suggest that the EU chemicals industry is more or less competitive since GHS (via CLP) was implemented. However, current literature does predict that its position as a key chemicals manufacturer is endangered due to other factors such as energy prices and investment in human and physical capital. Another hindrance is that the industry in the EU faces stricter regulation in other areas such as emissions, not just for chemicals, than their competitor regions and that this makes the EU less competitive.

8.4 Impact on EU businesses

8.4.1 Present impact of CLP

The real impacts of GHS on the EU chemicals industry are unlikely to be revealed by analysing trade data given that trade flows are affected by numerous other variables. Data collected from consultation with industry stakeholders reveals that few believe CLP has had an impact on international trade activities.

Table 8-2: “The CLP Regulation implements the UN GHS system of classification and labelling. Please select those statements with which you agree” (n=97)

Answer Options	Percentage of responses
Classification, labelling and packaging costs vary across the countries my company exports to because of differences in take-up of UN GHS building blocks, categories and sub-categories (please answer Q50)	39.2%
Classification and labelling costs for exports have decreased due to implementation adoption of CLP and hence greater harmonisation with the UN GHS (please answer Q51)	12.4%
Classification and labelling costs for imports have decreased due to implementation adoption of CLP and hence greater harmonisation with the UN GHS (please answer Q51)	8.2%
Classification and labelling costs are lower for countries that have adopted the UN GHS than for those that have not adopted the UN GHS	21.6%
There have been no savings in classification and labelling costs due to the more global adoption of the UN GHS system	60.8%

Responses indicate that on-going differences in the uptake of GHS building blocks is leading to a lack of savings in costs to exporters, with only 12% noting actual savings due to the introduction of CLP; although the responses also suggest that classification and labelling costs are lower for those countries that have adopted the UN GHS compared to those that have not for a fifth of the companies.

Furthermore, few industry stakeholders believe GHS will bring significant benefits to their trade with international partners. For example, most stakeholders believe that the savings that have arisen from CLP implementation and GHS are insignificant.

Table 8-3: “How significant have the savings been for your company due to the following:” (n=45)

Answer Options	Rating from low to high				
	1	2	3	4	5
Adoption of the UN GHS in the EU through implementation of the CLP Regulation	62%	9%	13%	4%	9%
Adoption of the UN GHS in North America	31%	24%	9%	7%	9%
Adoption of the UN GHS in China, Japan and other Asian countries	36%	20%	18%	4%	7%
Adoption of the UN GHS by Brazil and other South American countries	49%	16%	7%	9%	0%
Adoption of the UN GHS in other countries (e.g. South Africa, Australia)	49%	7%	11%	4%	9%

8.4.2 Future impacts

Similarly, stakeholders do not expect CLP to lead to savings in terms of classification, labelling or packaging for both intra-EU and extra-EU imports and exports.

Table 8-4: “Will CLP will lead to savings in the future?” (n=115)			
Answer Options	Yes	No	Don't know
Classification costs associated with the extra-EU export of mixtures	28%	44%	29%
Classification costs associated with the intra-EU export of mixtures	28%	52%	21%
Costs incurred in re-classifying and labelling imported mixtures	20%	47%	30%
Labelling costs associated with the extra-EU export of mixtures	23%	47%	29%
Labelling costs associated with the intra-EU export of mixtures	18%	55%	24%
Reductions in variable packaging requirements	17%	45%	38%

When asked about the expected impact CLP would have on trade and competition, responses were varied. Of the 101 respondents to this question, 23% believe there would be a low positive impact on intra-EU trade of chemicals, with 18% expecting a low positive impact on extra-EU trade of chemicals. Stakeholders are more optimistic about the prospects for harmonisation of classification and labelling: 22% anticipate CLP will have a large positive impact and 30% believe there will be a low positive impact. More generally, however, stakeholders do not anticipate any change arising from CLP.

Table 8-5: Views on future impacts of CLP with respect to trade and competition (n=101)						
Answer Options	Large positive impact	Low positive impact	Neutral/no change	Low negative impact	Large negative impact	Don't know
Intra-EU trade of chemicals	9%	23%	46%	5%	2%	10%
Extra-EU trade of chemicals	8%	18%	42%	12%	2%	14%
Harmonisation of classification and labelling	22%	30%	31%	6%	4%	6%
Access to markets for SMEs	4%	6%	40%	4%	2%	42%
The costs of substances placed on the EU market	3%	7%	50%	22%	3%	13%

However, these anticipated benefits are dependent on increased global harmonisation of the way in which GHS is implemented. Some comments from stakeholders in this regard include the following.

Comments from industry stakeholders regarding the harmonisation of GHS
<i>“In the long run we will see the positive effects of global implementation of GHS. Further alignment with other EU and global legislation necessary.”</i>
<i>“Global harmonization is key. The EU should put efforts into the further development of the UN GHS instead of any EU specifics. This includes harmonized classification”</i>
<i>“CLP is a missed opportunity for a truly Globally harmonised System. However, it is no worse than the previous System.”</i>
<i>“Very important to coordinate and harmonise with other non-European legislation. For example, with transport of dangerous goods (TDG) and globally harmonized system of classification and labelling (GHS).”</i>

8.5 Impact on non-EU companies

A questionnaire was developed for and distributed amongst non-EU companies involved in the chemicals sector (as defined in this study). Though responses were limited, those received relay some information about how the implementation of GHS has affected them, particularly in terms of the adoption of GHS in Europe through CLP.

Non-EU stakeholders were asked the same question listed in Table 8-2. Below, the responses from non-EU companies are given. Though the results are different, both EU and non-EU companies believe that GHS has had either negative or no impact in terms of their costs. When asked what the main reason for these differences in costs were, two thirds of the non-EU companies responding (9) indicated it was due to differences in labelling requirements. This is in line with the proportion of EU respondents answering this question (see Figure 7-1): 70% of EU respondents indicated labelling requirements were the reason for the differences in costs incurred in trading with other countries. A similar proportion of EU and non-EU respondents also indicated differences in take-up of categories and sub-categories as being a reason for these differences in costs (19% and 17%, respectively). There is greater disparity in respondents' beliefs about the impact of differences in take-up of building blocks, with 6% of EU respondents indicated this is the biggest reason for differences in costs and 17% of non-EU indicating this being the case.

Table 8-6: "The CLP Regulation implements the UN GHS system of classification and labelling. Please select those statements with which you agree" (n=9)	
Answer Options	Percentage of responses
Classification, labelling and packaging costs vary across the countries my company exports to because of differences in take-up of UN GHS building blocks, categories and sub-categories (please answer Q50)	66.7%
Classification and labelling costs for exports have decreased due to implementation adoption of CLP and hence greater harmonisation with the UN GHS (please answer Q51)	0%
Classification and labelling costs for imports have decreased due to implementation adoption of CLP and hence greater harmonisation with the UN GHS (please answer Q51)	0%
Classification and labelling costs are lower for countries that have adopted the UN GHS than for those that have not adopted the UN GHS	0%
There have been no savings in classification and labelling costs due to the more global adoption of the UN GHS system	33.3%

8.6 Increased global harmonisation of adoption of GHS

It was anticipated that by harmonising the requirements for classifying, labelling and packaging of chemicals, this would lead to a reduction in NTBs and thus lead to greater international trade of chemicals. However, as is seen in this case study, differences in requirements, choice of building block and implementation times means that the global system for managing chemicals is not yet harmonised. The general view of stakeholders responding to targeted interviews indicated that the intended benefits of GHS will not be felt until they system is adopted in a truly globally harmonised manner.

In terms of the future of GHS implementation, there are mixed opinions about the extent to which implementation will become more harmonised. The Secretariat believes that despite not being a legally binding obligation, GHS encourages the implementation of an identical set of hazard categories worldwide. They acknowledge that there are difficulties encountered by the competent authorities in some countries in implementing GHS owing to pressure from some industry sectors.

Furthermore, they acknowledge that the multi-sectoral scope of GHS requires substantial efforts from countries to adapt their existing chemicals legislation in order to accommodate the requirements of GHS.

UN GHS Secretariat

Do you envisage that adoption of the UN GHS and its building blocks will become more harmonised globally in the future?

The GHS is a set of recommendations and therefore they are not legally binding. Its implementation relies on the political willingness of the national or regional competent authorities and on the resources available to do so, and also on the stakeholders support at national level, among other factors. We are aware of the difficulties encountered by competent authorities wishing to implement the GHS in some countries because of the pressure put on them by some industrial sectors which are against GHS implementation (despite its implementation for the same sectors in other countries).

The GHS encourages the implementation of an identical set of hazard categories at a worldwide level within each sector (see note 2 to paragraph 1.1.3.1.5.4 on interpretation of the building block approach). However, due to its multi-sectoral scope (transport, consumers, occupational health and safety and the environment), its effective implementation requires significant efforts from countries to amend many existing legal texts concerning chemical safety in each sector or to enact new legislation.

In the transport sector the situation is less complex given that the Model Regulations are regularly updated to reflect the relevant provisions of the Globally Harmonized System. All the major international instruments based on the Model Regulations (e.g. IMDG Code, ICAO technical instructions, ADR, RID or ADN) are also amended accordingly, as are all national regulations that are based on those instruments or that are regularly updated on the basis of the Model Regulations.

The situation is more complex in other sectors because implementation requires the amendment or revision of a considerable number of different legal texts and guidelines for application.

Achieving worldwide harmonisation as regards the hazard classes and categories implemented for each sector as well as on the sectors applying GHS would imply for most countries commitment to implement the GHS in sectors such as supply and use, or agricultural products, while for others it would imply adoption of the additional hazard classes/categories which are currently not implemented (i.e. regulating chemicals which are currently not regulated or which are covered by other types of legislation (e.g. risk assessment based classification and labelling)).

In addition to the above, there are differences among countries as regards the mandatory nature of GHS implementing instruments. While in some countries GHS provisions are mandatory, others have issued voluntary standards or recommendations allowing its implementation (i.e. GHS classification and labelling is recommended and/or accepted but it is not mandatory).

In view of the above, the secretariat believes it is not possible at this stage to anticipate a time frame for achieving global harmonisation. The secretariat is not aware of any discussion at Sub-Committee level addressing the possibility of agreeing on further harmonisation on the building blocks to be adopted globally.

9 Conclusions

The purpose of UN GHS was to increase international trade of chemicals by reducing non-tariff barriers to trade. However, GHS has yet to be implemented in a harmonised manner: there are differences in the dates of initial implementation of GHS across countries, with some countries having adopted much earlier or much later than others and, in some cases, countries have yet to implement. Other differences include the differences in the scope of GHS implementation in terms of the product groups to which GHS is applied (e.g. consumer products), as well as the differences in the labelling and classification requirements in place in each country. These differences will all impact on the extent to which the adoption of GHS via CLP will be reducing the costs of global trade in chemicals with respect to classification, labelling and packaging for EU companies. However, it has not been possible to establish quantitatively whether CLP has or has not had a significant impact on the competitiveness of the EU chemicals industry. It is noted though that the EU has maintained its position as one of the leaders in this industry.

Other factors which are arguably more important in determining the competitiveness of the sector are energy (in terms of international prices, consumption and sources) as well as a lack of investment in Europe; statistics show that investment is concentrated in other regions, such as the Middle East and South East Asia, where labour and other production factors are more cost-competitive.

More generally, it is too early to assess the impact of GHS on the international market as implementation is in its infancy in most countries (Japan, EU, and China) and in some cases, implementation deadlines have yet to pass (Australia and Canada).

Annex 1 Global implementation of GHS building blocks

Hazard Category	Europe						Americas					Asia								Others		
	EU	CH	NO	RS	RU	TR	BR	CA	MX	US	UY	CN	JP	KR	MY	PH	SG	TH	VN	AU	NZ	ZA
Physical Hazard																						
Unstable explosives																						
Explosives, Div1.1																						
Explosives, Div1.2																						
Explosives, Div1.3																						
Explosives, Div1.4																						
Explosives, Div1.5																						
Explosives, Div1.6																						
Flammable gases, Cat. 1																						
Flammable gases, Cat. 2																						
Pyrophoric gases																						
Chemically unstable gases, Cat. A																						
Chemically unstable gases, Cat. B																						
Aerosol, Cat. 1																						
Aerosol, Cat. 2																						
Aerosol, Cat. 3																						
Oxidizing gas																						
Gases under pressure, Compressed gas																						
Gases under pressure, Liquidified gas																						
Gases under pressure, Refrigerated liquidified gas																						
Gases under pressure, Dissolved gas																						
Flammable liquids, Cat. 1																						
Flammable liquids, Cat. 2																						
Flammable liquids, Cat. 3																						
Flammable liquids, Cat. 4																						
Flammable solids, Cat. 1																						
Flammable solids, Cat. 2																						
Self-reactive substances or mixture, Type A																						

Hazard Category	Europe						Americas					Asia								Others		
	EU	CH	NO	RS	RU	TR	BR	CA	MX	US	UY	CN	JP	KR	MY	PH	SG	TH	VN	AU	NZ	ZA
Self-reactive substances or mixture, Type B																						
Self-reactive substances or mixture, Type C																						
Self-reactive substances or mixture, Type D																						
Self-reactive substances or mixture, Type E																						
Self-reactive substances or mixture, Type F																						
Self-reactive substances or mixture, Type G																						
Pyrophoric liquids																						
Pyrophoric solids																						
Self-heating substances or mixtures, Cat. 1																						
Self-heating substances or mixtures, Cat. 2																						
Substances and mixtures, which in contact with water, emit flammable gases, Cat. 1																						
Substances and mixtures, which in contact with water, emit flammable gases, Cat. 2																						
Substances and mixtures, which in contact with water, emit flammable gases, Cat. 3																						
Oxidizing liquids, Cat. 1																						
Oxidizing liquids, Cat. 2																						
Oxidizing liquids, Cat. 3																						
Oxidizing solids, Cat. 1																						
Oxidizing solids, Cat. 2																						
Oxidizing solids, Cat. 3																						
Organic peroxides, Type A																						
Organic peroxides, Type B																						
Organic peroxides, Type C																						
Organic peroxides, Type D																						
Organic peroxides, Type E																						
Organic peroxides, Type F																						
Organic peroxides, Type G																						
Corrosive to metals																						
Desensitized explosives, Cat. 1																						
Desensitized explosives, Cat. 2																						

Hazard Category	Europe						Americas					Asia								Others		
	EU	CH	NO	RS	RU	TR	BR	CA	MX	US	UY	CN	JP	KR	MY	PH	SG	TH	VN	AU	NZ	ZA
Desensitized explosives, Cat. 3																						
Desensitized explosives, Cat. 4																						
Health Hazard																						
Acute toxicity, Cat. 1																						
Acute toxicity, Cat. 2																						
Acute toxicity, Cat. 3																						
Acute toxicity, Cat. 4																						
Acute toxicity, Cat. 5																						
Skin corrosion/irritation, Cat. 1																						
Skin corrosion/irritation, Cat. 1A																						
Skin corrosion/irritation, Cat. 1B																						
Skin corrosion/irritation, Cat. 1C																						
Skin corrosion/irritation, Cat. 2																						
Skin corrosion/irritation, Cat. 3																						
Serious Eye damage/Eye Irritation, Cat. 1																						
Serious Eye damage/Eye Irritation, Cat. 2																						
Serious Eye damage/Eye Irritation, Cat. 2A																						
Serious Eye damage/Eye Irritation, Cat. 2B																						
Respiratory or Skin Sensitisation, Cat. 1																						
Respiratory or Skin Sensitisation, Cat. 1A																						
Respiratory or Skin Sensitisation, Cat. 1B																						
Germ Cell Mutagenicity, Cat. 1A																						
Germ Cell Mutagenicity, Cat. 1B																						
Germ Cell Mutagenicity, Cat. 2																						
Carcinogenicity, Cat. 1A																						
Carcinogenicity, Cat. 1B																						
Carcinogenicity, Cat. 2																						
Reproductive toxicity, Cat. 1A																						
Reproductive toxicity, Cat. 1B																						
Reproductive toxicity, Cat. 2																						
Reproductive toxicity Lactation																						
STOT Single exposure, Cat. 1																						

Hazard Category	Europe						Americas					Asia								Others		
	EU	CH	NO	RS	RU	TR	BR	CA	MX	US	UY	CN	JP	KR	MY	PH	SG	TH	VN	AU	NZ	ZA
STOT Single exposure, Cat. 2																						
STOT Single exposure, Cat. 3																						
STOT Repeated exposure, Cat. 1																						
STOT Repeated exposure, Cat. 2																						
Aspiration hazard, Cat. 1																						
Aspiration hazard, Cat. 2																						
Environmental Hazards																						
Acute hazards to aquatic environment, Cat. 1																						
Acute hazards to aquatic environment, Cat. 2																						
Acute hazards to aquatic environment, Cat. 3																						
Long-term hazards to the aquatic environment, Cat. 1																						
Long-term hazards to the aquatic environment, Cat. 2																						
Long-term hazards to the aquatic environment, Cat. 3																						
Long-term hazards to the aquatic environment, Cat. 4																						
Hazard to the ozone layer																						

Key	
Building blocks implemented or can be used (voluntarily)	
Building blocks not implemented	

Case Study 2: Metals classification and the CLP Regulation

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1 Introduction

1.1 Background

Depending on how they are used, metals are subject to several regulations and directives¹. Organometallic substances are subject to other criteria than metals². Under the CLP Regulation, substances and mixtures are required to be classified according to their hazard properties, based on classification criteria which are specified in the Regulation. The toxicity of a metal depends on the extent to which the metal ion portion disaggregates from the rest of the compound. As a metal powder will have a greater specific surface area³ than the massive form, the rate of metal ion release from the powder will be greater than for the massive form. As such, a greater number of ions may be released from powder than from the same mass of the massive form during testing. This would potentially lead to a different classification of the metal powder compared to that of the massive form.

A metal alloy is not a simple mixture of metals, but a unique material of disparate intrinsic properties compared to its individual constituents (i.e. it is a 'special mixture'). Industry stakeholders and EU associations suggested that CLP does not take into account the specifics of metallic bondings and spinel inclusions, as a result, there may be arguments for alloys to be classified and labelled in a more differentiated way. In other words, it is argued that it should not be assumed that special mixtures and alloys will have the same intrinsic properties as those of its components, and to do so could result in an over/under-classification of metal alloys.

The precise number of alloys is unknown; however, there are online industry sources which have information for a number of alloys. Such an example is MatWeb (www.matweb.com), which lists over 14,000 types of metals and metal alloys. Although this is not an exhaustive list of all alloys, the number of unique alloys will be lower than this; many of the alloys have the same composition but may have a different size, form or are manufactured in a way that enables them to have different physical properties (e.g. hot finish, cold finish, different cold reduction percentages and hardening). However, the differences in finishing also highlight how alloys with the same composition may vary. For example, 305 Stainless Steel, cold reduction 60% and 305 Stainless Steel, cold reduction 0% will have different tensile strengths (Ultimate 1,131 MPa vs. 588 MPa) and elongation at break percentages (7.3% vs. 62.3%). In Table 1-1 a selection of metallic element classifications appears

¹ Namely; Classification, Labelling and Packaging (CLP) Regulation; Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation; the Plant Protection Products Regulation; the Biocidal Products Regulation; the Directives on Medicinal Products for Human Use and for Veterinary Use; the Cosmetic Product Regulation; the Batteries and Accumulators Directive; the Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive; End-of-life vehicles Directive; Waste Electrical and Electronic Equipment (WEEE) Directive; and the Toy Safety Directive.

² Organometallic substances containing metals are subject to the criteria and procedures for identifying persistent, bioaccumulative and toxic substances (PBT) and very persistent, very bioaccumulative substances (vPvB) (see case study 2a-6); the PBT and vPvB criteria do not apply to inorganic substances. Metals with carcinogenic, mutagenic and reproductive (CMR) properties are subject to the risk management procedures triggered by CMR classifications (see case study 3b-1).

³ Specific surface area (SSA) is a property of solids defined as the total surface area of a material per unit of mass with units of m²/kg or m²/g.

along with the number of alloys and grades containing the metallic elements (found on MatWeb, search conducted April 2016) at or above different concentrations that would require labelling.

Table 1-1: CLP and ATP metal classifications, the concentration for classification and the number of alloys and grades that appear on MatWeb

Element	Classification	Concentration for labelling classification	Number of alloys and grades
Beryllium (Be)	Carc. 1B; Acute Tox. 2; STOT RE 1 (ATP)	≥ 0.1 ; ≥ 0.1 ; ≥ 1	499 (≥ 0.1); 347 (≥ 1)
Chromium (Cr) compounds [#]	Carc. 1B; Aquatic Acute & Chronic 1	≥ 0.1 ; (≥ 0.1)	6,031 (≥ 0.1)
Nickel (Ni)	Carc. 2; STOT RE 1 (ATP)	≥ 0.1 (Skin sens); ≥ 1 (carc. cat. 2); ≥ 10 (STOT1)	5,565 (≥ 0.1); 4,583 (≥ 1); 2,715 (>10)
Zinc (Zn)	Aquatic Acute & Chronic 1	M-Factor consideration (≥ 0.1)	2,682 (≥ 0.1)
Silver (Ag)	<i>Aquatic Acute & Chronic 1 (proposed)</i>	M-Factor consideration (≥ 0.1)	702 (≥ 0.1)
Cadmium (Cd)	Carc. 1B; Muta. Cat 2; Repr. Cat. 2; STOT RE 1	≥ 0.1 ; ≥ 1 ; ≥ 1 ; ≥ 1	24 (≥ 0.1); 5 (≥ 1)
Mercury (Hg)	Acute Tox. 2; Repr. 1B; STOT RE 1; Aquatic Acute & Chronic 1 (ATP)	≥ 0.1 ; ≥ 0.3 ; ≥ 1 ; ≥ 0.1	3 (≥ 0.1); 3 (≥ 0.3); 3 (≥ 1)
Thallium (Tl)	Acute Tox. 2; STOT RE 2; Aquatic Chronic 4	≥ 0.1 ; ≥ 10 ; ≥ 1	2 (≥ 0.1); 1 (≥ 10); 1 (≥ 1)
Arsenic (As)	Acute Tox. 3; Aquatic Acute & Chronic 1	M-Factor consideration (≥ 0.1 ; ≥ 0.1 ; ≥ 0.1)	49 (≥ 0.1)
Lead (Pb) powder	Powder Classification	≥ 0.03	1,605 (≥ 0.03)*
Lead (Pb) massive	Massive Classification/Repr 1A (lact)	≥ 0.3	796 (≥ 0.3)
[#] Chromium (VI) compounds are the main compounds of concern for chromium, various forms of chromium as chromates will also be of concern			
* Very few metals or alloys are likely to be powders by design			

Metals are essential to most living organisms and they are also found in a variety of everyday objects. Excessive exposure to some essential metals can lead to toxic effects, and a narrow range exists for some metals between beneficial effects and toxic effects. Other metals have no established biological functions and exposure to these can cause toxic effects, for example, arsenic, cadmium, lead and mercury. The health effects of cadmium and lead have been considered as part of the United Nations Environment Program where there was a review of scientific information. The review considered lead⁴ to be a multi-organ system toxicant that can cause neurological, cardiovascular, renal, gastrointestinal, haematological and reproductive effects. In the environment, it was considered as being toxic to plants, animals and micro-organisms. The review considered cadmium⁵ to be a toxic element for humans mainly affecting kidneys and the skeleton, and that it is a carcinogen by inhalation. In the environment, is toxic to plants, animals and micro-organisms.

The majority (Eurometaux estimate >90%) of metals are used in the form of an alloy. The properties of alloys can be different to that of the pure elemental or bulk metal material; by combining metals together and creating an alloy it is possible to create an alloy that has specific beneficial properties (e.g. strength, resistance and conductivity) that may not be achievable by using the bulk material alone.

⁴ United Nations Environment Program - Final review of scientific information on lead (2010).

⁵ United Nations Environment Program - Final review of scientific information on cadmium (2010).

A good example of this is alloying elements used in steel. Small quantities of carbon can increase the hardenability and wear resistance of steel. Manganese can increase the strength and hardness penetration of steel. Chromium can improve the hardness penetration and wear resistance of steel, and steels with 14% or more chromium are commonly known as stainless steels. Silicon, nickel, molybdenum, boron, titanium and other metals can be added to increase hardenability or provide other properties.

Other examples of (the properties of) alloys include:

- Beryllium-copper alloys, which are stronger when alloyed together and have higher electrical conductivity than other copper alloys;
- Nickel-cobalt alloys, which are used in aircraft engines due to their corrosion and heat resistance;
- Aluminium alloyed with small amounts of silicon, iron, copper, manganese, magnesium and zinc, which provides an alloy specifically designed for the manufacture of beverage cans;
- Copper-zinc alloys, which are used to make brass which has a variety of fittings; and
- Copper-tin alloys form bronze which is used for plumbing fixtures.

The classification of metals as part of CLP is a concern for manufacturers, importers and downstream users of metals, this is due to the implications that the classification has under various pieces of EU legislation. For example, over-classification of metals and alloys would mean that there may be unnecessary market restrictions in place, leading to undue costs; conversely, where a substance has been under-classified, there may be adverse effects (e.g. health) on users, society and the environment.

Metal and alloy classifications are primarily an EU-wide issue. However, EU decisions may impact international developments.

1.2 Objectives

This case study feeds into Task 1 and Task 2 with respect to both classification and the identification of properties of concern across EU chemicals legislation.

The main aim of the case study is to answer the following questions:

- Are CLP classification rules appropriate for the classification of metals (i.e. metallic forms)?
 - To what extent do default classification rules under the CLP regulation trigger under/over classification of metals?
 - Do inconsistencies and gaps exist in the CLP Regulation relating to the classification of metals and alloys?
 - Are there mechanisms and factors that cause possible inconsistencies and gaps?
 - If present, are specific concentration limits (SCL) and generic concentration limits (GCL) appropriate?
 - Does a new EU-testing method or a new OECD testing protocol need to be developed and recognised for the classification of metals or specific metal forms (e.g. alloys)?
- What are the impacts of risk management measures triggered by metal classifications?

1.3 Methodology

Desk research was first carried out to obtain further information on the nature and extent of the CLP classification rules for metals and whether there is the potential for the over- and under-classification of metals and metal alloys. This involved the analysis of the legal provisions of CLP for metals and metal alloys. Following the initial desk research, stakeholder consultation was carried out, via open and targeted consultation and targeted interviews. Consultation aimed at obtaining further information on the issues identified during the desk research, gathering information on specific examples of where companies have had challenges with proposed and adopted classifications.

Information was collected from consultation responses and a number of interviews were requested and held. It is recognised that many of the issues discussed have been identified by responses from industry. A number of NGOs and other associations were contacted in order to obtain their input, however, there was either no or a limited response with this recognised as an important limitation to this case study. Nevertheless, it should be noted that some responses were received from non-industry respondents (e.g. environmental NGOs and Member State authorities) and were incorporated into the assessment presented below. In addition, comments received from Member States relating to the use of the bioelution method are presented where relevant. It is also important to note that, as part of the broader consultation process for the study, environmental NGOs provided comments, although these related to specific hazards (including the identification of endocrine disrupting chemicals, carcinogens, mutagens and substances toxic for reproduction) rather than metal classification in particular.

The desk research, as well as feedback received during the discussions at the workshop in April 2016, was used to validate the issues identified during the consultation and to draw conclusions.

2 The Classification of Metals and Metal Alloys

2.1 Introduction

The following points raised regarding the classification of metals and metal alloys were taken from desk research, interviews, consultation and workshop feedback. During the consultation process for this study, most comments about metals were provided by industry, however, some information was also provided by Member States and NGOs.

The CLP Regulation does not specify separate criteria for the classification of different forms of metals (powder, flake, massive and other forms). However, Recital 30 of the CLP Regulation indicates that tests should be carried out on the form(s) or physical state(s) in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used. If the classification criteria applied to metals are inappropriate, the chemicals legislation will not be able to effectively or efficiently regulate the risks they pose. Although environmental and human health classification under CLP must be derived on the basis of available data, data may be generated for the purposes of CLP and data may also be generated as part of other legislation such as the Biocidal Products Regulation⁶, Plant Protection Products Regulation⁷ and REACH⁸. The generation of data offers a good opportunity to complement the deriving of fully documented classifications as part of CLP. Eurometaux (an association for the non-ferrous metals industry) believes that, process-wise, the legal texts of CLP, Biocidal Products Regulation and REACH do not foresee a timely sequence or practical code of work to maximise the use of generated data and the efficiency of the overall classification process. Eurometaux also believes that, at present, there are methodologies documented under one piece of legislation (e.g. approach to test insoluble compounds of metals or read-across between inorganics under REACH) that may benefit another piece of legislation (e.g. interpreting the result of a test on an active substance under the Biocidal Products Regulation). These differences may result in classifications decided on the basis of incomplete datasets or datasets that are not fit-for-purpose. The result is classifications that may be over- or under-protective, and triggering impacts under other downstream legislation, without the expected added-value for society. Ideally, all legislation which leads to the generation of data and which informs on the classification of substances and mixtures should work in synergy rather than in isolation. Eurometaux indicated that the metals sector had developed a freely available web based tool, known as MeClas⁹. The tool can be used to facilitate classification of complex metal containing materials.

⁶ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

⁷ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

⁸ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

⁹ MeClas – Metals Classification Tool - <http://www.meclas.eu/>

2.2 Metallic properties

As part of the formulators targeted consultation questionnaire, a respondent within the metals industry indicated that CLP does not take into account the specifics of metallic bonding (in metals and alloys) and CLP is poorly suited for the classification of these kinds of mixtures. The respondent also indicated that the CLP classification rules are based on the science of ionic and covalent bonding¹⁰, and not metal bondings and spinel inclusions, which is why the classification may be misleading.

2.3 Form and bioaccessibility

2.3.1 Overview

As part of interviews and the open public consultation an institute indicated that CLP was crafted with organic substances in mind. As such, when it is applied to inorganic substances, a number of default rules/criteria may trigger under- or over-classification of metals, their compounds and alloys. They, along with several other institutes, EU associations and confederations suggested that there is a lack of developed and recognised metal-specific hazard assessment approaches and guidance (e.g. for alloys). Furthermore, they suggest that the development of rules for metals and other inorganic substances along with ensuring that EU hazard assessment experts apply such approaches whenever applicable could improve the assessment of inorganic substances including metals. For metals, some of the criteria used to define hazards (and possible resulting classifications) appear to miss out on the specific aspects of metals, metal compounds and their mixtures (modes of action, bioavailability, or fate).

Furthermore, it was indicated that as regards to the physical form, for human health endpoints there is currently a limited possibility to classify differently a metal in massive and powder forms with lead being a notable exception (see earlier Table 1-1). The assumption that a mixture will have the same intrinsic properties of its components does not necessarily apply to complex materials such as alloys. Eurometaux indicate that metals and especially alloys behave completely differently. They indicate that it is therefore important to acknowledge the specific status of alloys, it is also acknowledged that a new method (i.e. bioelution) is being developed but that it has not yet been validated or accepted at EU or OECD level. However, the potential acceptance and incorporation of this method as part of CLP and other legislation, along with guidance, may lead to more realistic classification. It is critical that the method is validated and that the classification criteria associated with the method is well thought out, a situation should not develop where the test method underestimates the hazard.

Comments provided by institutes, EU associations and confederations also suggested that the environmental classification criteria in many respects are much stricter for inorganics than for organics. It was highlighted that a lack of criteria for degradability leads to the classification of many metals one category stricter. Also, the absence of data triggers a default chronic category 4 environmental classification for metals, it was suggested that this does not happen for organic substances. Also, for environmental classifications, metals may be assessed based on the finest

¹⁰ Ionic bonding is the process where electrons are transferred from one atom to another resulting in the formation of positive and negative ions. The electrostatic attraction holds the compound together. Covalent bonding is the process where pairs of electrons are shared by atoms. This results in atoms which gain more stability which is gained by forming a full electron shell.

forms, which may represent a worst-case reference or representative for the massive form, while for organic substance the form as manufactured or used is tested.

2.3.2 Specific surface area

As part of the interviews, the interviewees were asked whether the classifications of substances are based on the powder or nano forms (i.e. those with an overall greater specific surface area) or the massive forms. It is anticipated that these smaller forms will be more reactive and release a greater number of ions than larger forms and therefore these might be more toxic.

As part of an interview with ECHA in May 2016, ECHA highlighted that, as indicated in CLP Article 9(5), the classification of a metal or alloy will depend on its foreseeable use. For example, even if a company purchases a metal in bulk form, its use could generate chips or particulates which could result in exposure. ECHA also indicated that, in the specific case of lead, the SCL that is being introduced (0.03% for the powder) will apply if the material is of a certain particle size (massive forms have a particle size of more than 1 mm while powder forms have a particle size of less than 1 mm). Whether this would apply to alloys as well is still unclear.

Eurometaux indicated that it is now expected that companies will be documenting the possibility that powders could be generated under conditions of reasonable expected use along the lifecycle of the substance. Eurometaux suggested that this may present a problem for some companies and it may lead to some discussions between regulators and companies as to what constitutes 'reasonable expected use'. However, Eurometaux also indicated that in situations where only the massive form is handled this would be an improvement, i.e. a classification may not be required. It was suggested that, for instances where nanomaterials are used, it would be in a company's interest if it was possible to have an additional entry to appear in CLP, i.e. massive, powder (micro) and nano, to avoid the possibility of the nanoform properties having an impact on the both the powder and massive forms.

An EU association indicated that, in essence, there are two separate effects to consider when assessing the hazards of metals and alloys. The first of these is the surface effect and the second is the matrix effect. The surface effect addresses differences in the physical form and will generate higher releases for larger surface areas. This is expressed as the release to surface ratio which is a constant and intrinsic property of the material. The matrix effect should be considered as it can affect the release. The matrix can create extra bonds and therefore reduce the release to surface ratio or it can cause a preferential leaching, for example by electrochemistry effects, thereby increasing the release to surface ratio. Eurometaux indicated that surface and matrix effects can be measured in Transformation Dissolution protocol (T/D) and bioelution tests, either separately or together.

For human health classification, when comparing powders and massive forms, an association indicated that the principle of the release per surface area of a material is a physical constant, and consequently an intrinsic property of that material, they indicated that such a distinction has been used several times, under the Dangerous Substances Directive assessment scheme. The association indicated that RAC, so far, had not recognised this despite toxicity being driven by the release to surface ratio for metals like lead.

For environmental classification, Eurometaux indicated that, for some substances, there is already recognition of the surface effect with different classification entries in CLP Annex VI for massive and powder forms. The classification is always surface-release related. An example of this is that massive zinc does not have an environmental classification, whilst zinc powders (pyrophoric and stabilised) are classified as aquatic acute category 1 and aquatic chronic category 1. For mixtures,

the matrix effect can be accounted for by the manufacturer using the outcome of the transformation/dissolution protocol. Where zinc is alloyed with another material the zinc ions may be more strongly held in a matrix, therefore the ion release may be lower and this could be shown in a transformation/dissolution test.

2.3.3 Bioavailability and a new EU-testing method

Bioavailability

Bioavailability (or biological availability) is defined in CLP Annex I as being the extent to which a substance is taken up by an organism, and distributed to an area within the organism. Bioavailability is dependent upon physico-chemical properties of the substance, anatomy and physiology of the organism, pharmacokinetics, and route of exposure. The bioavailability of metals is influenced by physical factors such as temperature, phase association, adsorption and sequestration (Tchounwou *et al*, 2012¹¹). It is also affected by chemical factors that influence speciation at thermodynamic equilibrium, complexation kinetics, lipid solubility and octanol/water partition coefficients (Hamelink *et al*, 1994¹²).

Based on the properties of a metal in its pure form, the classification may also apply to the alloy, although, the metal, as part of an alloy, may be held more strongly within a matrix. In other cases, some metals may be more biologically available in an alloy form and may therefore be under classified.

A Member State indicated that they consider the intrinsic properties of a metal to be the same regardless of the physical form, but noted that there are examples of split classifications for some metals based on the different physical forms. They also indicated that differences in bioavailability should be qualified by subsequent risk assessment and that it may be difficult to include within the CLP criteria that are more substance-specific.

The issue of biological availability has been discussed by the Commission, at CARACAL meetings and at industry workshops¹³.

Bioelution

Eurometaux indicated that data currently available for lead metal demonstrates a significant difference in the release of metal ions between the soluble, powder and massive forms. This evidence, provided by an animal study (Barltrop and Meek, 1979¹⁴), as well as from *in vitro* bioelution tests, illustrates that differences in bioavailability, related to different physical forms, should to be taken into account when classifying metals. The bioelution test is a test whereby the bioaccessibility of metals/alloys is tested in synthetic gastric fluid and other fluids (simulating other body fluids such as saliva).

¹¹ Tchounwou, PB, Yedjou, CG, Patlolla, AK, Sutton, DJ, (2012): Heavy metal toxicity and the environment.

¹² Hamelink, JL, Landrum, PF, Bergman, HL, Benson, WH, (1994): Bioavailability: Physical, Chemical and Biological Interactions.

¹³ See, for example, workshop summary available at: <http://www.reach-metals.eu/force-download.php?file=/images/BioelutionWorkshop/report%20em%20bioelution%20workshop%2022052014.pdf>

¹⁴ Barltrop D & Meek F (1979): Effect of particle size on lead absorption from the gut.

In May 2014, Eurometaux held a workshop¹³ on the bioelution test method. This included various speakers who identified a range of possible applications, including, as an alternative to animal testing for human health effects, for substances where there is a scarce amount of data, to group substances together, to undertake read across of toxicity endpoints and for read across of toxicity for the classification of mixtures and alloys.

A few Member States indicated that they do not support the introduction of additional criteria for the classification of metals in different forms, into CLP as, in their view, too many classification criteria could call into question the 'fitness' of CLP. However, a Member State also indicated that the classification of alloys for health effects is a longstanding unresolved issue in CLP; and they understood that ECVAM has recently agreed to take forward the development of a standardised OECD test method, the bioelution test. The Member State supports the initiative and, if successful, the acceptance of the method as part of metal classifications for CLP. The Member State also suggested that additional guidance could be produced to deal with the classification of specific forms, noting that such an approach may be of particular help to the waste and major hazards (Seveso) sectors.

In October 2015 at the 2nd meeting on biological availability in the framework of Article 12 (b) of CLP, the Commission¹⁵ stressed the importance to move forward with the work on 'bioavailability'. The Commission regretted that no Member State had volunteered to lead activities at the OECD level.

During the meeting, industry provided data on correlations between metal bioaccessibility and *in vivo* bioavailability and/or toxicity for the different exposure routes (i.e. oral, dermal and inhalation) and bioelution was discussed. Most data were provided for the oral route for various metals and metalloids. Industry considered that the data shows that for several metals (e.g. lead, arsenic, zinc, cadmium and nickel) there is good evidence that bioaccessibility of metal ions in simulated gastric fluid correlates well with *in vivo* systemic bioavailability and/or toxicity. There was, however, not a consensus that sufficient data were provided to conclude the matter.

At the meeting, several issues were highlighted and discussed, including:

- Comparison of default and proposed approach (bioaccessible concentration) including whether the approach is conservative enough;
- Reference material;
- Representativity of the fluids;
- Correlation between *in vitro* and *in vivo*;
- Sequential versus parallel testing;
- Enforceability of the classification system; and
- SOP (Standard Operating Procedure) and SPSF (Standard Project Submission Form).

In November 2015, as part of the 19th meeting of competent authorities for REACH and CLP (CARACAL)¹⁶, a number of issues surrounding biological availability were discussed. From previous meetings there was agreement that the best approach was to develop an OECD test guideline. The guideline would be on bioelution and it would be based on, but not limited to, the testing of metals, inorganic metal compounds and metal-containing complex materials. At the previous meetings, it was discussed whether metal release/surface area is an intrinsic property of metals and alloy

¹⁵ Embedded within, European Commission, CA/90/2015, 19th Meeting of Competent Authorities for REACH and CLP (CARACAL)

¹⁶ European Commission, CA/90/2015, 19th Meeting of Competent Authorities for REACH and CLP (CARACAL)

samples. Overall it appeared that the T/D protocol was more an 'external' measure (i.e. in the environment) while bioelution is 'internal' (i.e. it is more representative of human digestion). The acceptance of bioelution testing would support the 3R's (Reduction, Refinement or Replacement) of animal testing.

The Commission suggested focusing on the development of a method for the oral route as a pilot case, including the consideration of the gastric fluid compartment. Additional methods may be developed when more data becomes available for additional routes, where considered relevant.

In parallel ECHA, together with the Commission services, agreed to continue the discussion with stakeholders on the use of data from bioelution testing in the framework of the CLP Regulation.

However, some Member States have raised concerns about the bioelution test. Austria¹⁵ highlighted a number of scientific and legal points on why bioavailability should not yet be used in the assessment for the classification of alloys. The points included references that Eurometaux were making to CLP Article 12, the term 'not biologically available' and Austria was seeking the legal view of the Commission. Austria indicated that in their view the term 'not' can only be interpreted as not at all. Austria also indicated that CLP Article 6(3), which makes reference to mixtures, seems to exclude CMR substances. Austria also raised questions about the test methods reproducibility and its development. It was suggested by Austria that for the time being it may be preferable in terms of regulatory practicality to pragmatically adapt concentration limits for alloys with high particle size that would effectively prevent ingestion and inhalation.

Denmark¹⁵ and Germany¹⁵ made similar comments about Article 6(3) and 12. Germany also indicated that there were too many unresolved issues for bioelution protocols to be used for regulatory purposes and that the development and validation process of a full set of methods covering all uptake pathways would take at least 6 to 10 years.

In addition to comments made by Denmark, Germany and Austria at CARACAL, an EU association indicated that some Member States (Denmark, Germany and Sweden) would not support the use of the bioelution test method on the basis that it would not be appropriate under CLP based on recital 22, which says testing should not be carried out for mixtures containing CMRs – a view shared by ECHA. However, ECHA do not *a priori* exclude the use of bioelution or similar data for classification of CMRs. ECHA has noted that not all test methods are appropriate for testing mixtures and that mixtures with CMR ingredients should in principle always be classified based on their ingredients (Article 6(3), CLP) (e.g. by applying the generic concentration limits for classification). Industry and industry associations are of the opinion that the bioelution test is not a test *per se* but a calculation method, so should still be allowable for CMRs and that the original intention of the recital 22 in CLP was to prohibit animal testing in relation to mixtures, not any other testing.

An EU association indicated that the CLP rules for mixtures classification do not fit with the matrix effect seen in a number of metal containing materials, unless Article 12(b) can be used with a bioelution test. They highlighted how discussions on this matter are being held at UN level. They also suggested that there is a need for further guidance on how to apply appropriate classification schemes for complex metal substances, materials and mixtures.

Rapid removal

Another EU association also indicated that there is a lack of a level playing field between metals and organic substances. They indicated that the metals industry has conducted numerous research projects on specific metals, including literature surveys, environmental fate modelling, field experiments and laboratory tests. This has built up a wealth of evidence that demonstrates that

these metals do not persist in the water column and that they are rapidly removed to the sediment and transformed into chemical species that are not available to biota. For metals the concept of degradability, under the name of ‘transformation’ or ‘rapid removal (from the water column)’, has gained recognition for some metals, but has not yet gained full regulatory acceptance for most metals. The association highlighted an ECHA report¹⁷ from a workshop where the concept of ‘rapid removal’ was discussed. At the workshop it was suggested that three groups of metals could be distinguished:

1. Metals that methylate such as Hg;
2. Metals that quickly hydrolyse and form different species that precipitate in the water column (Fe, Al, Sb, Sn, Mo, Cr, ...); and
3. Metals for which the key question is ‘irreversibility’ (i.e. binding to a non-bioavailable form under a range of environmental conditions). This group would cover, for example, Cu, Ni, Zn and Pb.

The Chairman concluded that there is no overall consensus on whether and how the concept of ‘rapid removal’ should be used in the environmental hazard classification of metals and metal compounds. But, there was broad agreement that certain ‘rapid removal’ mechanisms are evident for certain types of metals. The Chairman also concluded that references to the concept of rapid removal in the current Annex VI CLP Guidance document should be amended in the short term before further consultation with CARACAL. It was also concluded that an expert group should be established to further discuss the concepts and relevant information requirements.

EU associations, industry stakeholders and consultants have indicated that they have since provided additional evidence to ECHA. The ECHA Workshop also concluded that metals that methylate are not rapidly degraded, metals that quickly hydrolyse and form different species that precipitate in the water column are considered rapidly degraded and that further discussion is needed for the ‘irreversibility’ group of metals.

ECHA, regarding the concept proposed by the industry for degradation, indicated that in principle it is a risk-based concept, which is not acceptable from a classification point of view. They also suggested that there are other limitations in scope (e.g. the concept has been validated only for lakes and not for river or marine waters).

Further comments on the T/D protocol and bioelution

For the environment, an EU association indicated that the T/D exists as a guidance note and allows the same general principles to compare the concentration in the T/D test with the reference ecotoxicity value for the given metal in a standardised way. The T/D has therefore been included in both the GHS text as well as in the CLP. The T/D can be used for the environmental classification of metal and metal compounds, so presently there is a gap in that there is a method that can be used for the environment but not human health.

The EU association indicated that having the OECD involved is essential to avoid different classifications for the same material which would cause economic discrepancies between jurisdictions covered by CLP and GHS. The EU association indicated that there is a need to have the rules implemented worldwide to avoid competitive (or non-competitive) advantages.

¹⁷ ECHA (2012): Report from the Workshop on the validity of the use of the concept of ‘rapid removal’ on 8th February 2012

When asked how successfully T/D has been applied worldwide, Eurometaux indicated that as it is described in the UN GHS Annexes (9.7 and 10) it is applicable in systems where the UN GHS is implemented. However, Japan does not seem to have implemented these Annexes. Bioelution, on the other hand, is a new tool. Presently there are two approaches: there are those nations which are applying the CLP/GHS by the rules and other nations (e.g. Australia and Japan) that are exempting alloys from classification, this creates an inconsistency between different countries.

An EU association indicated that they had made use of the T/D protocol. Furthermore, a not-for-profit scientific arm of the EU association was one of the commodity groups that jointly developed the T/D protocol approach and eventually got it accepted as an OECD protocol. They indicated that the bioelution test would be especially useful for alloys. They highlighted that there is a range of metals that nickel is alloyed with and, in varying amounts, the alloys as such behave differently to their alloying elements. Both the T/D protocol and the bioelution concept would allow the identification of the relevant environmental and human health classifications.

ECHA noted that for human health endpoints, there has been a suggestion to use relative bioelution of the metal and the alloy using artificial body-fluid systems which have been developed. They indicated that this is relevant for some human health endpoints; however, since such a comparison is relative (i.e. based on comparison between the pure metal and the alloy), it cannot really be used for determining hazards of pure metals. An EU association indicated that they were aware of a situation where bioelution data were provided for a restriction proposal (copper in brass) and this was accepted by RAC, but not for CLP. ECHA indicated that for CLH the relative bioelution would not be of use as CLH regards substances, however, there is no principal hindrance of using bioelution in CLH. ECHA also indicated that the use of bioelution for the classification of mixtures are under discussion in EU.

ECHA also indicated that the T/D protocol has been used for some metal compounds (e.g. copper) to evaluate environmental hazards, but not as much as it should be. In most cases, metal and mixture (alloy) REACH and CLH dossiers, contained data generated using the OECD TG 105 protocol for water solubility and did not provide information based on the T/D protocol. In general, even if there is chronic aquatic toxicity, one needs to know whether the metal is irreversibly removed from the water column and rapidly transformed into non-bioavailable forms to allow the application of the metals classification scheme in an appropriate way.

2.3.4 Using read across for similar alloys

An EU association indicated that in accordance with CLP guidelines for classification of mixtures, the use of bridging principles should be considered for the classification of alloys for which toxicology data are not available. This approach can be used to group target alloys with other similar alloys for classification where sufficient data on alloy characteristics (e.g. metal bioaccessibility and physicochemical properties, metal bioavailability in T/D, chemical composition, technical performance etc.) are available. This ensures that the classification process uses the available alloy data to the greatest extent possible, without relying on additional animal testing when it is unnecessary.

The main principle driving this approach is that bridging can be used if hazard classifications exist (based on data) for a 'source' alloy and sufficient data exist to demonstrate a 'target' alloy has similar properties (e.g. release rate of metal ions) relative to the source alloy. An EU association indicated that bridging has taken place for some alloys, for example chromium and boron alloys.

For human health, the association indicated that bioelution could be used to support the bridging approach. Four steps would be involved:

- Step 1: Derive metal release data (i.e. bioaccessibility data) for equivalent amounts of the source alloy and the target alloy using the appropriate bioelution protocols and artificial biological fluids relevant to the oral route of exposure.
- Step 2: Develop a matrix listing data on bioaccessibility, additional physicochemical properties (e.g. surface properties), health effects, hazard classifications, and other relevant properties for both the source alloy (with their metal constituents) and the target alloy. For example, many alloys are already grouped in numerous national and international standards (e.g. AFNOR, AISI, DIN, ASTM, JISI, UNS, etc.) based on their chemical composition. In addition, they can also be grouped with respect to their technical performance (e.g. Council of Europe Guidelines on metals and alloys for food contact applications). Such information is part of the weight-of-evidence approach.
- Step 3: Use the relationship between bioaccessibility and health effects in the source alloys to read-across to, or predict, the unknown health effects information for the target alloy, based on similarities in bioaccessibility and other factors, using a weight of evidence approach.
- Step 4: Use relevant and applicable information to verify that the assumptions behind the read-across paradigm are valid. This may require generation of additional *in vitro* or *in vivo* toxicological or toxicokinetic data in one or more alloys.

For the environment, the association indicates that the T/D is a key element. A screening test (24 hours T/D) is used to provide indications on release, to consider grouping and/or bridging in a weight of evidence approach with other information as outlined in Step 2 above. For metals and metal compounds a full 7-day or full 28-day test T/D can also be commissioned.

2.3.5 Peer reviewed literature

Various scientific peer reviewed journal articles indicate that alloys release significantly less metal into solution than when the same metal substances have been tested in their non-alloyed form. Although an extensive literature review has not been performed here, information from some specific studies are highlighted below.

Lillicrap *et al* (2013)¹⁸ published information that highlights how care needs to be taken when conducting a T/D test and the substance grade being tested. As part of a test, the data for a low-grade silica fumes may have resulted in a false hazard classification. The low-grade substance showed that levels of some of the impurities (e.g. lead and zinc) measured in the solutions exceeded the acute ecotoxicity threshold limits and would effectively lead to a hazard classified as acute 2 according to the GHS classification scheme. In comparison, the high-grade silica fumes were found not to be acutely or chronically toxic up to and including an initial loading concentration of 100 mg/L and 1000 mg/kg respectively. The example of the low-grade substance highlights how the T/D test can identify potentially hazardous grades and would not result in an under classification. Furthermore, this identification may encourage the use of higher grade silica fumes instead of lower grade substances and this may have positive impacts on health and the environment.

¹⁸ Lillicrap A, Allan I, Friede B, Garmo Ø, Macken A (2013): Is the transformation/dissolution protocol suitable for ecotoxicity assessments of inorganic substances such as silica fume?

Skeaff *et al* (2011)¹⁹ assessed the inter-laboratory reliability and precision of the T/D. They found that the T/D could be applied to generate reliable results for each of the reference substances, and the T/D data could be linked to ecotoxicity reference values (ERV) to yield consistent GHS hazard classification outcomes for each substance. They also found that the alloy released significantly less metal into solution than when the same metal substances were tested in a non-alloyed form.

Skeaff *et al* (2008)²⁰ indicated that although approaches for metals appear in GHS, an approach for alloys has yet to be formulated. In the study, they applied the T/D Protocol to several economically important metals and alloys: iron powder, nickel powder, copper powder, and the alloys Fe–2Cu–0.6C (copper = 2%, carbon = 0.6%), Fe–2Ni–0.6C, Stainless Steel 304, Monel, brass, Inconel, and nickel–silver. The data revealed that the extent of the reaction of the metals and alloys with the aqueous media was only slight, resulting in less than 2% reaction and dissolution of the metal cations at the 100 mg/L loadings. The sintered alloys Fe–2Me–0.6C did not exhibit metal release to levels that would trigger classification. However, their component copper and nickel powders would classify as Acute 1–Chronic 1 and Acute 3, respectively, although the iron powder would not classify at all. The summation method, if applied, could result in false positive classification or overestimation of the hazard. A potential case of over-classification would be stainless steel, which is primarily 18% chromium and 10% nickel, with the balance being iron. The maximum average metal concentrations and corresponding extents of transformation at 100 mg/L, and classification proposals for metals and alloys tested are shown in Figure 2-1 (next page).

Midander *et al* (2006)²¹ studied the metal release from stainless steel particles in artificial biological media. The results suggested that a small particle loading, bi-linear shaking and centrifugation for separation of particles from the solution give the most reproducible results. They also show that metal release rates are strongly influenced by the physico-chemical properties of the test medium and the effective surface area of particles during exposure.

Henderson *et al* (2014)²² performed inter-laboratory validation of the bioaccessibility of metals using the bioelution test method. They found the method to be overall satisfactory in terms of within-laboratory variability in bioaccessibility data for synthetic gastric fluid, lysosomal fluid, interstitial fluid and perspiration fluid for all treatment conditions. However, there was some inter-laboratory variation. The authors recommended that the degrees of freedom within the Standard Operating Procedure (SOP) need to be addressed to achieve better concordance in absolute metal releases.

¹⁹ Skeaff JM, Adams WJ, Rodriguez P, Brouwers T, Waeterschoot H (2011): Advances in metals classification under the United Nations Globally Harmonized System of Classification and Labelling.

²⁰ Skeaff JM, Hardy DJ, King P (2008): A new approach to the hazard classification of alloys based on transformation/dissolution.

²¹ Midander K, Wallinder IO, Leygraf C (2006): In vitro studies of copper release from powder particles in synthetic biological media.

²² Henderson RG, Verougstraete V, Anderson K, Arbildua JJ, Brock TO, Brouwers T, Oller AR (2014): Inter-laboratory validation of bioaccessibility testing for metals.

Substance	At 100 mg/L loading				GHS classification proposal
	Analyte	µg/L	Extent of transformation, %		
			Loading basis	Component basis	
Iron metal powder	Fe	1,814	1.8	1.8	nul
Nickel metal powder	Ni	541	0.54	0.54	Acute 3
Copper metal powder	Cu	1,383	1.38	1.38	Acute 1–Chronic 1
Fe-Cu-C sintered alloy cuttings	Fe	78	0.08	0.08	nul
	Cu	1.2	—	0.06	—
Fe-Cu-C sintered and forged alloy cuttings	Fe	138	0.14	0.14	nul
	Cu	0	—	0	—
Fe-Ni-C sintered alloy cuttings	Fe	395	0.42	0.4	nul
	Ni	25	—	1.3	—
Stainless steel 304 powder	Ni	0.27	0.012	0.002	nul
	Cr	0.19	—	0.001	—
	Fe	12	—	0.02	—
Inconel powder	Ni	6.6	0.011	0.009	nul
	Cr	2	—	0.01	—
	Fe	2	—	0.03	—
Monel powder	Ni	154	0.2	0.22	Acute 3–Chronic 3
	Cu	37	—	0.13	—
	Mn	7	—	0.8	—
Nickel-silver powder	Ni	384	1.48	2.26	Acute 2–Chronic 2
	Cu	32	—	0.051	—
	Zn	1,060	—	5.92	—
Brass	Cu	399	0.71	0.57	see Table 5
	Zn	310	—	1.03	—

Figure 2-1: Maximum average metal concentrations and corresponding extents of transformation at 100 mg/L, and classification proposals for metals and alloys tested (Source: Skeaff et al (2008)²⁰)

Wallinder *et al* (2006)²³ published the results of a multi-disciplinary research project on release rates of chromium (Cr), nickel (Ni) and iron (Fe) from stainless steel grades 304 and 316 as part of a combined field and laboratory investigation. The research concluded that the yearly release rates from ‘as-received’ (pickled and skin passed) grade 304 stainless steel exposed in Stockholm over the 4-year period ranged from 0.2 to 0.6 mg Cr m⁻², 0.1 to 0.5 mg Ni m⁻² and 10 to 140 mg Fe m⁻². Corresponding release rate ranges from grade 316 stainless steel were 0.2 to 0.7 mg Cr m⁻², 0.3 to 0.8 mg Ni m⁻², and 10 to 200 mg Fe m⁻².

The research also considered the release of pure metals compared to the alloys. The release rates of iron and nickel from stainless steel were found to be significantly lower than from the pure metals, but rates were similar for chromium. Immediately after release, chromium in runoff water is predominantly present as Cr(III) (>98.5%) and Ni as Ni(II) (>99%). These chemical forms change when the runoff water passes through different media (e.g. soils) in accordance with the chemical

²³ Wallinder IO, Bertling S, Kleja DB, Leygraf C (2006): Corrosion-induced release and environmental interaction of chromium, nickel and iron from stainless steel.

conditions of the media. The actual concentrations of chromium, nickel and iron in runoff water from stainless steel are far below reported ecotoxic concentrations of the metals for plants and other organisms, and also far below the recommended limits for these metals in drinking water. The investigated soils exhibited high retention capacity: >98% chromium and >99% nickel for the OECD soil and >94% chromium and >95% nickel for the Rosenlund soil, simulating 2 to 20 years of outdoor exposure. Most nickel is retained in the top surface layer, suggesting a very fast reaction between nickel in runoff water and soil. A somewhat slower reaction between chromium and soil was indicated.

The Lead REACH Consortium / International Lead Association (ILA) Europe, Chromium Alloys Consortium and the Molybdenum Consortium also indicated that they have T/D data. T/D data have also been obtained for use in Chemical Safety Reports (CSR). The Zinc REACH consortium have a CSR on their website for slags, from lead-zinc smelting. Within the CSR the results from T/D indicated that zinc is released from the slags in a very limited way. The observed levels of zinc released after 7 days for 100 mg/l loadings are below the reference concentrations for aquatic toxicity at both the pH values of 6 and 8 tested. The release of other metal ions (copper, nickel, cadmium, lead) was negligible at both pH values tested.

2.4 Over/under-classification

2.4.1 Introduction

Industry expressed concern with regard to the situation where there are inconsistencies in over and under classifications. For example, Eurometaux indicated that the original classification proposal for lead did not make a distinction between the hazard classification of the powder and the massive metal form. Such a distinction had been used for substances several times under the Dangerous Substances Directive assessment scheme, based on the principle that the release per surface area of a material is a physical constant and, consequently, an intrinsic property of that material. In the October 2015 CARACAL meeting, it was proposed that lead be further discussed at the December 2015 REACH Committee. At this meeting, the Committee had a first discussion on the proposed revisions to the CLP Regulation²⁴ which included the following for lead:

“... in view of the lack of certainty regarding the degree of bioavailability of lead in the massive form, a distinction needs to be made between the massive form (particle size of more than 1 mm) and the powder form (particle size up to 1 mm). It is therefore appropriate, for the time being, to introduce a specific concentration limit (SCL) of $\geq 0,03\%$ for the powder form and a generic concentration limit (GCL) of $\geq 0,3\%$ for the massive form.”

This differentiation could result in inconsistencies with other EU legislation. For example, under the End of Life Vehicles Directive²⁵ and Restriction of Hazardous Substances in Electrical and Electronic

²⁴ Draft Commission Regulation (EU) No .../.. of XXX amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures – as discussed at the meeting of the REACH Committee on 10 December 2015.

²⁵ Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles.

Equipment (RoHS) Directive²⁶, products can be labelled as being lead-free if they contain less than 0.1% lead, however, components can contain up to 0.1% lead (exemptions include up to 4% lead in copper alloys) but if they contain more than 0.03% lead then a lead label would be required according to the CLP Regulation. A European industrial association indicated that lead-free standard alloys may contain up to 0.8% lead as an impurity²⁷.

Eurometaux argue that there is a degree of inconsistency and overlap between CLP and REACH, especially for substances which are already listed on Annex VI of CLP. The inconsistency is two-fold:

- Several substances listed in Annex VI of CLP are not (or are no longer) placed on the EU market. They are the result of discussions on groups of substances that were classified as such, assuming a number of read-across principles. Today some of these (group) entries contradict the classifications derived using REACH data and affect discussions on classifications of substances that do exist on the EU market.
- For other substances listed in Annex VI of CLP, information generated for the purpose of REACH may indicate that the harmonised classification is either:
 - Correct but needs to be completed for some hazard classes (which can be done through self-classification in the short-term and through the CLH process over the longer term);
 - Incorrect and leads to confusion for companies which have to respect the harmonised classification to comply with law, but which also must inform their supply chain of the most accurate classification, to avoid liability concerns.

It should be noted that if industry have data suggesting that an entry is wrong, they are obliged to submit a CLH proposal to a Member State (Art. 37(6)). Where the inconsistency should lead to more severe classifications, experience indicates that this can be discussed swiftly with decisions taken quickly and adopted relatively quickly. In other cases, where the classifications should be downgraded or refined (in case of group entries), leading to a less severe or more substance-specific classification, there is generally no support from the Member States. As part of the consultation process a supplier indicated that to re-open a case about the classification of a substance, they would need the support of a Member State where the substance is being produced. The supplier indicated that if there are only one or two countries where the substance is being produced a situation can develop where the supplier is unable to re-open the case as the Member States are not supportive or they may be supportive but lack the resources. A comment made by a National representative who sits on RAC suggested that some Member States appear to have resource problems and may find it difficult to undertake large reviews. As a result, there are no rapid mechanisms for agreeing such corrections.

2.4.2 Are specific concentration limits (SCL) and generic concentration limits (GCL) appropriate?

In Eurometaux's opinion, the ECHA CLP guidance on the determination of SCL for reproductive toxicity (2013) is probably not appropriate for metals. They believe this is the case as the cut-off points reflecting different potencies were defined on the basis of a series of studies in animals exposed to organic substances. No study using metals was part of the database used to define cut-

²⁶ Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

²⁷ Lead is also discussed in more detail as part of the waste management case study.

offs. Aspects like bioavailability and speciation could therefore not be considered. Also, Eurometaux believes that some metals like lead have a huge amount of human data and potency should therefore rely on the assessment of human data, which cannot be included in the proposed methodology.

The ILA indicated that lead metal has predominantly human data rather than animal data to support toxicology. The data are based on workplace exposures and epidemiology in relation to blood lead levels and male fertility and developmental effects. When the RAC reviewed the classification, there was new guidance out from ECHA on how to assess fertility effects and in relation to potency. It appeared to the association that, given its newness, the RAC did not know how to adapt this for human data. In addition, it seemed that RAC was uncertain as to how they should take potency into account for the classification of a mixture (in this case alloys).

Eurometaux indicated in parallel the classification of mixtures for the environment (where M factors are applied to cover for 'potency') should be corrected for the matrix effect, and be measured on a standardised surface.

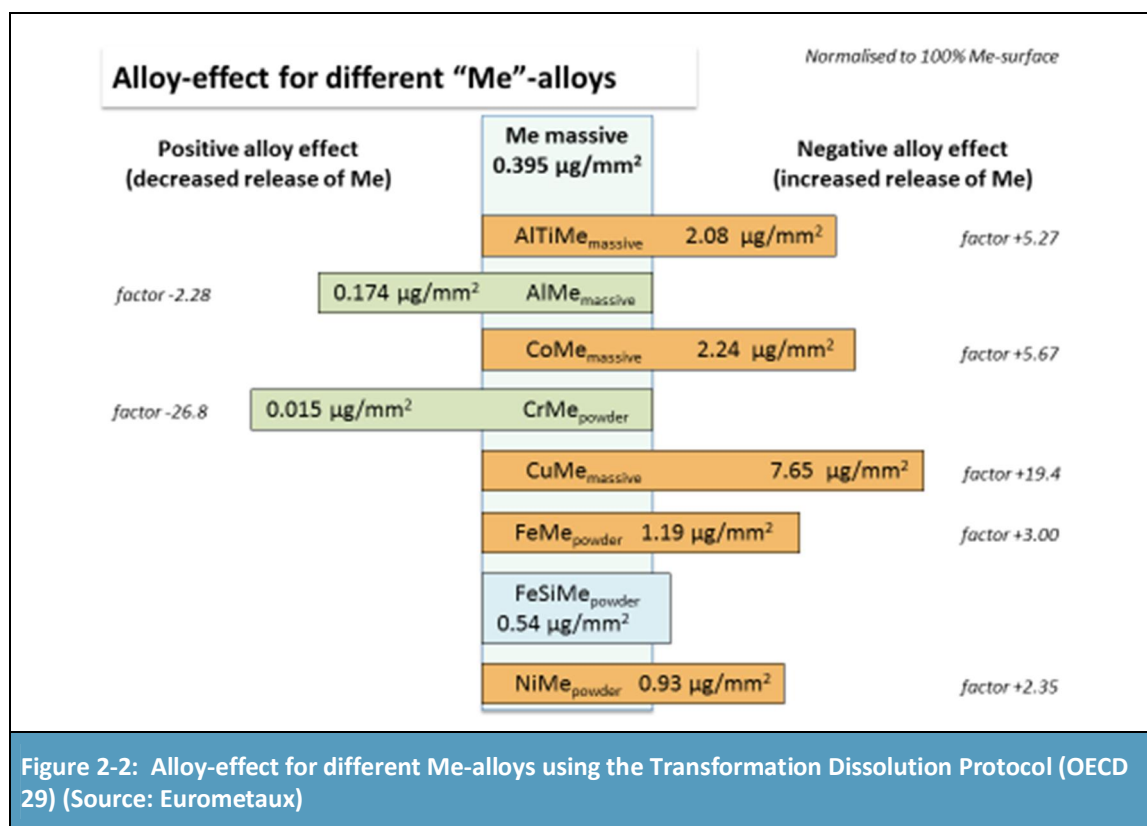
2.4.3 Special mixtures and impurities in substances

An EU association indicated that situations about over- and under-classification would mainly relate to 'special mixtures' and impurities in substances. They indicated that for a mixture, for example an alloy, the starting point of a classification will typically be the composition of the mixture. However, it is known that metal ions will exert the toxic effects and that there are alloys whose physical forms, inclusion in a matrix or in a complex alloy form, have an impact on the release of the metals ions and therefore on their bioavailability.

The association indicated that the metal industry may therefore face cases of over-classification for health hazards when there is a clear matrix effect that will affect the release of metal ions, their bioavailability and their toxicity potential. An example of this is stainless steel where there is lower bioavailability of nickel ions and therefore a difference in sensitisation properties. This has been observed in inhalation studies where inhalation of stainless steel and nickel powder has been compared. Bioaccessibility testing has shown that in comparable physical forms the release of lead ions from aluminium alloys containing a limited concentration of lead is lower than from lead metal. The association noted that it has been observed that the bioaccessible concentration of a metal in an alloy is typically a better predictor of toxicity than the metal's nominal concentration in the alloy.

The association went on to highlight situations where, depending on the type of alloy, bioavailability could be affected in both directions. Therefore, there would be situations where there is an increase and decrease of metal ions released relative to the release of ions from the pure constituents. It was suggested that this may occur in situations where there is not a real matrix effect and situations where preferential leaching takes place due to electrochemical processes. In these situations, the CLP mixtures approach based on nominal concentrations may lead to an under-classification as the classification will be based on theoretical cut-offs rather than on what can be observed.

For the environment, the association indicated that they had found up to three orders of magnitude of release differences, both increased and decreased releases and that this covered the complete span between classification and no classification. The tests were conducted with the T/D Protocol (OECD 29) and were based on different metal ion (Me) alloys. A summary of the results is presented in Figure 2-2 (next page).



One industry stakeholder indicated that the REACH programme established a need for the development of alternative testing pathways to save time, resources, and avoid unnecessary animal testing. The Bioaccessibility paradigm was developed to do just that. As part of that paradigm, acute tests were utilized to provide confirmatory data on the read-across and these tests demonstrated erroneous classification of nickel compounds both as over-classified and under-classified.

2.4.4 Biotic Ligand Models (BLMs)

As part of the consultation, the Environment Agency for England and Wales (EA) was contacted and two separate interviews took place. When asked whether EU chemicals legislation is meeting its objectives for substances (and specifically metals) the EA highlighted two papers by Donnachie *et al* which identified that metals were of high concern to the environment. Donnachie *et al* 2014²⁸ ranked metals and two organic substances (triclosan and lindane) according to the threat they pose to aquatic organisms. The study found that copper, aluminium, zinc, nickel and triclosan appear to be chemicals of great concern, with copper being of most concern. In Donnachie *et al* 2015²⁹, twelve pharmaceuticals were selected based on previous prioritisation. The study found that pharmaceuticals appeared to be less of a threat to aquatic organisms than some metals (copper, aluminium and zinc) when using the ranking approach.

²⁸ Donnachie, RL, Johnson, AC, Moeckel, C, Gloria Pereira, M, Sumpter, JP, (2014): Using risk-ranking of metals to identify which poses the greatest threat to freshwater organisms in the UK, Environmental Pollution 194 17-23

²⁹ Donnachie, RL, Johnson, AC, Sumpter, JP, (2015): A rational approach to selecting and ranking some pharmaceuticals of concern for the aquatic environment and their relative importance compared with other chemicals, Environmental Toxicology and Chemistry, Vol. 35, No. 4, pp

The studies also indicated that it has been known for decades that water chemistry factors will play a critical role in determining bioavailability and hence toxicity of metals; these factors include pH, hardness, and Dissolved Organic Carbon (DOC). When all these factors are known, speciation and biotic ligand models (Di Toro *et al.*, 2001³⁰) can be used to assess the most realistic exposure and risk at a particular river location. It should be noted that, in most cases, the bioavailable toxic species of a metal account only for a proportion of the total, so risks tend to decrease.

The EA also highlighted how the Water Framework Directive (WFD) requires that EU Member States ensure that all inland and coastal waters are achieving 'good' water quality status. To do this a range of measures are taken, including the use of environmental quality standards (EQSs) for a number of individual chemicals. They indicated that the UK and the Netherlands have done a lot of work involving Biotic Ligand Models³¹ (BLM) and that these models could be used in other Member States. BLM considers the relationship between free metal ions and the abiotic ligands by Particulate Organic Carbon (POC), Dissolved Organic Carbon³² (DOC), CO_3^{2-} , and factors including pH and calcium concentration are also important³³. Real world testing and comparisons were used when developing BLM.

The EA highlighted that the use of BLM has meant that there has been a reduction in EQS in some areas and an increase in others. The associated calculations take account of both dissolved metal concentrations and (the lower) bio-available metal concentrations.

The information provided by the EA suggests that once other factors are taken into consideration (e.g. DOC, pH and calcium concentrations), the number of areas where compliance is a problem both decreases and increases compared to previous calculation methods. In particular, for copper the BLM suggests that copper in the environment may be less of a hazard in water bodies when bioavailability is considered.

2.4.5 Nanomaterials

Concerns have also been expressed about the under-classification of certain metals. For example, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) published an opinion on nano silver and its safety, health and environmental effects and role in antimicrobial resistance in 2014³⁴. The opinion states how silver compounds have different physico-chemical properties, such as solubility and surface charge, which may all affect their fate and biological activity. Nano silver is currently being evaluated (under REACH) by the Netherlands.

³⁰ Di Toro, D.M., Allen, H.E., Bergman, H.L., Meyer, J.S., Paquin, P.R., Santore, R.C., 2001. Biotic ligand model of the acute toxicity of metals. 1. Technical basis. *Environ. Toxicol. Chem.* 20, 2383e2396

³¹ Environment Agency (2009): Using biotic ligand models to help implement environmental quality standards for metals under the Water Framework Directive

³² Water Framework Directive - United Kingdom Technical Advisory Group (2009): The importance of dissolved organic carbon in the assessment of environmental quality standard compliance for copper and zinc

³³ Water Framework Directive - United Kingdom Technical Advisory Group (2009): Desk top study to evaluate options outside BLM thresholds (low pH and low calcium issues)

³⁴ http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihc_consultation_17_en.htm

2.5 Industry concerns

Industry groups have expressed their concerns about what the classification of metals may mean for them. EU associations indicated that they had concerns about metal recycling (see Section 3) as outlined in a little more detail below:

Europe:

- An industry association suggested that there is sometimes a lack of coherence in implementation and enforcement of some Directives and Regulations which results in differences between the Member States.
- An EU association indicated that there is some concern about a lack of consistency in how Member States engage with industry and the extent to which they will draw on information provided in CSRs (prepared under REACH).

Europe compared to the rest of the world:

- The ILA suggested that as Europe is the only region which has included a specific concentration limit concept within the GHS, this is a major source of potential inconsistency with the UN GHS and this may give rise to possible World Trade Organization (WTO) implications.

By-products:

- Presently, lead acid batteries have a recycling efficiency >90%, the main by-products generated are silver, polypropylene and sulphuric acid. The by-products will contain lead >0.03% and should be classified as Repro 1A; this will impact their market value, potentially making recycling uneconomical and increasing waste disposal costs.
- CEN (European Committee for Standardization) standardized final copper slags have a residual reduced lead content between 0.02% and 0.65% while the content in other slags can amount up to 2.7%. The classification of being a CMR may result in the non-acceptance of the material and turn it from being an economically valuable by-product into a waste.

Alloy classification and impacts of the classification of alloys:

- The market value of copper alloys is around €7.6 billion a year³⁵. Lead has some positive effects on alloys. Around 80% of the alloys market has a lead content above 0.03%. The copper alloy industry has acknowledged that lead is a hazardous substance and has been searching for substitutes. There are, however, still uses where leaded copper alloys are the only solution. This has, for example, been acknowledged in the RoHS and End of Life Vehicles Directives by exempting lead in copper alloys in concentrations of up to 4% (compared to the 0.3% lead GCL and 0.03% lead SCL). This creates discrepancies compared to other legislation e.g. CLP, for example up to 4% lead is allowed in copper alloys as part of the End of Life Vehicles Directive but lead in aluminium drinks cans may prevent them from being recycled as they would be considered as being hazardous.

³⁵ European Copper Institute (2014): Comments on the classification proposal: lead to be classified as reproductive toxicant (SCL 0.03%). Available at <http://copperalliance.eu/docs/default-source/resources/pb-scl-eci-20140213-position-paper.pdf?sfvrsn=0>

Articles:

- An EU association also indicated that an incoherence is that there would be alloys that are classified as being hazardous, but as soon as they are shaped and become a finished article, they will no longer be classified as hazardous. The reason for this is that articles are not classified, not that articles are not hazardous. Substances/mixtures with certain hazards may not be used in certain articles.

Consistency with existing lead/alloys legislations:

- As highlighted previously, a CMR classification with an SCL of 0.03% is not consistent with other existing EU legislation and this may result in increased costs due to a manufacturer driven requirement to be 'lead free' (e.g. RoHS Directive: 0.1%, End of Life Vehicles Directive: 0.1%, REACH Regulation Jewellery restriction: 0.05% and standards for lead in articles in contact with drinking water: 1.5%). There are presently some regulatory exemptions - for example, lead batteries are exempt as part of the End of Life Vehicles Directive.

2.6 Citizen concerns

Metals, like other chemicals, have the potential to cause adverse health effects in humans and the environment. Humans may be exposed to metals from both naturally occurring sources and anthropogenic sources. In recent years, technological developments have accelerated and the time lapse before mass adoption of new technologies has shortened, this has resulted in increased human exposure to a rapidly expanding array of substances³⁶.

Greenpeace Research Laboratories³⁷ indicated that the metal fraction of e-waste, including iron, copper, aluminium, gold and other metals, can be over 60% of the total by weight and that some of these metals have a relatively high market value when isolated from the mixed waste, however most obsolete computers, and other forms of e-waste, are not recycled in environmentally sound ways. Realff *et al* 2004³⁸ estimated that globally the 315 million computers which became obsolete between 1997 and 2004 resulted in the discarding of 550,000 tonnes of lead (Pb), 900 tonnes of cadmium (Cd), 180 tonnes of mercury (Hg) and 500 tonnes of hexavalent chromium (Cr VI).

International Conventions, Regulations and Directives have been implemented to reduce the exposure and environmental emissions of hazardous metals and other chemicals. The European Environment Agency (EEA)³⁹ indicates that the trend in environmental emissions of heavy metals (cadmium, lead and mercury) in the EU has been decreasing since 1990. There are also a few exceedances of EU standards for ambient air quality and these are typically caused by specific industrial plants.

³⁶ European Environment Agency (2015): The European Environment State and Outlook 2015, 5. Safeguarding people from environmental risks to health.

³⁷ Greenpeace Research Laboratories Technical Note 01/2010 (2010): Toxic Transformers; a review of the hazards of brominated & chlorinated substances in electrical and electronic equipment.

³⁸ Realff, M. J., M. Raymond, et al. (2004): E-waste: An opportunity. *Materials Today* 7(1): 40-45.

³⁹ European Environment Agency (2015): Heavy metal emissions.

The changes in the emissions of cadmium, mercury and lead for each sector compared with 1990 levels, can be seen in Table 2-1. The single largest reduction in emissions can be observed for lead in road transport. This reduction in emissions is attributed to the promotion of unleaded petrol within the EU and in other EEA member countries, through a combination of fiscal and regulatory measures, however the EEA also indicates that the road transport sector still remains an important source of lead (residual lead in fuel, from engine lubricants and parts, and from tyre and brake) and that this sector is contributing approximately 15% of the remaining total lead emissions in the EEA-33 countries.

Table 2-1: Change in cadmium, mercury and lead emissions for each sector (Source – European Environment Agency)			
Sector	% change		
	Cadmium	Mercury	Lead
Agriculture	-65.47	-85.21	-29.17
Commercial, institutional and households	-51.22	-51.35	-61.27
Energy production and distribution	-78.97	-71.2	-77.48
Energy use in industry	-78.54	-73.65	-58.4
Industrial processes	-75.18	-72.92	-74.22
Non-road transport	-51.18	-39.79	-89.05
Other	1.18	0	1.53
Road transport	-34.46	-1.82	-98.42
Solvent and product use	-9.71	-61.42	-61.39
Waste	-95.21	-89.75	-95.94

The sector which has seen the largest overall decrease in cadmium, mercury and lead emissions is the waste sector (over 89% for each metal). However, the increased adoption and development of new technologies (e.g. televisions, computers, mobile phone and smartphones) has likely caused an increase in the amount of certain waste electrical and electronic equipment (WEEE) in the EU. Although WEEE collection and treatment in the EU has improved, substantial amounts are exported to countries outside of the EU and enter the informal recycling sector where sub-standard processes are normally used. An increase in metal classification and costs associated with recycling products classified as waste may mean that recycling of WEEE and non-WEEE products decreases.

Although there has been a reduction in the emissions of cadmium, lead and mercury, as part of the OPJ, the Danish Consumer Council has raised concerns that chronic and very severe diseases such as cancer, cardiovascular diseases, fertility problems, obesity and allergies are increasing in the EU and that these diseases may be linked to constant exposure from multiple sources to harmful chemicals. The Danish Consumer Council indicates that consumers may be exposed through the products they use and consume everyday such as food, drinking water, textiles, cosmetics and toys but also from construction products which may pollute indoor air. The Danish Consumer Council also specifically highlighted how the Packaging Directive contains just one limit for heavy metals (lead, cadmium, mercury and hexavalent chromium) ignoring all other substances, and how the RoHS Directive does not include limits for many substances identified in various studies.

CECED, the European Committee of Domestic Equipment Manufacturers, urge the European Commission to work on the harmonisation of legislation in the area of food contact materials, they indicate that presently the legislation scope is limited to a few materials, thus leaving to Member States room to implement requirements at national level. They suggest that it is crucial that the European Commission start to harmonise requirements for key materials such as metals at EU level as soon as possible. They also indicate that the same situation is experienced for the Drinking Water Directive. The lack of harmonised requirements for materials suitable for contact with drinking

water creates a regulatory burden for companies that have to face different requirements for different products in different Member States.

2.7 Is the EU legislative framework meeting its objectives?

One EU association believes that the bioelution tests work for metals, and that this is what is needed for the classification of the massive vs. powder form for human health purposes (the T/D is available in relation to the environment). They indicated that the lack of a validated test at OECD or EU level is the real problem as having an agreed test method would enable more reliable classification of alloys. The association highlighted four main points:

- The CLP rules for mixtures classification do not fit with the matrix effect seen in a number of metal containing materials, unless Article 12(b) can be used with a bioelution test.
- The criteria for inhalation toxicology and lung overload should be reviewed. The association believes that, at present, the STOT-RE cut-offs are too low for poorly soluble particles of no intrinsic toxicity (e.g. titanium dioxide, antimony). Those materials will be classified as STOT-RE, which could be considered as being 'equivalent concern'. In addition, the concept of lung overload and secondary effects should be re-discussed by RAC. The association also noted that discussions on this matter are being held at UN level.
- The reversibility of some inflammatory effects should be debated as well: do they justify a classification? If not, which criteria should be handled?
- Environmental classification of complex metal substances and materials/mixtures: there is a need for further guidance on how to apply appropriate classification schemes.

An EU association intimated that they believe there is a lack of recognition (and experience) in the RAC for metal specificities/metal guidance. Furthermore, the association considers that RAC has an overloaded agenda as it handles not only CLH proposals but also restriction cases and applications for authorisation. With these points in mind, it was suggested that RAC could have a more balanced representation of the expertise needed, for example through more epidemiologists, medics and people with environmental backgrounds. This would then allow for a more informed discussion on sector-specificities like speciation, bioavailability, lung overload for inorganics, secondary effects and other issues that arise.

Although uncommon, it was also suggested (by the association) that if an incorrect decision had been made, then a subsequent related decision may use the first decision as a basis which could also result in an incorrect outcome. ECHA indicated that RAC does take care not to repeat what was later found to be a mistake. However, an EU association suggested that there appear to have been occasions in the past where industry believes it has raised valid questions of detail which are not reflected in subsequent RAC discussions.

The association also indicated that the CLH process would be improved if there was a greater openness from Member States at the start of the process to enable an exchange of information. Also, at the beginning of the process it is important that all of the information should be used as part of a scientific process free of politics and preconceptions. The association believes that industry would benefit from greater communication with RAC as part of the process.

The association suggested that RAC could be divided into two Committees, one for CLH and the other specifically for REACH. This would require a change of the legal text. The EU association recognises that even though the overall length of the CLH process can be an issue, they felt that there were situations where more time should be spent on dossiers. The association highlighted

SCOEL as a committee where more time is allowed for reviewing information and making use of expert knowledge.

As part of a target consultation questionnaire, a chemical company responding to one of the questions indicated that as part of a CLH dossier the classification of coated copper flakes and nine copper compounds was made under the Biocidal Products Regulation and Plant Protection Products Regulation, however, industry felt that the classification was overly conservative and not aligned with previous assessments under the Plant Protection Product Directive and Biocidal Product Directive and did not recognise all of the available copper data set. To industry it appeared that RAC did not recognise the copper chronic ecotoxicity database was based on a data gap. Instead, an EU association indicated that there appeared to be a focus on the most extreme studies (lowest toxicity thresholds, possibly due to the pre-cautionary principle), which poorly reflects the weight-of-evidence and this tends to be harsh on data-rich substances. The EU association indicated that the CLH procedure is not very transparent and RAC experts have enormous weight in the final classification decisions. Although stakeholders from industry are involved, the association suggested that their evidence and arguments are sometimes poorly recognised. In the case of the RAC ruling on copper, the RAC opinion on environmental classification was much more stringent (Aquatic Chronic 1 rather than Aquatic Chronic 2) than the original CLH proposal from the French authorities. Industry responses to the more stringent proposal were not considered, because RAC has no formal obligation to consider any comments received after the public consultation. They suggest that appointing an independent advisory body to accompany RAC's work (similar to SCHER) could, on occasions, be helpful to address and resolve, in full transparency, specific scientific questions where expertise is scarcer, or has a divided opinion. Although this may prolong the process, these contributions could be used to increase the robustness and acceptance of a CLH proposal.

A comment received as part of the open public consultation suggested that in practice, despite strengthening datasets, ever decreasing toxicity reference points are used for classification. The comment also suggested that this may partly be due to a publication bias - scientists try to find the most sensitive species, or the most sensitive endpoint, otherwise their work may not be considered as being novel and therefore may not get published. Similar views were also provided by a chemical company (during the targeted consultation) concerning its experiences with the classification (as part of a CLH dossier) of coated copper flakes and nine copper compounds under the Biocidal Products Regulation and Plant Protection Products Regulation.

Of course, data published in scientific journals have also been used to support less stringent classification. In any event, the data used should be checked for relevance and quality for inclusion as part of a classification decision. In other legislative frameworks (e.g. REACH) data poor substances will have a larger assessment factor applied when calculating threshold values. One suggestion (from industry) was to establish an independent advisory body to accompany RAC's work (similar to SCHER) which could, on occasions, be helpful to address and resolve, in full transparency, specific scientific questions where expertise is scarce or expert opinion is divided. Although this may prolong the process, these contributions could be used to increase the robustness and acceptance of a CLH proposal.

3 Downstream Consequences

3.1 Identified impacts

Due to the classification of metals as part of the CLP Regulation, there will be a number of downstream consequences. An EU association indicated that there are unnecessary regulatory burdens in the case of alloys where they see many of those being classified according to the mixture rules – however, their use is known to be safe as shown in various tests and studies. ECHA indicated that if there are tests on the mixture these data can be used for classification (except CMRs). In some cases, mixture data may be available; however this will not be available for all alloys.

To provide some structure, this section comprises three sub-sections:

- regulation of metals and metal alloys with particular reference to Seveso III;
- regulation of metals and metal alloys in products; and
- regulation of metals and metal alloys in waste/recycling.

3.2 Seveso III (Directive 2012/18/EU)

The Seveso III Directive⁴⁰ builds on previous versions of the Seveso Directives and aims to reduce the consequences involving dangerous substances from major accidents, not only for human health but also for the environment. One of the changes from Seveso II to Seveso III was to update and align the list of substances covered by the Directive to the EU legislation on the classification of dangerous substances, i.e. CLP.

The linkages between CLP and the Seveso III Directive are explored in the Seveso III case study. It is not the intention to reproduce that work here. Rather, the intention is to focus on the implications of Seveso III on the metals industry.

Properties which are used to classify a substance as being dangerous are set out in Annex I to the Directive. Based on these categories, a number of metals in their pure form and their various alloy forms will be subject to the lower-tier and upper-tier dangerous substance requirements. A sample of metallic elements and metal alloys is presented in Table 3-1.

Table 3-1: Sample of metals and alloys subject to SEVESO III based on CLP classification					
Metal / Alloy	CLP Classification		SEVESO III		
	Hazard Category(s)	Hazard Statement	Hazard Category(s)	Threshold (tonnes)	
				Lower-tier	Upper-tier
Beryllium	Acute Tox. 2	H330	Acute Tox 2 (all exposure)	50	200
	Acute Tox. 3	H301	Acute Tox 3 (inhalation)		
Cadmium (non-pyrophoric)	Acute Tox. 2	H330	Acute Tox 2 (all exposure)	50	200
	Aquatic Acute 1	H400	Aquatic Acute 1	100	200
	Aquatic Chronic 1	H410	Aquatic Chronic 1		

⁴⁰ Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC, OJ L 197/1, 24.7.2012, p. 1-37.

Table 3-1: Sample of metals and alloys subject to SEVESO III based on CLP classification

Metal / Alloy	CLP Classification		SEVESO III		
	Hazard Category(s)	Hazard Statement	Hazard Category(s)	Threshold (tonnes)	
				Lower-tier	Upper-tier
Cadmium (pyrophoric)	Pyr. Sol. 1	H250	Pyrophoric solids, 1	50	200
	Acute Tox. 2	H330	Acute Tox 2 (all exposure)	50	200
	Aquatic Acute 1	H400	Aquatic Acute 1	100	200
	Aquatic Chronic 1	H410	Aquatic Chronic 1		
Mercury	Acute Tox. 3	H301	Acute Tox 3 (inhalation)	50	200
	Aquatic Acute 1	H400	Aquatic Acute 1	100	200
	Aquatic Chronic 1	H410	Aquatic Chronic 1		
Thallium	Acute Tox. 2	H330	Acute Tox 2 (all exposure)	50	200
Arsenic	Acute Tox. 3	H301	Acute Tox 3 (inhalation)	50	200
	Aquatic Acute 1	H400	Aquatic Acute 1	100	200
	Aquatic Chronic 1	H410	Aquatic Chronic 1		
Zinc powder – zinc dust (stabilised)	Aquatic Acute 1	H400	Aquatic Acute 1	100	200
	Aquatic Chronic 1	H410	Aquatic Chronic 1		
Zinc powder – zinc dust (pyrophoric)	Pyr. Sol. 1	H250	Pyrophoric solids, 1	50	200
	Aquatic Acute 1	H400	Aquatic Acute 1	100	200
	Aquatic Chronic 1	H410	Aquatic Chronic 1		
Chromium (VI) compounds	Aquatic Acute 1	H400	Aquatic Acute 1	100	200
	Aquatic Chronic 1	H410	Aquatic Chronic 1		
Various cadmium containing solder alloys	Acute Tox. 2	H330	Acute Tox 2 (all exposure)	50	200
	Aquatic Acute 1	H400	Aquatic Acute 1	100	200
	Aquatic Chronic 1	H410	Aquatic Chronic 1		

Euroalliages (an industry association) indicated that it is difficult to estimate the compliance costs for establishments that would now fall under the Seveso III Directive for the ferro-alloys and silicon industry, the vast majority of which are non-Seveso plants today. It was suggested that the Seveso classification and costs contributed to the closing of a manufacturing site in Germany, however, the manufacturing site had already reduced employees working hours and there was some local pressure for residents to close the manufacturing site. Therefore, there are likely to have been other contributing factors in the closure of the manufacturing site.

Although Eurometaux indicated that the possibility of derogations exist under Article 4 of the Seveso III Directive, they suggested that the timelines for these arguments to be considered (five to seven years) would mean that sites would still need to implement the required measures. Eurometaux also indicated that the revision of CLP classifications has a direct impact on those sectoral regulations, which refer to the CLP classification of a substance to determine their scope and that it can be difficult to foresee these changes. Eurometaux suggest that this is not a problem of the CLP Regulation in itself, but rather is a problem stemming from ‘use’ that has been made of the CLP hazard classifications in policy-making under different EU regulatory frameworks.

Another EU association indicated that as there is currently no useful concept yet available to consider the principle of rapid environmental transformation, there will be alloys and metal concentrates that will be classified as environmentally toxic. ECHA indicated that a decision on whether or not a certain metal can be considered as being rapidly transformed to non-available forms and thus being irreversible is assessed on a case-by-case basis (adopted RAC opinions on metal compounds). The EU association indicated that lack of the concept may have large

implications for manufacturing plants and warehouses falling under the Seveso Directive due to the environmental classification as well as additional transport costs due to the Dangerous Goods designation. They estimate that the Seveso costs are between €15,000 and €100,000 per site, per year. In addition, there may be one off costs for the installation of adequate storage facilities. This will be site-dependent and the cost is estimated to range from €20,000 to €5 million. This would also result in additional annual costs, e.g. maintenance and overhead costs.

3.3 Regulation in products

Various industry associations suggested that some product-specific legislation use a hazard based approach to restrict the use of metals, without proper consideration of the associated risks. They also suggested that to do proper risk management, hazards need to be linked to exposure and use. This particularly applies to the restrictions on the use of alloys which may contain CMR substances as illustrated in the following examples:

1. EU Ecolabel (Regulation (EC) 66/2010) states in Article 6 that the EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR);
2. Toy Safety Directive (Directive 2009/48/EC) states in Annex II that substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toy; and
3. Proposed Medical Devices Regulation (COM(2012) 542 final) includes some hazard-based provisions as regards the use of substances classified under CLP and other legislation (as detailed in Annex I, Section II, Point 7).

Clearly, the risk a substance poses when used in an article, or embedded in a mixture (alloy), depends on a variety of factors, and not exclusively on its intrinsic hazardous properties. ECHA indicates that this is taken into account in the Toys Directive. Industry argues in favour of a common restriction framework based on risk, similar to the REACH restriction procedure, including use-specific releases and bioavailability (rather than on hazard).

As might be expected, classifications can lead to costs and difficulties for industries which are important for the EU economy as illustrated by the case of gallium arsenide (see box overleaf) – a critical substance for the micro-electronics industry.

Gallium Arsenide CLH Case Study

An EU association indicated that for gallium arsenide (GaAs), costs had been triggered by the CLH ruling, for a material that they believe has no risk for exposure, and that there are downstream consequences. RAC's adopted opinion was for GaAs to be assigned a Carcinogen Category 1A, however, it was identified that some of these studies that were used did not have a Klimisch reliability level. Following protests from industry, the carcinogen classification was changed to Carc. Cat. 1B instead of Carc. Cat. 1A.

An industry stakeholder indicated that GaAs is very important in the micro-electronics industry, not just at EU level but globally. They also indicated how GaAs is listed as being an EU critical raw material and that they are working with the Commission on this matter. However, the industry stakeholder highlighted that presently there is a very limited number of suppliers of GaAs and there are even fewer high purity suppliers. They

indicated that globally there are five high purity suppliers of GaAs and that they are the only supplier located within the EU.

The industry stakeholder highlighted that GaAs is subject to various legislation and not all users are known. They initially had problems understanding what was required as they struggled to understand some of the early CLH guidance documents especially as they were only available in English, which is not the company's primary language. However, they indicated that the guidance documents have improved. The industry stakeholder indicated that they also had a number of other problems. Because they are the only EU company, they have had to bear all the substances costs, so far, their costs for GaAs are in excess of €500,000.

In addition to the costs, the industry stakeholder indicated that GaAs has been stigmatised through its inclusion in the SIN (Substitute it Now) list and this can have supply chain effects. As the industry stakeholder is both a manufacturer and a downstream user of GaAs, they are responsible for OSH. They indicate that they have put strong systems in place and that they have even performed biomonitoring of staff, including workers exposed and administrative staff. This has resulted in some costs – loss of staff time and sampling costs. The industry stakeholder indicated that without GaAs society may have to give up its uses and effectiveness in certain applications, which include: use in smartphones, lasers, cars, radar, LEDs and solar panels.

3.4 Regulation in waste/recycling

An industry association indicated that, in principle, chemicals management legislation and circular economy should go hand in hand when applying the underlying principles consistently (including hazard/risk and science based legislation as well as life cycle analysis). However, they see a number of approaches that could create adverse impacts. For example, the association suggested that substances under REACH may be put into authorisation, triggering a phase out of their use. But, they claim that many of these substances are still in safe uses. Once a substance reaches the end of its life stage, these substances will have to be disposed of, undermining the targets of a circular economy. As part of the open public consultation it was suggested that a well-functioning circular economy can only work efficiently by using a risk-based approach instead of a completely categorised regulation under which only non-toxic substances are allowed. There is a need to define possible non-risky reusing or recovery for materials containing small quantities of risky substances, for example circulated metals including lead and cadmium.

An EU association indicated that the RoHS and Waste Electrical and Electronic Equipment Directive (WEEE) legislation are duplicating with risk management with REACH. An example provided is where lead compounds come up for authorisation under REACH for automotive batteries - the same type of questions for the substitution of lead in batteries will come up again for the third time (End of Life Vehicles, WEEE). They feel that the risk management triggered in downstream legislation could be streamlined.

Further thoughts on the use and reuse of alloys containing alloys is presented in the box below.

Lead Case Study

The European Aluminium Association (EAA)⁴¹ has also indicated that the 0.03% SCL classification for massive lead would have a serious impact on the recycling businesses operating in Europe.

The EAA indicated that today 90% of the secondary production of aluminium alloys manufactured according to the existing legal limits for lead and the relevant EU and international standards, contains lead above the Specific Concentration Limit (SCL) 0.03% level. Aluminium recycling accounts for around 35% of the total aluminium used in the EU27 and it has around 95% energy saving compared to primary aluminium production.

The main products that would be affected by the new classification are aluminium foundry alloys, the industry provides raw material which is used as a new material in the automotive, building, packaging, aerospace, and engineering sectors.

Many alloys, not just aluminium alloys, contain lead in the range of 0.20% – 0.40%, with this applying to around 80% of the alloys in EU regions.

The association notes that it is expensive to separate or remove dissolved lead impurities during the scrap processing or secondary refining due to the high reactivity of aluminium versus lead. In order to produce products with a level of lead below 0.03%, companies would need to dilute the scrap with a relatively high lead content with purer aluminium alloys or with primary metal. This would increase the cost of production to the extent of losing profitability. The cost is estimated at 200-300 Euro/tonne (it can differ depending on the facility). Eurometaux⁴² indicates that a similar situation for copper would cost around 700-1,200 Euro/tonne.

The EAA has indicated that there would be various consequences of a 0.03% SCL for lead. Europe is a world leader in aluminium recycling and it produces almost 4.1 Mt/year (in 2012) i.e. two third of the overall EU aluminium production. An increase in costs of 200-300 Euro/tonne for aluminium recycling would mean increased costs of between 820 and 1,230 million Euros annually. In 2014 around 2.1 Mt of copper was recycled, increased costs of 700-1,200 Euro/tonne for copper recycling would mean increased costs of between 1,470 and 2,520 million Euros per year. The aluminium recycling industry is essential for the European economy because it allows an increase in the recycling of end of life scrap metal and production of new raw materials with energy savings of 95% compared to the production of primary aluminium. Recycling actively contributes to the EU decarbonisation, resource efficiency and circular economy goals.

Downstream consequences of the SCL would therefore include a decrease in the market demand for recycled aluminium, a dependency on imported primary aluminium, an increase in the export of scrap, and an increase in the amount of landfilling in the EU. In addition, a change in classification would mean that products containing more than 0.03% lead would be classified as hazardous waste. This change in classification would mean companies granted environmental permits for End-of-Waste could not process the newly classified hazardous waste. European recycling industries would be placed in a disadvantaged position versus competitors elsewhere and there may be a substantial increase in cost, energy consumption and CO₂ emissions. Manufacturers may end up producing two qualities of metal materials, one for Europe and one for the rest of the world.

Sites that hold products containing lead, for example scrapyards, may also become subject to SEVESO III. There would also be higher costs associated with operations (transport and storage), administrative costs, and

⁴¹ EAA position paper on the impact of the new proposed harmonised classification of Lead on the European Aluminium industry.

⁴² Eurometaux, Proposed Lead metal harmonized classification highlights problems with existing regulatory approach in deriving SCL for metals classified as toxic to reproduction.

increased occupational health and safety costs.

The updated lead classification will also bring new activities into the scope of the definition of lead working under the Chemical Agents Directive (CAD) and occupational health legislation – if lead is classified at this level then it would impact on pregnant workers that are handling lead containing substances and alloys. It would be a requirement for workers handling lead to have their blood lead levels tested. Therefore, there will be additional costs to industry for the processing of employee blood samples (the cost of a blood lead test ranges from \$10 to \$75 (Kemper *et al*, 1998⁴³)) and there will be losses in staff time. This would be the case if employees blood levels were not already being analysed for other reasons.

⁴³ Kemper, A.R., W.C. Bordley, and S.M. Downs. "Cost-Effectiveness Analysis of Lead Poisoning Screening Strategies Following the 1997 Guidelines of the Center for Disease Control and Prevention." *Arch. Pediatr. Adolesc. Med.* Vol. 152. pp. 1202-08. 1998

4 Conclusions

When considering the questions posed as part of the objectives, the following conclusions can be drawn.

Are CLP classification rules appropriate for the classification of metals (i.e. metallic forms)?

Specifically,

- To what extent do default classification rules under the CLP regulation trigger under/over classification of metals?
- Do inconsistencies and gaps exist in the CLP Regulation relating to the classification of metals and alloys?
- Are there mechanisms and factors that cause possible inconsistencies and gaps?
- If present, are specific concentration limits (SCL) and generic concentration limits (GCL) appropriate?
- Does a new EU-testing method or a new OECD testing protocol need to be developed and recognised for the classification of metals or specific metal forms (e.g. alloys)?

It is clear that there are human health effects and environmental effects related to the exposure of metals. Legislation has been a significant factor in the reduction of emissions of particular hazardous metallic substances and the control of metals in the workplace. However, the classification rules appear to have the potential to result in under- and over-classification of metals and metal alloys.

CLP does not presently take into account the specifics of metallic bondings (metals and alloys) and CLP is poorly suited for the classification of these kinds of mixtures. The CLP rules for mixtures classification do not fit with the matrix effect seen in a number of metal containing materials. However, a 'one fits all' approach for classification has both advantages and disadvantages. Advantages include that the level of protection of human health and the environment is consistent and that a hazard based system is simpler than a risk based system. By ensuring a consistent level of protection, this reduces the possibility of certain substances causing harm. The creation and use of SCLs and GCLs may further help protect human health and the environment but these may present challenges to industry and result in inconsistencies between the SCL and other EU legislation. Disadvantages include how some of the classifications may impact metals and alloys where the realistic use of the substance means there will be very limited or no release or exposure to the hazardous substance. This may result in compromising innovative or sustainable sectors, for example, recycling and urban mining. Material that could be reused may instead have to be treated as (hazardous) waste. This may lead to increased costs to industry, the loss of jobs, the loss of critical materials and increases in the cost of goods. In some situations, it may be that at present the substance cannot easily be substituted as the alternative substances offer a significantly reduced performance or are significantly more expensive.

In some cases, it may be more suitable to introduce longer targeted phase-in dates for the levels of materials in certain articles, for example aluminium cans. This may be beneficial and help avoid impacting sectors where recycling rates are high and the costs compared to primary manufacturing are considerably lower. For aluminium cans this would allow a longer time frame for levels of lead in aluminium cans to be reduced. An alternative would be to introduce exemptions, similar to authorisations under REACH or exemptions for certain metals in the End of Life Vehicles Directive, for the use of metals in certain product types.

There are some differences in the classification requirements of inorganic and organic substances, which include the lack of a degradability test for inorganics or the concept of rapid removal. However, the concept of rapid removal has been discussed at an ECHA workshop and it may be further developed. BLM models highlight that the availability and toxicity potential of metals will depend on various factors. Another area of development is where JRC ECVAM is developing the bioelution test. An important factor that influences the toxicity of metals is the release of metallic ions. The release rate will be influenced by the metallic form (characterised as massive, powder or nano) and the metallic bondings, for example, some metals will have lower ion release rates. Metals and metal alloys will also have different properties. The bioelution test is designed to test the bioaccessibility of metals/alloys in synthetic gastric fluid. The bioelution test method could be a useful test method for human health classification of metals and alloys.

There are a number of occasions where the legal text has been interpreted differently by individuals. For example, recital 22 and CLP Articles 6(3), 9(5), 10(3) and 12 have been discussed. The lack of easily accessible and understandable tools summarising the learning lessons (to be) drawn from the ECHA Committees discussions and outcomes (opinions and decisions) appear to make it challenging for companies to understand what they can do, plan data gathering or to learn from other cases. Where these have been discussed and a clear position has been indicated, the position and reasoning for the position could be clearly be set out (e.g. ECHA Q&A) and added to guidance documents. Where there may still be uncertainty these matters should be resolved. In some cases, more guidance is needed, for example, ECHAs Guidance on the Application of the CLP criteria suggests that guidance on the classification of alloys and complex metal containing materials is limited so far and that more guidance is needed.

What are the impacts of risk management measures triggered by metal classifications?

Where a metal classification results in the triggering of a risk management measure, relevant measures will apply (e.g. ways of working and substance transport) or changes may need to be made. For example, metals that are classified as being aquatic toxic are likely to also be classified as aquatic toxic in an alloy form unless Transformation/Dissolution information is available. Different transport and shipping requirements will apply to substances that are considered to be aquatic toxic. Also, metals (and alloys) that have CMR properties, those metals that gain a classification through a CLH or metals that are identified at being present at levels greater than the SCL/GCL will be subject to health and safety legislation. This may require changes in work practises to protect workers and human biomonitoring procedures to check the level of exposure to workers. Metals may also be subject to the Seveso requirements. These types of measures and changes are likely to involve one off costs for companies as well as increased annual costs.

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Annex 1 Metal and Alloy Classification in EU legislation

A1.1 CLP Regulation (EC) No 1272/2008 and GHS

General requirements

The CLP obligations for metallic substances, and others, are set out in Article 1. These include the obligation for manufacturers, importers and downstream users to classify substances and mixtures placed on the market; for suppliers to label and package substances and mixtures placed on the market; for manufacturers, producers of articles and importers to classify those substances not placed on the market that are subject to registration or notification under Regulation (EC) No 1907/2006.

Metallic substances and alloys

The definition of an alloy is the same in CLP⁴⁴ and GHS⁴⁵. Alloys, as well as their components, need to be classified and labelled in accordance with CLP.

Both CLP and GHS note for metals that aquatic toxicity will depend on the extent to which the metal ion portion of a metal (Mⁿ) compound can disaggregate from the rest of the compound (molecule).

This is indicated in ECHA's Guidance on the Application of the CLP Criteria⁴⁶ (Annex IV: Metals and inorganic metal compounds) and GHS which both detail how the dissolved metal ion concentration obtained at a loading rate and an Ecotoxicity Reference Value (ERV) can relate to acute and chronic classifications.

A point about biological availability is made in CLP Article 12 (b):

Where, as a result of the evaluation carried out pursuant to Article 9, the following properties or effects are identified, manufacturers, importers and downstream users shall take them into account for the purposes of classification:

(b) conclusive scientific experimental data show that the substance or mixture is not biologically available and those data have been ascertained to be adequate and reliable;

A similar point is made in GHS, Section 1.3.2.4.5 *Substances/mixtures posing special problems*.

The effect of a substance or mixture on biological and environmental systems is influenced, among other factors, by the physico-chemical properties of the substance or mixture and/or

⁴⁴ CLP Regulation (1272/2008), Article 2(27); *Alloy' means a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means; alloys are considered to be mixtures for the purposes of this Regulation.*

⁴⁵ GHS Sixth edition, Chapter 1.2; *Alloy' means a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means. Alloys are considered to be mixtures for the purposes of classification under the GHS.*

⁴⁶ ECHA (2015), Guidance on the Application of the CLP Criteria. Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures.

ingredients of the mixture and the way in which ingredient substances are biologically available. Some groups of substances may present special problems in this respect, for example, some polymers and metals. A substance or mixture need not be classified when it can be shown by conclusive experimental data from internationally acceptable test methods that the substance or mixture is not biologically available. Similarly, bioavailability data on ingredients of a mixture should be used where appropriate in conjunction with the harmonized classification criteria when classifying mixtures.

With regard to testing for classification purposes, in June 2015 ECHA updated a guidance document⁴⁷ on the application of the CLP criteria for substances and mixtures. The guidance document presents schemes for the determination of acute and long-term aquatic hazards of metals and metal compounds. The guidance document suggests that for the classification of alloys and complex metal containing materials, the metal alloys often react slowly and to a very limited extent, this makes the application of the Transformation / Dissolution protocol (T/D) more complex. The T/D protocol (OECD 29) is a test that is designed to determine the rate and extent to which metals and sparingly soluble metal compounds can produce soluble available ionic and other metal-bearing species in aqueous media under a set of standard laboratory conditions which are representative of those generally occurring in the environment. The information generated from the test can be used to evaluate the short term and long term aquatic toxicity of the metal or sparingly soluble metal compounds. For alloys and complex metal containing materials, special care should be taken in respect to the detection limit and the accurate determination of the measured surface. The ECHA guidance notes that initial testing of alloys, using the T/D protocol, shows that this can be a useful test but further additional guidance on this aspect is recommended.

Directive 1999/45/EC(10) stated:

Whereas the characteristics of alloys are such that it may not be possible accurately to determine their properties using currently available conventional methods; whereas it is therefore necessary to develop a specific method of classification which takes into account their particular chemical properties; whereas the Commission, in consultation with Member States, will examine this need and submit a proposal, if appropriate, before the implementation date of this Directive;

This suggests that the potential need for a new test method has long been recognised. A new test method, commonly known as the bioelution test, is discussed further in Section 3.

A1.2 Plant Protection Products Regulation (EC) No 1107/2009

The Plant Protection Products Regulation does not have specific requirements for metals or metal alloys, therefore, if metals are used as active substances in plant protection products they are subject to the Regulation like active organic substances. The approval criteria for active substances are set out in Article 4 and information about derogations for basic substances is set out in Article 23. Substances (including metals) that are candidates for substitution may be approved but for a more limited period compared with non-substitutable substances. Substances which are candidates for substitution are set out in Annex II (4) of the Plant Protection Products Regulation as listed below:

⁴⁷ European Chemicals Agency (2015): Guidance on the Application of CLP Criteria; Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures

- Substances classified as Carcinogenic or Toxic to reproduction Category 1A/1B;
- Substances with a low acceptable daily intake;
- Substances that meet two out of three PBT criteria;
- Substances that contain a significant proportion of non-active isomers or impurities;
- Substances for which there are reasons for concern linked to the nature of the critical effects; and
- Substances considered to have endocrine disrupting properties that may cause adverse effects in humans.

A1.3 Biocidal Products Regulation (EU) No 528/2012

The Biocidal Products Regulation does not have specific requirements for metals or metal alloys. Therefore, if metals are used as an active substance in a biocidal product they are subject to the Regulation. Substances which are candidates for substitution are set out in Article 10, with this including substances which meet the Article 5(1) criteria (CMR 1A/1B, PBT, vPvB and endocrine-disrupting) but are approved in accordance with Article 5(2). Active substances that are candidates for substitution may be approved if it is shown that at least one of the following conditions is met:

- The risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible;
- It is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; and
- Not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.

A1.4 Cosmetics Regulation (EC) No 1223/2009

Under the Cosmetics Regulation, substances classified for CMR categories 1A or 1B are prohibited from use in cosmetic products. Substances classified as CMR category 2 shall also be prohibited in cosmetic products unless they have been evaluated by the Scientific Committee for Consumer Safety (SCCS) and found to be safe for use in cosmetic products. Further information is set out in Article 15 of the Cosmetics Regulation.

Within the Cosmetics Regulation references to various metals appear in Annex II and Annex III, which place restrictions on their use.

- Annex II is a list of substances prohibited in cosmetic products. Metals within this Annex include nickel, antimony and its compounds, arsenic and its compounds, beryllium and its compounds, cadmium and its compounds, mercury and its compounds (except those special cases included in Annex V), lead and its compounds, gold salts, tellurium and its compounds, and thallium and its compounds. Compounds containing metallic elements are also present within Annex II; these include cobalt dichloride, cobalt sulphate, nickel monoxide, dinickel trioxide and nickel dioxide.
- Annex III is a list of substances which cosmetic products must not contain except subject to restrictions (product types, maximum concentrations and labelling) laid down. Compounds containing metals within Annex III include aluminium fluoride, tin difluoride, silver nitrate and magnesium fluoride.

Annex IV sets out a list of colorants allowed in cosmetic products. Metallic elements within Annex IV include aluminium, chromium (III) oxide, cobalt aluminium oxide, copper, gold, iron oxide, iron oxide red, iron oxide yellow, iron oxide black, ferric ammonium ferrocyanide, magnesium carbonate, silver, titanium dioxide and zinc oxide.

A1.5 Toy Safety Directive (EC) No 48/2009

The Directive requires that CMR substances and certain metals are subject to careful attention. The Directive states *“Limit values for arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, and which should therefore not be intentionally used in those parts of toys that are accessible to children, should be set at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee, in order to ensure that only traces that are compatible with good manufacturing practice will be present.”*

In Annex II of the Toys Directive, migration limits are set out for metals in dry, brittle, powder-like or pliable toy material, in liquid or sticky toy material and in scraped-off toy material. It is of note that the Directive specifically indicates that nickel, although it has CMR properties, is permitted for use in stainless steel in toys as it has been proven to be safe⁴⁸.

A1.6 Other Directives and Regulations

Specific metals, concentration limits and other conditions are mentioned in other legislation. This includes metal concentrations in batteries (Batteries and Accumulators Directive) and vehicles (End-of-life vehicles Directive), the substitution of metals in Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive, and the Waste Electrical and Electronic Equipment (WEEE) Directive.

⁴⁸ SCHER (2012): Assessment of the Health Risks from the Use of Metallic Nickel (CAS No 7440-02-0) in Toys

Annex 2 Suggestions Made by Interviewees

As part of the interview process a number of suggestions were made by the industry, EU associations and National associations, these are summarised below in terms of effectiveness, efficiency, relevance, coherence and EU added value.

A2.1 Effectiveness and efficiency

The means to achieve a high level of protection could differ and/or be adapted to specificities to ensure more efficiency. In recent years as part of CLP and other regulations, there has been a shift in the 'burden of proof' to industry and its subsequent generation of data and increasing level of knowledge and data as well as industry's responsibility when it comes to communication of operational conditions, hazards and safe use recommendations exert a positive impact on the set up and functioning of a correct chemicals framework. The building of chemical datasets and the maximal use of OECD protocols and GLP requirements result in 'reference datasets on hazard' that can be used for other chemical legislative purposes.

The overall complexity of the various chemical frameworks, including CLP, effects the correct understanding and its interpretation. Where possible, further guidance information could be created.

An EU association suggest that resource efficiency of legislation could be improved, for example, CLH dossiers and biocidal products. For copper, all biocidal dossiers and the REACH registration dossier read across from the Cu^{2+} ion for most hazards. They question the resource-efficiency from having to submit full new dossiers for every new copper-containing substance or form used as biocide, and having to discuss these each time at each of the technical committees. They suggest that for future dossiers, where relevant, it may be more efficient to use the existing information on the hazards of copper in soluble compounds, and to read-across, possibly using additional transformation-dissolution, bioelution, or pharmacokinetic data of the 'new' substance. ECHA indicate that the use of read across data is already possible, but that it may not be sufficient for all substances and hazard classifications.

A2.2 Relevance

Inconsistencies in classification considerations between organics and inorganics have been highlighted by industry, the development and acceptance of relevant and appropriate testing mechanisms along with clear guidance, for example bioelution, may help create more effective and efficient regulatory schemes. Disagreements about rapid removal, CLP recitals and articles would also need to be resolved. Although BLMs may indicate that certain inorganic substances may have reduced bio-availability in certain environments when certain factors are considered, these risk assessments will only be relevant to those environments and media. A larger amount of information representing all of Europe would be required.

Enforcement is presently the exclusive task of authorities but insurance companies and certification centers could play an important role. It was suggested that enforcement is nationally organized but it might be much more efficient, for measures that are aiming at ensuring level playing to be organized at EU level. Defining those is now done at the EU level and the lack of common playing field in implementing those cause market distortion and unfair competition.

A2.3 Coherence

Positive efforts have clearly been made by ECHA and other bodies to increase the transparency of decisions and the development of guidance and Q&A. Further transparency improvements have been suggested, for example, preparing response to comments documents and better justifications for specific legal acts.

In terms of robustness of decisions, it was indicated that taking relevant and evidence-based decisions requires the time and resources to assess the evidence, to debate the relevance with involved actors and experts and to remain state-of-the art on top of a number of fields (hazard assessment, exposure and risk assessment, risk management, enforcement, SEA, etc.). It was suggested that this range of expertise and continuous updating may be challenging for the same group of experts (e.g. RAC) and that appointing an independent advisory body to accompany RAC's work (similar to SCHER) could be helpful to clarify specific scientific questions, in full transparency, for which expertise is scarcer or where there is a divided opinion.

A2.4 EU Added value

There was broad agreement that harmonisation between Member States will help ensure an EU consistent framework, which is a key factor to be considered a credible partner at a global level.

Case Study 3: Parallel hazard assessments

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1. Introduction

1.1 Background and overview

Under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures¹ ('the CLP Regulation'), a manufacturer or importer must classify a substance or a mixture before it is placed on the market², either in accordance with a harmonised classification or self-classification.

Harmonised classification

Some of the most hazardous substances and mixtures (those that are carcinogenic, mutagenic, toxic for reproduction or respiratory sensitisers) are classified at the Union level, as set out in Annex VI to the CLP Regulation. Such classification is referred to as a harmonised classification. Where a decision has been taken to harmonise the classification of a substance for a specific hazard class or differentiation within a hazard class by including or revising an entry for that purpose in Part 3 of Annex VI to the CLP Regulation, the manufacturer, importer and downstream user must apply the harmonised classification³, and only self-classify for the remaining, non-harmonised hazard classes or differentiations within the hazard class.

Part 3 of Annex VI lists hazardous substances for which harmonised classification and labelling have been established at EU level, based on either Annex I to the CLP Regulation (Table 3.1) or Annex VI to Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances⁴ (the 'Dangerous Substances Directive'). All substances that previously had a harmonised classification under the Dangerous Substances Directive have been converted into CLP harmonised classifications.

Self-classification

Where a harmonised classification is not available, suppliers need to decide on the classification of a substance or mixture, i.e. self-classification. This involves collecting the available information, evaluating the adequacy and reliability of the information, reviewing the information against the classification criteria and taking a decision on classification. Provided that there are no further data available for a substance or mixture for the considered hazard class, the translation of the classifications from the Dangerous Substances Directive and Directive 1999/45/EC on the classification, packaging and labelling of dangerous preparations⁵ (the 'Dangerous Preparations Directive') into CLP classifications can be used for those substances that were classified under the Dangerous Substances Directive or the Dangerous Preparations Directive prior to 1 December 2010

¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353, 31.12.2008.

² CLP Regulation, Article 4(1).

³ CLP Regulation, Article 4(3).

⁴ Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ L 196, 16.8.67.

⁵ Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, OJ L 200, 30.7.1999.

and 1 June 2015 respectively. However, where there have been new scientific or technical developments, manufacturers, importers and downstream users will have to review the classification of the substance or mixture they place on the market.

Issue

It was intended that all active substances under Regulation (EC) No 1107/2009 on plant protection products⁶ (the 'Plant Protection Products Regulation') and Regulation (EU) No 528/2012 on biocidal products⁷ (the 'Biocidal Products Regulation') would be subject to harmonised classification and labelling. Article 36(2) of the CLP Regulation states that a substance that is an active substance shall normally be subject to harmonised classification and labelling. However, as there are no set deadlines for Member States to submit proposals for harmonised classification under the CLP Regulation, many active substances for which approval is sought under the Plant Protection Products Regulation are not yet subject to harmonised classification. For biocidal products, active substances are now subject to review in accordance with the deadlines set out in Regulation (EU) No 1062/2014⁸.

In the absence of a harmonised classification, companies must self-classify and therefore propose a classification of the substance as part of their dossier for approval or renewal of approval of the active substance under the Plant Protection Products Regulation. During the procedure for approval of the active substance, the applicant, the Rapporteur Member State and EFSA may reach different opinions on the classification of the substance. This case study considers how such conflicts can be resolved in the absence of a proposal for harmonised classification.

Where a proposal for harmonised classification is made, this is usually only submitted at the same time or after an application for approval of the active substance has been submitted under the Plant Protection Products Regulation. This can result in classification of the active substance being considered by two different scientific bodies, i.e. EFSA and ECHA, under different procedures and timescales. This case study therefore focuses on the different parallel procedures under the Plant Protection Products Regulation and the CLP Regulation, the possible inconsistencies in the conclusions on classification which can arise under the Plant Protection Products Regulation and the CLP Regulation respectively, and what happens when different conclusions on classification are reached.

While the case study focuses on the parallel procedures under the Plant Protection Products Regulation and the CLP Regulation, it takes into account the situation under the Biocidal Products Regulation. Under Article 6(7)(a) of Regulation (EU) No 1062/2014, the Member State Competent Authority (MSCA) is required to submit a proposal for the harmonised classification and labelling of a substance under the CLP Regulation, no later than the time of submission of the assessment report under the Biocidal Products Regulation, where it considers that one of the criteria in Article 36(1) of the CLP Regulation (CMR Cat 1A/1B) is fulfilled and not properly addressed in Annex VI to the CLP

⁶ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009.

⁷ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012.

⁸ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council, OJ L 294, 10.10.2014.

Regulation. In accordance with the CA Guidance Document on the procedures related to the examination of the exclusion criteria⁹, it is strongly recommended that Member States submit their draft assessment report only once a RAC opinion is available. This may offer possible solutions to some of the problems that have been identified with the linkages between the Plant Protection Products Regulation and the CLP Regulation.

These issues will be discussed in the following sections based on an analysis of the relevant legislation, guidance, workshop outputs and other sources, as well as information collected from stakeholders.

1.2 Case study objectives

The aim of the case study is to examine those cases where separate bodies are required to recommend classification of a substance under the CLP Regulation and the Plant Protection Products Regulation which can result in different conclusions being reached on the proposed classification of a substance, and draw conclusions on the effectiveness, efficiency, relevance and coherence of such procedures.

1.3 Case study methodology

Initial feedback received during stakeholder consultations early in the project indicated that there was an issue with regards to the classification of substances under the Plant Protection Products Regulation compared to the CLP Regulation.

Desk research was first carried out to obtain further information on the nature and extent of the issue, involving in-depth analysis of the legal provisions of the Plant Protection Products Regulation and the different procedures for approval of an active substance. Based on the initial analysis we identified the main case where different bodies recommend classification of a substance as being the procedure for approval of an active substance under the Plant Protection Products Regulation and the process of harmonised classification under CLP, with there being a potential for conflicting outcomes in terms of the classification of a substance during these parallel procedures.

Following the initial desk research, stakeholder consultation was carried out, mainly via targeted interviews. These were aimed at obtaining further information on the issues identified in the desk research, gathering information on specific examples of where different classifications have been proposed and how these cases have been resolved, and exploring potential recommendations for improvement. We also asked stakeholders to identify whether similar issues exist under other legislation that could also be incorporated into the case study. Examples of such issues arising under other legislation were not identified and therefore the case study focuses on the approval of active substances under the Plant Protection Products Regulation.

The desk research and interview responses, as well as feedback received during the discussions at the workshop in April, were used to write-up the case study and draw conclusions. Additional stakeholder views are also included from responses to the targeted consultation.

⁹ CA-Nov14-Doc.4.5 – Final, 58th meeting of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, ‘Further guidance on the procedures related to the examination of the exclusion criteria and the conditions for derogation under Article 5(2)’.

2. Detailed Description of the Issue

2.1 The importance of classification for application of the Plant Protection Products Regulation

2.1.1 Process for approval or renewal of approval of an active substance

In order to start the process for approval or renewal of approval of an active substance, the producer of the active substance is required to submit an application for the approval of an active substance or for the renewal of approval, to a Member State of their choice, known as the rapporteur Member State ('RMS'), or more than one Member State under the co-rapporteur system.

The application is to be submitted along with a summary and a complete dossier demonstrating that the active substance fulfils the approval criteria set out in Article 4 of the Plant Protection Products Regulation. The complete dossier shall contain the full text of the individual test and study reports that address each of the data requirements for the active substance and for the plant protection product. The RMS will carry out the initial scientific and technical evaluation of the active substance dossier. At any stage during the assessment of the application, the RMS may consult the European Food Safety Authority (EFSA)¹⁰.

Part A of the Annex to Regulation (EU) No 283/2013¹¹ sets out the data requirements for the active substances while Part A of the Annex to Regulation (EU) No 284/2013¹² sets out the data requirements for the plant protection products. Both cover classification and labelling in section 10 and section 12 respectively. With regard to hazard classification criteria, in each case the information submitted is to be sufficient to classify the active substance/plant protection product as a hazard in accordance with the CLP Regulation. The information submitted shall include the proposed classification and labelling of the plant protection product in accordance with the CLP Regulation, where relevant. Supplementary studies necessary for the classification of the plant protection product by hazard are to be carried out in accordance with the CLP Regulation and the relevant calculation methods used for the classification of mixtures under the CLP Regulation shall, where appropriate, be applied in the hazard assessment of the plant protection product. Under the sections on classification and labelling, proposals for the classification and labelling of the active substance/plant protection product in accordance with the CLP Regulation, where applicable, are to be submitted and justified, including pictograms, signal words, hazard statements and precautionary statements.

In accordance with Article 11 of the Plant Protection Products Regulation, within 12 months of the date of notification of admissibility of the application, the RMS will prepare and submit a 'draft assessment report' ('DAR') to the Commission, and provide a copy also to EFSA. The DAR will assess

¹⁰ Plant Protection Products Regulation, Article 7(5).

¹¹ Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, OJ L 93, 3.4.2013.

¹² Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, OJ L 93, 3.4.2013.

whether the active substance can be expected to meet the approval criteria and will also include where relevant, a proposal to set maximum residue levels¹³.

2.1.2 Criteria for approval

In accordance with Article 4(1) of the Plant Protection Products Regulation, the assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. Annex II sets out the procedure and criteria for the approval of active substances, safeners and synergists under Chapter II of the Plant Protection Products Regulation.

Under points 3.6.2 to 3.6.4 of Annex II, an active substance, safener or synergist shall only be approved if, on the basis of assessment of higher tier genotoxicity, carcinogenicity and reproductive toxicity testing and other available data and information, it is not or has not to be classified as mutagen category 1A or 1B, carcinogen category 1A or 1B, or toxic for reproduction category 1A or 1B. In the case of carcinogenicity and reproductive toxicity (points 3.6.3 and 3.6.4) this applies, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible.

Where the risk assessment establishes that the criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are not satisfied, the DAR shall be limited to those parts of the assessment. With a few exceptions (i.e. where the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible), active substances, safeners or synergists that are classified as CMR category 1A or 1B under CLP, or as having endocrine disrupting properties, cannot be approved. These criteria also apply for approval of an active substance as a candidate for substitution or for considering an active substance as a low-risk active substance. If the above criteria are satisfied, only then will the RMS continue with the assessment to establish whether the other criteria set out in points 2 and 3 of Annex II are satisfied¹⁴. The classification of the active substance is therefore key to the approval or non-approval of the substance.

At this stage, the risk assessment carried out by the RMS and reported in the DAR represents the initial evaluation of the data by a RMS; it is therefore preliminary in nature and subsequently peer reviewed by EFSA. EFSA provides access to the DAR submitted by a designated RMS for the review of existing and new active substances used in plant protection products. When a DAR becomes available, EFSA will start a public consultation process on its website¹⁵, through which comments can be submitted on the risk assessment presented in the DAR.

2.1.3 EFSA peer review

EFSA reviews the DAR and subsequently adopts conclusions as to whether or not the substance meets the requirements of the Plant Protection Products Regulation. The EFSA peer review comprises a number of steps including commenting, expert meetings (optional), consideration of comments, and the drafting of the EFSA conclusions. Within 30 days of receipt of the DAR from the RMS, EFSA is first required to circulate the DAR to the applicant and the other Member States and

¹³ Plant Protection Products Regulation, Article 11(1) and (2).

¹⁴ Plant Protection Products Regulation, Article 4(1).

¹⁵ See EFSA, Public consultation on rapporteur Member State assessment reports submitted for the EU peer review of active substances used in plant protection products, available at: <http://dar.efsa.europa.eu/dar-web/consultation>

will also make the DAR available to the public. EFSA will allow a period of 60 days for the submission of written comments.

In order to facilitate comments from the applicant, RMS and other Member States, EFSA will first comment on the DAR and collate these in a 'reporting table'. The applicant and the RMS are then invited to respond to the comments of EFSA, following which EFSA will review the comments and responses and decide on what further action requires to be taken in relation to each comment. EFSA will therefore indicate in the reporting table whether a point is closed, the point requires to be considered further by the RMS, the point requires to be discussed in an expert meeting, or additional information is required. The need for any additional information will be discussed between EFSA, the Commission and the RMS.

Before adopting its conclusion, EFSA will circulate its draft conclusions to the Member States for written comments, and will indicate how each of the comments received has been addressed. Thereafter, within 120 days of the end of the period provided for the submission of written comments (initially 60 days), EFSA will adopt a conclusion on whether the active substance, safener or synergist can be expected to meet the approval criteria and will communicate its decision to the applicant, the Member States and the Commission. EFSA will make its conclusions, the DAR and any addenda to it, and any documents produced during the peer review process available to the public on its website.

2.1.4 Commission decision on approval or non-approval

A decision on the approval or non-approval of the substance shall then be taken by the Commission on the basis of the assessment report and the EFSA conclusions, by adopting an approval regulation or a non-approval decision. The Commission has six months from the receipt of the conclusions from EFSA to present a 'review report' and a draft Regulation to the Standing Committee for Food Chain and Animal Health. At this stage, the applicant is provided with a further opportunity to submit comments on the review report prepared by the Commission¹⁶. In accordance with Article 13(2) of the Plant Protection Products Regulation, a Regulation will be adopted, providing that an active substance is approved, subject to conditions and restrictions, where appropriate, an active substance is not approved, or the conditions of approval are amended.

However, while the Plant Protection Products Regulation sets a deadline of six months from receipt of the EFSA conclusions, for the Commission to present a draft Regulation on the approval or non-approval of the active substance, in many cases this timescale is not adhered to. After the six month deadline, there are no other applicable deadlines. The only impetus thereafter for a decision to be taken on the approval or non-approval of the substance is where the case concerns an application for renewal of approval and a decision would therefore have to be taken prior to the expiry of the existing approval. However, as has been seen in a number of recent cases, the Commission is able to extend the approval period, where the approval of the active substance is likely to expire before a decision has been taken on its renewal.

¹⁶ Plant Protection Products Regulation, Article 13(1).

2.2 Harmonised classification under the CLP Regulation

2.2.1 Proposal for harmonised classification

Under Article 37(1), national competent authorities may submit a proposal for harmonised classification and labelling of a substance or for a revision of the harmonised classification of a substance to the European Chemicals Agency (ECHA). As highlighted in recital 52, the resources of the authorities are to concentrate on substances of the highest concern with regard to health and the environment and, therefore, competent authorities and manufacturers, importers and downstream users are able to submit proposals to ECHA for a harmonised classification and labelling of substances classified for carcinogenicity, germ cell mutagenicity or reproductive toxicity categories 1A, 1B or 2, for respiratory sensitisation category 1, or for other effects on a case-by-case basis.

The proposal, known as the 'CLH dossier', must follow the format set out in Part 2 of Annex VI and contain the relevant information provided for in Part 1 of Annex VI, which includes the identity of the substance or substances and the harmonised classification and labelling proposed, as well as justification for the proposed harmonised classification and labelling. ECHA has issued guidance on the preparation of dossiers for harmonised classification and labelling¹⁷. Manufacturers, importers or downstream users of a substance may also submit a proposal to ECHA for harmonised classification and labelling of a substance that is not already subject to harmonised classification¹⁸. However, no other person or authority, including the European Commission, may submit a proposal for harmonised classification.

With regard to plant protection products, Article 36(2) of the CLP Regulation states that a substance that is an active substance shall normally be subject to harmonised classification and labelling. For such substances, the procedures set out in Articles 37(1), (4), (5) and (6) apply. It is noted therefore that the provision allowing manufacturers, importers or downstream users of a substance to submit proposals for new harmonised classification does not apply to plant protection products. Instead, under Article 37(6), it is only manufacturers, importers and downstream users who have new information which may lead to a change of existing harmonised classification and labelling elements of a substance in Part 3 of Annex VI that can submit a proposal for a revision of the harmonised classification. In such cases, industry is required to submit the proposal to the competent authority in one of the Member States in which the substance is placed on the market. Thereafter, the Member State shall decide whether or not to submit a CLH dossier based on the proposal received.

It is noted that the ECHA Registry of Intentions¹⁹ includes a list of CLH dossiers that may be prepared by the competent authorities of Member States. The aim of the registry is to make interested parties aware of the substances for which a CLH dossier is intended to be submitted in order that they have time to prepare for commenting during the public consultation. It also aims to encourage cooperation between potential CLH dossier submitters in order to avoid duplication of work, and enable parties to check whether another dossier submitter has worked on a CLH dossier for a specific substance in the past or is currently preparing a dossier on the substance. The registry

¹⁷ ECHA (2014): 'Guidance on the preparation of dossiers for harmonised classification and labelling', Version 2.0, August 2014, available at: http://echa.europa.eu/documents/10162/13626/clh_en.pdf

¹⁸ CLP Regulation, Article 37(2).

¹⁹ See ECHA, Registry of Intentions, accessed at: <http://echa.europa.eu/addressing-chemicals-of-concern/registry-of-intentions>

therefore contains details of current CLH proposals, CLH proposals previously submitted and CLH intentions and submissions that have been withdrawn.

Feedback received from ECHA during stakeholder interviews, however, indicated that Member States are not always able to follow the timescales indicated in the Registry of Intentions, and in some cases it can be years later that they submit a CLH dossier. While the Registry of Intentions aims to provide as realistic a picture as possible of what CLH dossiers will be submitted, ultimately priorities at the Member State level change or the timing may not work.

2.2.2 Procedure for consideration of a CLH dossier

Following receipt of a CLH dossier, ECHA will carry out an accordance check in order to confirm that the CLH dossier meets all the legal requirements. Where the CLH dossier does not pass the accordance check, the dossier will need to be revised and re-submitted. Once a dossier is accepted by ECHA, ECHA will organise a public consultation²⁰ which shall run for 45 days. Comments in relation to the hazard classes can only be given on the hazard classes that are open for commenting during the public consultation in question. Comments regarding the proposed classification are encouraged and can relate to the classification itself, the information considered in the proposal, or the justification of the conclusions. Following the public consultation, ECHA may request some further clarifications and may contact the commenting parties in order to discuss specific issues related to the CLH proposal of the substance. Thereafter, ECHA will forward all comments received to the Member State that submitted the CLH dossier and invite it to provide its view on the comments.

The CLH dossier, the comments received during the public consultation and any response to these received from the Member State that submitted the CLH dossier will then be forwarded to ECHA's Committee for Risk Assessment (RAC), which is made up of experts nominated by the Member States. In accordance with Article 37(4) of the CLP Regulation, RAC is to adopt a scientific opinion on a CLH dossier within 18 months of receipt of the CLH dossier, which includes the period for public consultation. RAC will examine the available evidence for all hazard classes proposed and may consider another category more appropriate for the classification of the substance after having examined the available information. The RAC opinion has annexed a background document and a response to comments table based on the comments from the public consultation. When the opinion is adopted, it will be published on ECHA's website²¹ together with the background document and the response to comments. Thereafter, ECHA shall forward the RAC opinion and its annexes to the Commission.

2.2.3 Commission decision on harmonised classification

The Commission, assisted by the REACH Regulatory Committee which includes representatives of the Member States, will take a decision on the proposed classification and labelling of the substance. Article 37(5) of the CLP Regulation requires that where the Commission finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, it is to submit a draft decision concerning the inclusion of that substance together with the relevant classification and

²⁰ Details of all current public consultations are available at: <http://echa.europa.eu/web/guest/harmonised-classification-and-labelling-consultation>

²¹ See ECHA, Opinions of the Committee for Risk Assessment on proposals for harmonised classification and labelling, accessed at: <http://echa.europa.eu/web/guest/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling>

labelling elements in Table 3.1 of Part 3 of Annex VI. The CLP Regulation does not, however, specify a timescale for the Commission to adopt such a decision, stating only that a draft decision is to be submitted ‘without undue delay’.

After its inclusion in Part 3 of Annex VI to the CLP Regulation, all manufacturers, importers and users of the substance in the EU shall classify the substance in accordance with the entry in Annex VI (Article 4(3) CLP Regulation), enabling the users to be better informed about the substance, its potential effects and how best to make use of it safely. Hazard classes not included in the Annex VI entry must be self-classified and labelled accordingly.

2.3 Need for alignment of the Plant Protection Products Regulation and CLH procedures

As outlined in Sections 2.1 and 2.2 above, the procedures and timescales for the EFSA peer review of the dossier for approval of an active substance under the Plant Protection Products Regulation, and the adoption of a RAC opinion on the CLH dossier under the CLP Regulation, are different. Overall, RAC has a maximum of 18 months to adopt an opinion on a CLH dossier, while EFSA has 120 days following the public consultation to adopt its conclusions, though this may be extended where further information is requested. The timescales for each process are shown in the diagrams in Annexes 1 and 2.

While it is open to the Commission to proceed to a decision on the approval or non-approval of an active substance, where following this, a RAC opinion is then issued which states that the exclusion criteria are met and therefore that the substance no longer meets the criteria for approval, the Commission would be required to review the approval. Under Article 21 Plant Protection Products Regulation, the Commission may review the approval of an active substance at any time and where it concludes that the approval criteria are no longer satisfied, it shall adopt a Regulation to withdraw or amend the approval. If a decision on harmonised classification of a substance were to be taken after the non-approval of an active substance under the Plant Protection Products Regulation, the result of which is that the substance would have met the criteria for approval, the Commission could ultimately find itself open to legal challenge by the producer of the active substance.

In order to avoid such a situation, ideally the RAC opinion on the CLH dossier should be available to EFSA during its peer review of the DAR, and if this is not possible in all cases, the RAC opinion should be at least available prior to a decision being taken by the Commission on the approval or non-approval of an active substance under the Plant Protection Products Regulation. As the decision on harmonised classification has consequences for the approval or non-approval of the active substance, the Commission should take the decision on harmonised classification first. A number of steps have therefore been taken to align both procedures, as set out in Section 4 below.

In cases where a RAC opinion is not available to EFSA during its peer review of the DAR, the RAC opinion should be at least available prior to a decision being taken by the Commission on the approval or non-approval of an active substance under the Plant Protection Products Regulation. While the Commission has a deadline of 6 months from receipt of the EFSA conclusions to present the review report and a draft Regulation on the approval or non-approval of the active substance²², there is no deadline as such for the adoption of a Regulation. The Commission has, therefore, been able to extend the approval period in cases of renewal, where the approval of the active substance is likely to expire before a decision has been taken on its renewal. In the case of glyphosate, the

²² Plant Protection Products Regulation, Article 13.

approval period was extended for a further period to allow time for the RAC opinion to be made available.

However, in both cases, either for the RAC opinion to be available to EFSA during its peer review of the DAR or at the latest prior to decision on approval or non-approval being taken by the Commission, this presumes that a CLH dossier is submitted at some stage by a Member State to ECHA. This is not always the case and ultimately there is no obligation on the Member State to submit a CLH dossier at any time throughout the whole process.

3. Case Examples Concerning Classification

3.1 Overview

Stakeholders identified a number of examples of where different conclusions on classification of an active substance had been reached by different authorities both under the Plant Protection Products Regulation and separately under CLP. Specific examples include Calciumcarbid, Penthiopyrad and Terbutylazine, all of which have since been approved as a Plant Protection Products Regulation. The examples of Amitrole and Isoproturon, which are subject to non-approval for reasons other than classification, and the recent case of Flutianil for which a decision is yet to be taken are set out below. While Flutianil therefore appears to be the only case at stake for which the issue has arisen to date, it is not yet known how many substances may be subject to different conclusions on classification in the future, as further substances come through the review programme, and applications are made for the approval of new active substances.

3.2 Examples concerning classification

3.2.1 Amitrole and Isoproturon

In two recent cases concerning applications for renewal of the approval of the active substances, Amitrole and Isoproturon, under the Plant Protection Products Regulation, EFSA proposed a different classification to that put forward by the RMS, which followed the existing CLP classification. Under CLP, Amitrole was classified as toxic for reproduction category 2 in 2004; however EFSA proposed a classification as toxic for reproduction category 1B. due to potential endocrine disrupting properties. Isoproturon is classified as carcinogenic category 2 (harmonised classification under the CLP Regulation and proposed to be classified as toxic for reproduction category 2.

In both cases, the approval as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expired on 30 June 2016 and therefore a decision required to be taken by the Commission on the renewal of the approval of the active substance by that date.

The Commission issued Implementing Regulations (EU) 2016/871 and (EU) 2016/872 on 1 June 2016 concerning the non-approval of the active substances Amitrole and Isoproturon respectively. In both cases, the approval of the active substance was not renewed due to a number of risks identified by EFSA, which concluded that it was not established with respect to one or more representative uses that the approval criteria provided for in Article 4 of the Plant Protection Products Regulation would be met.

The identified risks to groundwater and operators, workers and bystanders in the case of Amitrole, and groundwater, birds, wild mammals and aquatic organisms in the case of Isoproturon, precluded approval of the active substance. It therefore could not be concluded whether each active substance met the approval criteria related to endocrine disrupting properties as outlined in the first paragraph of point 3.6.5 of Annex II to the Plant Protection Products Regulation.

Further details on the procedure followed and conclusions reached following the applications made for renewal of approval of Amitrole and Isoproturon, are set out in Annexes 3 and 4 respectively.

3.2.2 Flutianil

An application for approval of the new active substance, Flutianil, under the Plant Protection Products Regulation, was received by the UK as RMS on 23 February 2011. Following its initial evaluation of the dossier in the DAR, the RMS sent this to EFSA for a peer review in June 2013. The conclusions of the EFSA peer review (published 6 August 2015) suggested classification as carcinogen category 2 and reproductive toxicant category 2. However the RMS remained of the opinion that classification regarding carcinogenicity was not appropriate. The DAR stated that the weight of evidence was insufficient to conclude that the test substance is carcinogenic for classification purposes and did not support classification for reproductive toxicity.

A CLH dossier for Flutianil was submitted by the UK on 23 February 2015, following which the RAC published its opinion on harmonised classification on 10 March 2016. Taking into account that there is not sufficient evidence of a carcinogenic effect in rats and mice, and considering the lack of genotoxicity of Flutianil, RAC is of the opinion that Flutianil does not warrant classification as carcinogenicity.

Whilst the two procedures of applying for approval of the active substance under the Plant Protection Products Regulation, and applying for harmonised classification under CLP, did not run in parallel in this case, but rather one process followed the other, the situation now is that the conclusions on classification reached within the CLH process differ from the EFSA peer review within the Plant Protection Products Regulation process. This will therefore be the first case where ECHA and EFSA may have to resolve the divergence or produce a joint opinion for the Commission, explaining their views and why they have reached different conclusions on classification.

Further details on the procedure followed and conclusions reached, are set out in Annex 5.

3.3 Extent of the issue

Although Flutianil is the only example to date where ECHA and EFSA need to collaborate to resolve the differences in conclusions on classification, the potential impacts of such differences should not be underestimated, nor the possibility of this issue arising again. Responses to targeted consultation by plant protection products and biocidal products manufacturers highlights the difficulties they are currently facing in getting Member State authorities to act as rapporteurs for active substances through the CLH process. This means that classification decisions may not be available from the Commission prior to the need for such a classification for active substance approval.

This is an important issue. As highlighted by a recently published report by steward redqueen²³, as a result of the EU moving towards hazard-based legislation, several substances for plant protection used in the EU are at risk of automatic bans on approval linked to classification as a PBT/vPvB, mutagenic or an endocrine disruptor. Based on the interim criteria, the study identifies 75 active substances out of the 400 currently available that may be impacted by classification and other regulatory decisions (e.g. under the Water Framework Directive), as well as the final choice of endocrine disruptor criteria. The latter is the most important with the majority of the substances identified as potentially meeting cut-off criteria for endocrine disruption. The study notes that if substances are withdrawn they will not be easily replaced for two reasons. Firstly, the development of new active ingredients up to market introduction takes about 11 years and costs over €280

²³ steward redqueen (2016): Cumulative impact of hazard-based legislation on crop protection products in Europe, final report, April.

million. Secondly, the pipeline of products waiting for approval for the European market is also declining due to rising research and development (R&D) time and costs (i.e. 70 substances in pipeline in 2000, down to 28 in 2012).

The economic impacts linked to the potential loss of the 75 substances considered by steward redqueen^{Error! Bookmark not defined.} were estimated for seven staple crops at the EU level and 24 speciality crops across nine EU member states, representing 49% (in value) of EU crop output (indicated as being €204 billion). The study found that for the seven staple crops alone, losses could equate to around €15 billion in crop value due to lower yields and increased production costs; this is associated with 1.2 million direct jobs, 30% of which could be lost due to lost margins (profits) for these crops. Further implications in terms of self-sufficiency and land use were also identified.

These impacts are associated with the automatic triggers that exist with the Plant Protection Products Regulation following CLP classification for the active substance. They are therefore the impact of the automatic trigger rather than the potential consequences of the parallel hazard assessment process that may currently take place. Such impacts will only be attributable to the parallel hazard assessment process if a ban is due to a classification proposal from EFSA, which is later overturned in a Commission decision on harmonised classification based on a RAC opinion.

A review of the EU pesticides database provides an indication of the number of substances on which decisions may need to be taken in the near future. Table 3-1 indicates that, under the Plant Protection Products Regulation, there are 56 substances which may require re-assessment within the next five years. Given the types of costs reported above, one could expect that if the Commission adopts a non-approval decision based on a classification proposal by EFSA, which is later overturned in a CLH decision based on a RAC opinion, then the non-approval decision will be challenged by manufacturers.

Table 3-1: Plant Protection Products Regulation: substances not approved (or banned) and those requiring re-approval within the next five years	
CLP classification	Number of substances
<i>Substances not approved (or banned)</i>	
Carc. 1B	17 banned
Carc. 2	30 not approved
Muta. 1B	6 not approved
Muta. 2	8 not approved
Repr. 1A	1 not approved
Repr. 1B	15 not approved
Repr. 2	13 not approved
<i>Substances currently approved but requiring re-assessment within the next five years</i>	
Carc. 1B	none
Carc. 2	27 approved
Muta. 1B	none
Muta. 2	2 approved
Repr. 1A	none
Repr. 1B	5 approved
Repr. 2	22 approved
Source: European Commission (2016): EU Pesticides database. Available at http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN on 27 th June 2016	

It should also be noted that the differing legal position for industrial and plant protection substances would result in considerable uncertainty within supply chains for the industrial chemical industry. Furthermore, it would raise questions internationally and would be likely to trigger WTO objections.

4. Alignment of the Plant Protection Products Regulation and CLH Procedures

4.1 Actions to align the Plant Protection Products Regulation and CLH procedures

A workshop was held in Berlin on 12 and 13 April 2011, co-organised by the Federal Institute for Risk Assessment (BfR), the European Commission, EFSA and ECHA. The main objective of the workshop was to discuss how the processes of assessing active substances in plant protection products under the Plant Protection Products Regulation and classifying and labelling active substances under the CLP Regulation could be aligned at the level of Member State authorities, EFSA and ECHA. Amongst the main recommendations following the workshop were that there should be early involvement of ECHA where the active substance is considered a potential candidate for harmonised classification and labelling, early notification to the registry of intentions, and the CLH dossier should preferably be submitted one month prior to the submission of the DAR. It was recommended that there should be improvements to data sharing to ensure that experts are evaluating the same data package and harmonisation of the different dossier formats in order to avoid inefficiencies in both processes and that EFSA and ECHA should aim to conduct their public consultations at the same time in order to streamline the process. Although RAC has 18 months to provide their opinion, the timescales during alignment should allow RAC to adopt their opinion before the expiry of the six month period which is given to the Commission following the receipt of EFSA's conclusions to develop its review report and draft regulation on the approval or non-approval of the active substance under the Plant Protection Products Regulation. Based on the results of the workshop, the Organising Committee took the initiative to produce a draft working procedure, incorporating these recommendations amongst others, which was to form the basis for further steps in the parallel processing of dossiers. The workshop concluded that in the long-term "one substance, one dossier, one procedure and one discussion" would be the ideal situation²⁴.

It is noted that early in 2013 ECHA adopted Rules of Procedure for Cooperation of ECHA with EFSA²⁵, which define the framework of their cooperation with a view to sharing relevant information and ensuring coherence in the work of ECHA and EFSA, in particular on matters concerning substances for which an opinion has been sought in a food safety context. With regard to prevention of potential conflicts of scientific opinions, similar to the requirement under Article 30 of the General Food Law Regulation, the following mechanisms were put in place:

- ECHA is to act proactively and on a regular basis to resolve potential sources of conflict between opinions of ECHA and EFSA (Article 2(d));

²⁴ Report of the Workshop on Harmonised Classification and Labelling (CLH) of Active Substances in Plant Protection Products held in Berlin on 12 and 13 April 2011, available at: http://www.intechopen.com/journals/international_journal_of_agricultural_chemistry/report-of-the-workshop-on-harmonized-classification-and-labelling-clh-of-active-substances-in-pla

²⁵ ECHA Decision of the Management Board, Rules of Procedure for Cooperation of the European Chemicals Agency with the European Food Safety Authority, available at: https://echa.europa.eu/documents/10162/13608/final_mb_30_2013_rop_efsa_echa_en.pdf

- ECHA is to identify substances that are, or are likely to be, under discussion in both ECHA and EFSA by exchanging relevant information (Article 4(1));
- ECHA is to facilitate the participation of experts from EFSA in working groups and seek to provide an opportunity for early exchange of views between rapporteurs of its Committees and EFSA's panels (Article 4(3) and (4)); and
- When a potential conflict of opinions between ECHA and EFSA is expected or identified, the possibility of sharing data which have been used as the basis of opinions is to be considered, and where appropriate, ECHA should facilitate an analysis of the methodologies used (Article 4(5) and (6)).

Following the adoption of the Rules of Procedure and by way of practical follow-up to the 2011 Workshop, the procedural framework and the steps taken by ECHA to align the CLH process with the peer review for active substances under the Plant Protection Products Regulation were outlined in a document following the 13th Meeting of Competent Authorities for REACH and CLP (CARACAL)²⁶. It was noted that it is “highly desirable that the opinion on a CLH dossier for an active substance is adopted by RAC before the Commission Comitology decision on the (non-)approval of the active substance is taken”. On the basis of two pilot cases that ECHA and EFSA had been working on (the new active substance Sulfoxaflor and an application for renewal of approval of Flumioxazin), alignment was to cover the following aspects:

- The timing of both processes;
- Exchange of relevant information and views generated during both processes; and
- How to solve any contentious issues identified.

Timing

As noted above, RAC has a maximum of 18 months to adopt an opinion on a CLH dossier, while EFSA has 120 days for the peer review process. As the CLH process timescales are longer and more flexible, ECHA outlined that the CLH process would be adapted for cases of alignment in order that a RAC opinion may be available before EFSA published its conclusions on classification.

While steps have been taken to align both procedures, the main problem remains that the timelines for each procedure are very different. While RAC is able to deliver opinions within the EFSA timeframes, problems arise in cases where RAC does require the full 18 months to deliver its opinion, in which case EFSA would need to publish its peer review in advance of this. In such cases, ECHA has agreed to try and reach a conclusion on the main elements, and publicise its full opinion ahead of the Commission taking a decision on the approval or non-approval of the active substance. However, it has been suggested by ECHA that this is an area which may require a change in the legislation in order to harmonise the timelines for both procedures.

Exchange of information

In order to facilitate exchange of information, the daily contact points in ECHA and EFSA for alignment were to be identified and regular teleconferences and meetings were to be held between these points of contact. EFSA was to be invited to every RAC meeting and ECHA invited to EFSA expert meetings and participate in these where useful. It was also agreed in cases of alignment that

²⁶ Document CA/47/2013, 13th Meeting of Competent Authorities for REACH and CLP (CARACAL), 26 – 28 November 2013, Concerns: Alignment of the PPP approval and CLH opinion development processes.

the periods of consultation would be launched at the same time. While the CLH process involves a single public consultation of 45 days and is launched once the CLH dossier is received, the Plant Protection Products Regulation approval process involves a period of 60 days during which the DAR is circulated to Member States, the applicant and to EFSA for comments. The Plant Protection Products Regulation approval process also includes a public consultation on the final DAR, the main outcome of which is the 'reporting table' in which the comments received are compiled for further consideration by the applicant, EFSA and the RMS. By launching both consultations in parallel, ECHA and EFSA could encourage consistent commenting under both consultations at the same time. It was recognised however that where new data and information are submitted during the consultation phase, it would be difficult to ensure that both processes have a common information base as a starting point. In practice therefore, the alignment of the information base would require the inclusion of new information in the CLH process after the public consultation, provided that the adoption of the opinion is not delayed. It was also noted that during the EFSA expert meeting late in the Plant Protection Products Regulation approval process, further views pertaining to the hazard evaluation may be generated that could affect the RAC opinion.

Industry representatives commented that there remain significant differences in the consultation procedures for each process. The ECHA process is considered to be very open and transparent, allows new data and studies to be submitted during the public consultation, industry and experts are permitted to attend RAC meetings, and the outcome of the consultation and meetings is well documented. The process with EFSA is considered by industry to be not as good, since companies are not invited to attend the peer review and will only be contacted by phone. It is not clear how comments are dealt with, and the process is therefore not considered to be open or transparent.

In general, however, coordination between ECHA and EFSA is working well. The only problem with the cooperation identified by EFSA is a lack of resources, which therefore places limits on the ability to send colleagues to physically attend RAC meetings. As most RAC meetings involve discussion of pesticides (four to eight meetings per year), ideally EFSA would like to have two experts from EFSA in every RAC meeting but have not been able to send two persons to Helsinki for several days at a time. EFSA have between 15 and 20 meetings per year that could be relevant to ECHA.

ECHA participates in the Pesticide Steering Network but recognises that coordination is much more difficult where questions of classification arise in the context of an application for approval or non-approval of an active substance under the Plant Protection Products Regulation, than under the Biocidal Products Regulation where it is the relevant authority and can therefore coordinate with colleagues in the same building. ECHA is therefore trying to increase collaboration in such cases, for example, through more regular use of video conferences. Aside from the Pesticide Steering Network, ECHA coordinates with EFSA on specific cases, although in many cases the EFSA peer review is already completed by the time ECHA receives the CLH dossier. Where new evidence arises, ECHA is invited to attend meetings at EFSA so that there is a flow of information between the two Agencies.

Resolution of issues identified

In order to identify as early as possible any potential conflicts in the respective opinions, ECHA and EFSA agreed to exchange all documents produced in the respective processes in order to identify any potential source of conflict as early as possible and those arising from different scientific interpretations of the data.

4.2 CLH dossier submission

4.2.1 Member State submission of CLH dossier

As highlighted throughout the case study, in order for alignment to work, a CLH dossier must be submitted to ECHA in advance of the DAR being submitted to EFSA. ECHA and EFSA have taken steps to identify the expected dates of submission of CLH dossiers for new active substances and those under the renewal process for which a CLH proposal or revision of the CLH would be submitted. However, in many cases, even where a Member State had previously indicated its intention to submit a CLH dossier, no CLH dossier is received by ECHA. For example, during the first three quarters of 2013, in three out of four cases that were expected for alignment, no CLH dossier or CLH intention was received by ECHA. The only CLH dossier received by ECHA was for the pilot case Sulfoxaflor²⁷.

As there is no clear legal obligation on Member States to submit a CLH dossier at a given moment in time, the alignment of this process with the EFSA peer review process has so far relied on the willingness and ability of a Member State to prepare a CLH dossier for the particular active substance at the same time as preparing the DAR. The coordination of the submission of these two reports requires an extra effort for Member State competent authorities to prepare two different reports in a limited timeframe. Alignment is therefore dependent on the work and resources of the Member State competent authorities and in particular will be difficult in cases where the authorities responsible for the CLP Regulation and the Plant Protection Products Regulation are different. The reasons as to why a Member State does or does not proceed with a CLH dossier submission were therefore considered during stakeholder interviews.

In some Member States there are different competent authorities responsible for the preparation of the DAR under the Plant Protection Products Regulation and the CLH dossier under the CLP Regulation; therefore there is no guarantee that the Member State which has been allocated an active substance under the review programme will prepare a CLH dossier at the same time. Interviewees commented that many Member States are still grappling with how to manage CLP, and REACH remains their priority. As there is no cost recovery for the preparation of CLH dossiers by Member States, in most Member States it is a question of resources and priorities. Without a legal obligation to prepare CLH dossiers, with no prospect of cost recovery and there being other key priorities, there appears to be little incentive for Member States to prepare and submit CLH dossiers.

Some Member States, such as the UK and Germany are at the forefront in terms of CLH dossier submission and have established internal targets each year to submit CLH dossiers for a particular number of substances. In the UK, the intention going forward is to focus on those substances where it is anticipated that there may be an issue for approval or that trigger a classification concern for approval. The UK authorities establish a yearly plan and notify ECHA of any substances that they are intending to take through alignment, prioritising those that are anticipated to have key issues. During the initial admissibility check following receipt of an application for approval of an active substance under the Plant Protection Products Regulation, a toxicologist will consider whether there are likely to be any concerns regarding carcinogenicity or reprotoxicity (CMR end points) and alert the CLH team, who will consider whether they need to proceed with alignment. This initial check is

²⁷ Document CA/47/2013, 13th Meeting of Competent Authorities for REACH and CLP (CARACAL), 26 – 28 November 2013, Concerns: Alignment of the PPP approval and CLH opinion development processes, at page 7.

carried out before the full evaluation of the dossier is carried out and therefore time is very tight, particularly in cases where further data is submitted.

Ultimately the cases taken forward for alignment may not follow the yearly plan notified to ECHA. Priorities can change and cases that were initially thought to require alignment may in fact raise no classification issues. In such cases the applicant may still want a CLH dossier to be taken forward for certainty, but the UK authorities need to consider resources and prioritise other cases.

On the other hand, there are cases where it was not anticipated that there would be issues concerning classification, but it later transpired following comments received from Member States that there are issues concerning classification, and therefore a CLH dossier is required. The UK has been the RMS for a number of cases that were not taken forward in alignment when the DAR was submitted, but later recognised the need for a CLH dossier. For example, in the case of Flutianil, the UK did not prepare a CLH dossier at the time the DAR was submitted, but did so later on in the process after concerns over classification were raised.

The UK authorities commented that industry is now also more aware that classification could be an issue. During an application meeting, the applicant is therefore asked to alert the UK authorities to any CMR issues in order that they can consider whether alignment will be required early on in the process. If industry states that there is no issue even when there may be, this will be picked up during the admissibility check following receipt of the application for approval of the active substance. It is therefore in the interest of industry to raise the matter as early as possible and assist Member States as much as they can.

It should be noted that in order to assist Member States with the submission of CLH dossiers, steps have been taken to develop a common template which may enable more Member States to prepare a CLH dossier at the same time as producing the DAR. Following a workshop held by ECHA in June 2014 to further discuss the format for CLH dossiers and the DAR, a group was created in ECHA with representatives from volunteer Member States in order to develop a single template which would include all necessary information for both submissions. The aim was to develop a common template that would help competent authorities to produce a CLH dossier whilst completing the DAR, thus allowing competent authorities to take information during the development of the DAR and put it into a subset to allow a CLH dossier to be run off without additional work. The process of development of the common template has been ongoing and a draft template is now undergoing stakeholder consultation. Depending on feedback received during stakeholder consultation, the new common format for both submissions may be available later this year.

While the use of a common format in the future has been welcomed, one concern raised was that it may not be appropriate in all circumstances and therefore that Member State authorities should not be required to fill in the merged application where classification will not affect the approval or non-approval of the active substance. It was also noted that while it will help to cut down on the work required to produce a CLH dossier, there will still be significant input required in order to produce a quality CLH dossier. Finally, some information for the risk assessment will not be relevant for the hazard assessment and vice versa.

4.2.2 Industry submission of CLH dossier

Under Article 37(1) of the CLP Regulation it is only national competent authorities that may submit a CLH dossier to ECHA. Manufacturers, importers or downstream users of active substances in plant protection products are not able to submit proposals to ECHA for new harmonised classification and labelling of a substance. Under Article 37(6), it is only manufacturers, importers and downstream users who have new information which may lead to a change of existing harmonised classification

that can submit a proposal for a revision of the harmonised classification. In such cases, industry is required to submit the proposal to the competent authority in one of the Member States in which the substance is placed on the market. Thereafter, the Member State shall decide whether or not to submit a CLH dossier based on the proposal received. As highlighted above, Member States do not always take forward a CLH dossier and therefore industry stakeholders have argued that the legislation should be changed to allow CLH dossier submission by industry.

Industry stakeholders commented that given that there are now clear procedures and timescales, and that industry is more responsible, manufacturers, importers and downstream users of active substances should be allowed to submit CLH dossiers directly to ECHA. The concerns raised by industry suggest that the allocation of responsibilities to Member States is leading to inefficiencies within the system and is also impacting on its effectiveness in terms of ensuring a level playing field across the internal market. As part of the targeted consultation exercise undertaken for the study more generally, Member State authorities were asked whether they agree or disagree with a number of statements regarding the CLH process and coherence with other legislation (e.g. the Plant Protection Products Regulation). With respect to industry development and submission of dossiers to ensure coherence with other legislation (in particular the Plant Protection Products Regulation), 8 out of 11 Member States agreed that companies should be encouraged to do so, thereby reducing some of the pressure on Member State authority resources.

However, EFSA has argued that while industry is not able to submit a CLH dossier for a plant protection product active substance directly to ECHA, industry is only required to convince one Member State that there is a need to change classification, in order to take a CLH dossier forward. In EFSA's opinion, the current system does not therefore need to be changed.

The UK authorities commented that, in their view, the current position provides the appropriate flexibility. The current system of Member State submission of CLH dossier provides the appropriate checks and balances and ensures the consistency and quality of submissions. Were ECHA to receive dossiers from lots of different actors this would remove an important stage carried out at the Member State level and could affect the time and resources of ECHA. Currently, Member States check the quality and consistency of information included in a CLH dossier; this would need to be carried out by ECHA if industry was allowed to submit a CLH dossier directly to ECHA. At present, industry already works closely with Member State authorities to help prepare CLH dossiers. For example, in the UK applicants are encouraged to submit a CLH dossier to the UK competent authority. When the UK decides to take a CLH dossier forward the applicant is contacted first, to see where they can help in the preparation of information in order to speed up the process. Industry is therefore actively involved during the preparation of the CLH dossier.

5. Resolution of Conflicts of Opinion

Ultimately even where alignment does take place, and both the EFSA peer review and RAC opinion are available prior to a decision being taken on the approval or non-approval of an active substance, different conclusions on classification of a substance may be reached by EFSA and ECHA. While EFSA is obliged to apply CLP criteria in the classification of a substance, EFSA may reach a different conclusion to that ultimately taken by RAC and may not always reach the same conclusion as the RMS. ECHA have produced guidance on the criteria for classification, but two scientific groups can still reach different opinions even when applying the same rules and guidance to the same set of data. While there is only one set of rules, differences in classification can arise from different interpretations of the data, or in cases where new information becomes available during the ECHA public consultation, which was not available to EFSA when evaluating the substance. This could create difficulties in the implementation of the Plant Protection Products Regulation, in particular where it concerns classification that would meet the cut-off criteria in Article 4 of the Plant Protection Products Regulation.

To date, there have been no examples of where ECHA and EFSA have reached different conclusions on classification and this has had to be resolved. In some cases, full alignment occurs, for example in two pilot cases that were carried out during 2013 for the active substances Sulfoxaflor and Flumioxazin. In other cases, while alignment does take place in order to ensure that a RAC opinion is available prior to a decision being taken on the approval of the active substance; the timings are not aligned, as the submission of the CLH dossier followed the EFSA peer review. In the case of Flutianil, where ultimately the authorities reach different conclusions on classification, the process cannot be reopened unless the Commission gives EFSA a mandate for this, taking into account the RAC opinion. Also, as highlighted above, there have been two cases where other reasons for non-approval of the active substance have come into play, thus avoiding the need to resolve the issue of classification. Flutianil will therefore be the first case where a resolution will have to be found.

Article 95 of REACH makes provision for conflicts of opinion with other bodies. In such cases, ECHA is to ensure early identification of potential sources of conflict between its opinions and those of other bodies established under Community law, including EFSA, and where ECHA identifies a potential source of conflict, it shall contact the body concerned in order to ensure that any relevant scientific or technical information is shared and to identify the scientific or technical points which are potentially contentious²⁸. However, where there is a fundamental conflict over scientific or technical points, Article 95(3) provides that ECHA and the body concerned, in this case EFSA, shall work together either to solve the conflict or to submit a joint document to the Commission clarifying the scientific and/or technical points of conflict.

It is noted that having regard to Article 95 of REACH, having consulted RAC and EFSA, and in agreement with the Commission, ECHA adopted Rules of Procedure for Cooperation of ECHA with EFSA²⁹. These rules define the framework of their cooperation with a view to sharing relevant information and ensuring coherence in the work of ECHA and EFSA, in particular on matters concerning substances for which an opinion has been sought in a food safety context. As noted

²⁸ REACH, Articles 95(1) and (2).

²⁹ ECHA Decision of the Management Board, Rules of Procedure for Cooperation of the European Chemicals Agency with the European Food Safety Authority, available at:
https://echa.europa.eu/documents/10162/13608/final_mb_30_2013_rop_efsa_echa_en.pdf

above in Section 4.1, when a potential conflict of opinions between ECHA and EFSA is expected or identified, the possibility of sharing data which have been used as the basis of opinions is to be considered, and where appropriate, ECHA should facilitate an analysis of the methodologies used. With regard to mechanisms for dealing with conflicts of scientific opinions, the following is to be identified:

- a. the scientific and/or technical points of conflict;
- b. The relevant uncertainties in the data and the reasons for the differences in taking them into account; and
- c. The relevant differences in the application of the methodologies used by ECHA and EFSA.

ECHA is to arrange joint meetings between experts, rapporteurs and Secretariats of ECHA Committees and EFSA Scientific Committee and Panels, or ECHA may invite EFSA representatives to attend a meeting in order to discuss the specific issue.

In the case of Flutianil, it is likely now that ECHA and EFSA will be required to produce a joint opinion stating that each authority's opinion is based on the same evidence, explaining their views and why they have different interpretations on classification. In principle there should not be any difference of opinion on classification as both agencies apply the same criteria from the CLP Regulation. The only exception to this is where there is new evidence available to one authority that can modify classification. If the different conclusions have been reached as a result of there being new evidence available to ECHA, as EFSA had already finalised its opinion by that stage, the process cannot be reopened unless the Commission gives EFSA a mandate for this.

While ECHA, EFSA and the Commission are now required to work together to resolve the conflict, there is no set procedure or timescales within which ECHA and EFSA are to submit a joint document to the Commission, or what steps the Commission will take next. This therefore leaves uncertainty for industry as to the approval or non-approval of the active substance, and when any decision will be taken. Industry representatives commented that should ECHA and EFSA reach different conclusions on classification in the future, they do not want to have to go down the Article 95 route every time.

If a decision on harmonised classification of a substance were to be taken after the approval of an active substance under the Plant Protection Products Regulation, which would affect the exclusion criteria and thus mean that the substance no longer meets the criteria for approval, the Commission would be required to review the approval. Under Article 21 of the Plant Protection Products Regulation, the Commission may review the approval of an active substance at any time and where it concludes that the approval criteria are no longer satisfied, it shall adopt a Regulation to withdraw or amend the approval. If a decision on harmonised classification of a substance were to be taken after the non-approval of an active substance under the Plant Protection Products Regulation, the result of which is that the substance would have met the criteria for approval, the Commission could ultimately find itself open to legal challenge by the producer of the active substance.

6. Evaluation

6.1 Effectiveness

Under both the procedure for applying for approval of an active substance under the Plant Protection Products Regulation and consideration of proposals for harmonised classification under the CLP Regulation, the criteria to be applied to the classification of a substance are set out in the CLP Regulation. While there is only one set of rules which is applied to the same set of data in each case, different conclusions on classification can still arise from different interpretations of the data. If different conclusions have been reached as a result of there being new evidence available to ECHA, following EFSA having published its conclusions on the approval of the active substance, the process can only be reopened where the Commission gives EFSA a mandate for this. Different conclusions on classification create difficulties in the implementation of the Plant Protection Products Regulation, in particular where it concerns classification that would meet the cut-off criteria in Article 4 of the Plant Protection Products Regulation. Different conclusions on classification can affect the implementation of the CLP Regulation, as this can cause uncertainty where the proposed classification under the Plant Protection Products Regulation differs from an existing harmonised classification, which is used in applications other than under the Plant Protection Products Regulation. It should be noted that the differing legal position for industrial and plant protection substances would result in considerable uncertainty within supply chains for the industrial chemical industry. Furthermore, it would raise questions internationally and would be likely to trigger WTO objections.

There are clear procedural steps and timelines as set out in the CLP Regulation and the Plant Protection Products Regulation, for the CLH and active substance approval process respectively. However in order to avoid divergence of opinions between these two processes, and thus ensure the effectiveness of both the substance approval procedure and the harmonised classification procedure, ECHA and EFSA have taken steps to align the timing and coordination of both procedures in order to ensure that a RAC opinion on classification is available when decisions on classification are likely to affect the process of approval of an active substance. Further measures are also ongoing, such as the development of a common template for both submissions. However, manufacturers have highlighted difficulties that they are currently facing in getting Member State authorities to act as rapporteurs for active substances through the CLH process. This means that classification decisions may not be available from the Commission prior to the need for such a classification for active substance approval, which will further impact on the effectiveness of the CLP Regulation.

6.2 Efficiency

The lack of harmonised classification for all active substances under the Plant Protection Products Regulation affects the efficiency of both the substance approval procedure and the harmonised classification procedure. If, as intended under Article 36(2) of the CLP Regulation, substances that are active substances in plant protection products were subject to harmonised classification and labelling, in many cases the need for two different authorities to carry out a hazard evaluation and reach conclusions on the classification of the substance would not arise, and thus both procedures would be more efficient.

While steps have been taken to align both procedures and ensure that the RAC opinion is available before EFSA conclusions on classification are drafted, ECHA and EFSA may still reach different

conclusions on the classification of the substance. The efficiency of the procedure is also affected where the case concerns an application for renewal of approval of an active substance and the Commission extends the expiry date of the existing approval in order to allow a decision on renewal to be taken once the RAC opinion is available. It may therefore be necessary in future to consider placing a legal requirement on Member States to submit the CLH dossier to ECHA at the latest when they send the DAR to EFSA, similar to the situation which applies to biocidal products under the Biocidal Products Regulation, in order to ensure that alignment of both procedures occur.

To date, there have been no examples of where ECHA and EFSA have reached different conclusions on classification and this has had to be resolved. Flutianil will therefore be the first case where a resolution will have to be found. In the case of Flutianil, it is likely now that ECHA and EFSA will be required to produce a joint opinion stating that each authority's opinion is based on the same evidence, explaining their views and why they have different interpretations on classification, which again affects the efficiency of both procedures as this requires the resources of both authorities to restate their position and the reasons for this. While ECHA, EFSA and the Commission are now required to work together to resolve the conflict, there are no set procedures or timescales within which ECHA and EFSA are to submit a joint document to the Commission, or what steps the Commission will take next. This therefore leaves uncertainty for industry as to the approval or non-approval of the active substance and when any decision will be taken, and has wider implications for the efficiency of both procedures, due to the resources required for two separate authorities, in addition to the RMS, to undertake hazard evaluation and reach conclusions on substance classification.

6.3 Relevance

The procedure of applying for approval or renewal of approval of an active substance under the Plant Protection Products Regulation and the submission of a CLH dossier under the CLP Regulation are both highly relevant. Without approval of an active substance under the Plant Protection Products Regulation, an active substance cannot be used in a plant protection product. Under Article 36(2) of the CLP Regulation, a substance that is an active substance should be subject to harmonised classification and labelling.

The CLP Regulation aims to provide harmonised classification of substances for hazard classes of highest concern and of other substances on a case-by-case basis. The need for consistency between the conclusions on classification reached by two different scientific bodies, under different procedures and timescales, in the context of substance approval under the Plant Protection Products Regulation and harmonised classification under the CLP Regulation, is therefore highly relevant in order to meet the objectives of the CLP Regulation.

6.4 Coherence

The proposals for classification of a substance within the procedure for approval of an active substance under the Plant Protection Products Regulation are not always coherent with the classification of a substance under the CLP Regulation. Proposals for classification have to be put forward as part of a dossier for approval or renewal of approval of an active substance under the Plant Protection Products Regulation, which undergoes peer review by EFSA. Meanwhile, in the absence of a harmonised classification under CLP, or where a revision to the harmonised classification is proposed, a CLH dossier may be submitted to ECHA. While there is coherence in the criteria applied for classification of the substance as the Plant Protection Products Regulation apply the CLP criteria to the classification of a substance, the different authorities involved may nevertheless reach different conclusions on the classification of a substance. As stated above, to

date, there have been no examples of where ECHA and EFSA have reached different conclusions on classification and this has had to be resolved. However, in the current case of Flutianil, in accordance with Article 95 of REACH, ECHA, EFSA and the Commission will now be required to work together to resolve the conflict, and thus aim to ensure coherence in the classification of the substance.

If a decision on harmonised classification of a substance were to be taken after the approval of an active substance under the Plant Protection Products Regulation, which would affect the exclusion criteria and thus mean that the substance no longer meets the criteria for approval, the Commission would be required to review the approval. Under Article 21 of the Plant Protection Products Regulation, the Commission may review the approval of an active substance at any time and where it concludes that the approval criteria are no longer satisfied, it shall adopt a Regulation to withdraw or amend the approval.

If a decision on harmonised classification of a substance were to be taken after the non-approval of an active substance under the Plant Protection Products Regulation, the result of which is that the substance would have met the criteria for approval, the Commission could ultimately find itself open to legal challenge by the producer of the active substance.

In order to avoid either scenario above arising, not only should the RAC opinion on harmonised classification be available before the Commission takes a decision on the approval or non-approval of the active substance under the Plant Protection Products Regulation process, but the Commission should take the decision on harmonised classification first. As the decision on harmonised classification has consequences for the approval or non-approval of the active substance, and not vice versa, this should take priority.

7. Conclusions

The procedures and timescales for the EFSA peer review of the dossier for approval of an active substance under the Plant Protection Products Regulation, and the adoption of a RAC opinion on the CLH dossier under the CLP Regulation, are not always implemented in the least burdensome manner, where these result in different opinions on the classification of a substance. Different conclusions on classification may be reached by each authority under the respective procedures. While EFSA is obliged to apply CLP criteria in the classification of a substance, EFSA may reach a different conclusion to that ultimately made by RAC even when applying the same rules and guidance to the same set of data. This creates difficulties in the implementation of the Plant Protection Products Regulation, in particular where it concerns classification that would meet the cut-off criteria in Article 4 of the Plant Protection Products Regulation, and thus affects the effectiveness and efficiency of the approval procedure.

In order to avoid such a situation and ensure coherence in both sets of legislation, ideally the RAC opinion on the CLH dossier should be available to EFSA during its peer review of the DAR, and if this is not possible in all cases, the RAC opinion should be at least available prior to a decision being taken by the Commission on the approval or non-approval of an active substance under the Plant Protection Products Regulation. Where possible, the Commission should take a decision on harmonised classification first where this has consequences for the approval or non-approval of an active substance under the Plant Protection Products Regulation.

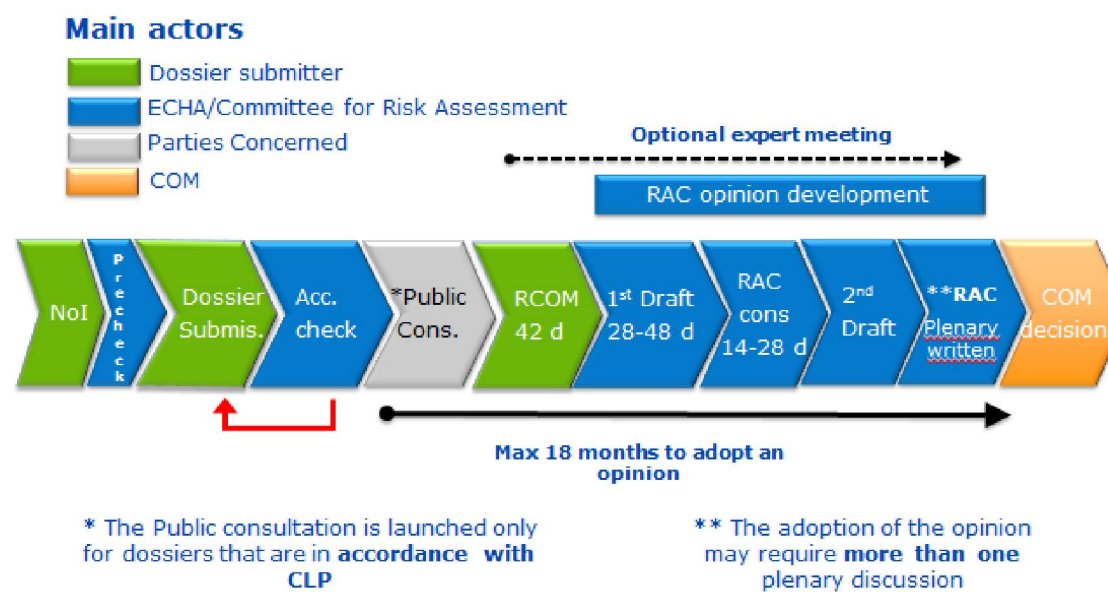
While steps have been taken to align these procedures to enable this to happen, this is dependent on the submission of a CLH dossier by the relevant Member State. To this end, the development of a common template may enable more Member States to prepare a CLH dossier at the same time as producing the DAR. Industry considers that a change in the legislation is required in order to allow industry submission of CLH dossiers. With respect to industry development and submission of dossiers to ensure coherence with other legislation (in particular the Plant Protection Products Regulation), a number of Member State authorities (8 of 11) replying to the targeted consultation exercise agree that companies should be encouraged to do so, thereby reducing some of the pressure on Member State authority resources. However, EFSA disagrees and is of the opinion that the current system does not need to be changed. Information received from UK authorities also indicates that, in their view, the current system of Member State submission of CLH dossiers provides the appropriate checks and balances and ensures the consistency and quality of submissions. Should industry submission of dossiers be taken forward, ECHA would require additional time and resources to carry out an important first step of checking the information provided by many different actors, and this would not necessarily improve the situation in terms of timescale for achieving alignment. It is therefore concluded that at this stage further steps should be taken to facilitate Member State submission of dossiers through the use of a common template. However, it may be necessary in future to consider placing a legal requirement on Member States to submit the CLH dossier to ECHA at the latest when they send the DAR to EFSA, similar to the situation which applies to biocidal products under the Biocidal Products Regulation, as well as to further align the timelines for both procedures.

Ultimately even where alignment does take place, and both the EFSA peer review and RAC opinion are available prior to a decision being taken on the approval or non-approval of an active substance, different conclusions on classification of a substance may be reached by EFSA and ECHA. The case of Flutianil will therefore be followed closely to see how ECHA, EFSA and the Commission work together to resolve this conflict in opinion over the classification of the substance. As noted above,

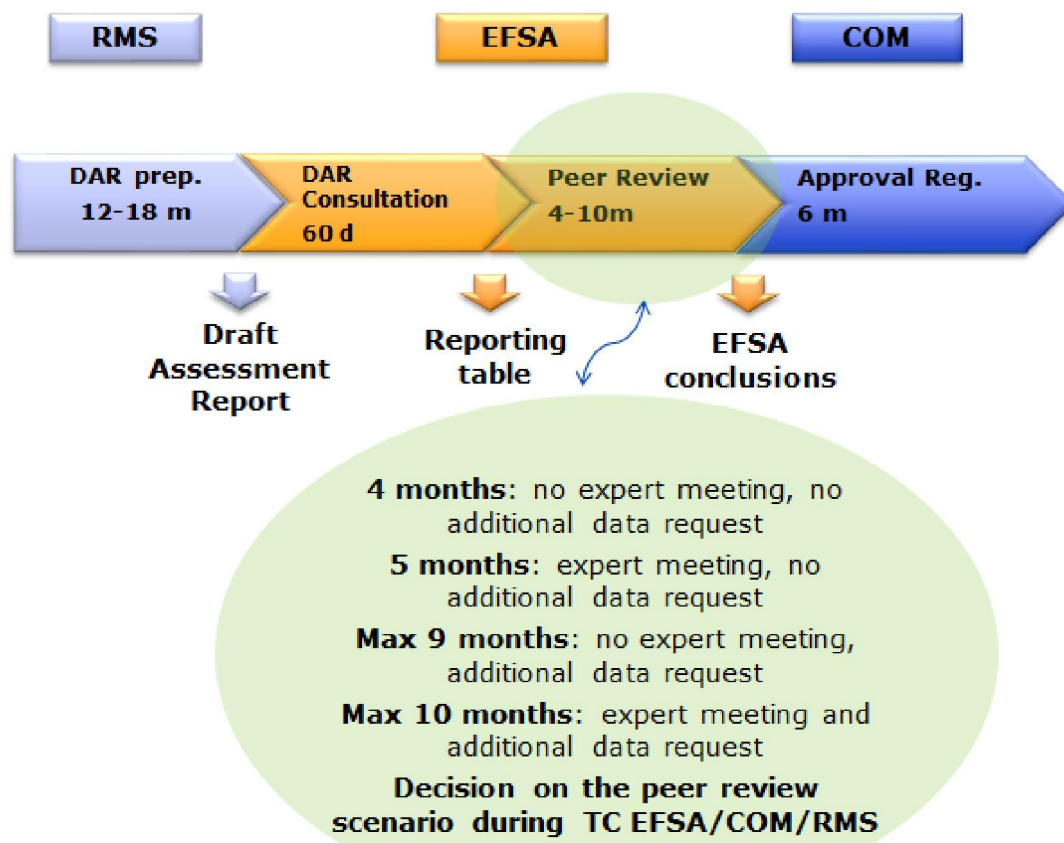
where possible, the Commission should take a decision on harmonised classification first where this has consequences for the approval or non-approval of an active substance under the Plant Protection Products Regulation.

Although Flutianil is the only example to date where ECHA and EFSA need to collaborate to resolve the differences in conclusions on classification, the potential impacts of such differences should not be underestimated, nor the possibility of this issue arising again.

Annex 1 Timescale for RAC Opinion on CLH Dossier



Annex 2 Timescale for EFSA Peer Review on Plant Protection Products Regulation Dossier



Annex 3 Amitrole

Amitrole is listed as an active substance for **renewal of approval** in Commission Regulation (EU) No 1141/2010, as amended by Commission Implementing Regulation (EU) No 380/2013.

France (RMS) provided its initial evaluation of the dossier on Amitrole in the **Renewal Assessment Report (RAR)**, which was received by the EFSA on **2 April 2013**. The peer review was initiated on 17 April 2013 by dispatching the RAR for consultation of the Member States and the applicant Nufarm SAS. Following consideration of the comments received on the RAR, it was concluded that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour, and ecotoxicology, and EFSA should adopt a conclusion on whether Amitrole can be expected to meet the conditions provided for in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and the Council. **EFSA conclusions** were published on **1 July 2014**³⁰. The conclusions were reached on the basis of the evaluation of the representative uses of Amitrole as a herbicide on orchards (citrus fruits, pome and stone fruits, assorted fruits-edible or inedible peel, tree nuts), grapes, olives and non-crop uses, as proposed by the applicant.

Amitrole is classified as toxic for reproduction category 2, in accordance with the provisions of Regulation (EC) No 1272/2008, and toxic effects were observed in endocrine organs (thyroid), and therefore the second interim provision of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 indicates that Amitrole may be considered to have endocrine disrupting properties (critical area of concern). **EFSA however proposed a different classification.**

A number of areas of concern were raised by exposure estimates exceeding the AOEL, by the classification as Repr. Cat. 1B proposed by the EFSA Peer Review, by the potential endocrine disruption of Amitrole, and by the non-representativeness of the batches used in toxicity studies with regard to the technical specification.

Under Article 13 of the Plant Protection Products Regulation, within **six months** of receiving the EFSA conclusions, the Commission is to present the review report and a draft Regulation, taking into account the DAR and the EFSA conclusions. The Agenda for the Commission's Standing Committee on Plants, Animals, Food and Feed on 20 March 2015 stated that a **draft Review Report** has been prepared for Amitrole. However before any decision on the renewal of Amitrole was taken, **EFSA was requested to update the EFSA conclusion on Amitrole** with respect to the second interim criterion as regards possible toxic effects on endocrine organs. EFSA published its **updated conclusions** on **26 August 2015**, providing clarification regarding the determination of potential endocrine disrupting properties in accordance with the interim provisions of Annex II, Point 3.6.5 of the Plant Protection Products Regulation (see sections 2 (p. 8) and 9.2 (p. 18)).

The approval of Amitrole, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 **expired on 30 June 2016**. Commission Implementing Regulation (EU) 2016/871³¹ of 1 June 2016 concerning the **non-renewal of approval** of the active substance Amitrole refers to the risks identified by EFSA, which concluded that there is a high potential for the representative uses assessed to result in groundwater exposure above the parametric drinking water limit of 0.1µg/L by

³⁰ EFSA (2014): Conclusion on the peer review of the pesticide risk assessment of the active substance Amitrole, available at: <http://www.efsa.europa.eu/en/efsajournal/pub/3742>

³¹ Commission Implementing Regulation (EU) 2016/871, accessed at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0871&from=EN>

a relevant metabolite of Amitrole in situations represented by all pertinent groundwater scenarios. In addition, a high risk to operators, workers and bystanders from the use of Amitrole was identified. Based on these identified risks, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 are satisfied and therefore it is not appropriate to renew the approval of Amitrole in accordance with Article 20(1)(b) of Regulation (EC) No 1107/2009.

As the identified risks to groundwater, operators, workers and bystanders preclude approval of Amitrole, it was not appropriate to consider whether exposure to Amitrole under realistic proposed conditions of use is negligible. Therefore, it could not be concluded whether Amitrole meets the approval criteria related to endocrine disrupting properties as outlined in the first paragraph of point 3.6.5 of Annex II to Regulation (EU) No 1107/2009.

The Regulation entered into force on 1 July 2016 and Member States are required to withdraw authorisations for plant protection products containing Amitrole as an active substance by 30 September 2016.

Annex 4 Isoproturon

Isoproturon is listed as an active substance for **renewal of approval** in Commission Regulation (EU) No 1141/2010, as amended by Commission Implementing Regulation (EU) No 380/2013.

Germany (RMS) provided its initial evaluation of the dossier on Isoproturon in the **Renewal Assessment Report (RAR)**, which was received by the EFSA on **28 February 2014**. The peer review was initiated on 10 March 2014 by dispatching the RAR for consultation by the Member States and the applicants Nufarm UK Ltd. (on behalf of the BCS-CGNS Isoproturon Task Force) and Makhteshim Agan Holding B.V.

Following consideration of the comments received on the RAR, it was concluded that EFSA should conduct an expert consultation in the areas of mammalian toxicology and ecotoxicology and EFSA should adopt a conclusion on whether Isoproturon can be expected to meet the conditions provided for in Article 4 of Regulation (EC) No 1107/2009. **EFSA conclusions** were published on **20 August 2015**³². The conclusions were reached on the basis of the evaluation of the representative uses of Isoproturon as a herbicide on winter cereals and spring cereals as proposed by the applicant.

Isoproturon is **classified as carcinogenic category 2 (harmonised classification under Regulation (EC) No. 1272/2008)** and **proposed to be classified as toxic for reproduction category 2**, in accordance with the provisions of Regulation (EC) No 1272/2008 and therefore, the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are met. With regard to the scientific risk assessment, results from the reproductive toxicity studies indicated that Isoproturon may be an endocrine disrupting compound in mammals. Effects on fertility and overall reproductive performance in the two-generation reproductive toxicity studies in rats might be endocrine-mediated. Scientific literature indicated that Isoproturon might have mild anti-estrogenic and anti-androgenic activity. Available data are not sufficient to rule out an endocrine-mediated mode of action. EFSA identified a data gap.

Under Article 13 of the Plant Protection Products Regulation, within **six months** of receiving the EFSA conclusions, the Commission is to present the review report and a draft Regulation, taking into account the DAR and the EFSA conclusions. The Agenda for the Commissions Standing Committee on Plants, Animals, Food and Feed on 8/9 October 2015 included discussion of the EFSA conclusions on Isoproturon.

The approval of Isoproturon, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 **expired on 30 June 2016**. Commission Implementing Regulation (EU) 2016/872³³ of 1 June 2016 concerning the **non-renewal of approval** of the active substance Isoproturon refers to the risks identified by EFSA, which concluded that there is a high potential for the representative uses assessed to result in groundwater exposure above the parametric drinking water limit of 0.1µg/L by the relevant metabolites of Isoproturon in situations represented by all pertinent groundwater scenarios. In addition, a high long-term risk to birds and wild mammals and a high risk to aquatic organisms from Isoproturon were identified. Based on these identified risks, it has not been

³² EFSA (2015): Conclusion on the peer review of the pesticide risk assessment of the active substance Isoproturon, available at: <http://www.efsa.europa.eu/en/efsajournal/pub/4206>

³³ See Commission Implementing Regulation (EU) 2016/872, accessed at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0872&from=EN>

established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 are satisfied and therefore it is not appropriate to renew the approval of Isoproturon in accordance with Article 20(1)(b) of Regulation (EC) No 1107/2009.

As the identified risks to groundwater, birds and wild mammals and aquatic organisms preclude approval of Isoproturon, it was not appropriate to consider whether exposure to Isoproturon under realistic proposed conditions of use is negligible. Therefore, it could not be concluded whether Isoproturon meets the approval criteria related to endocrine disrupting properties as outlined in the first paragraph of point 3.6.5 of Annex II to Regulation (EU) No 1107/2009.

The Regulation entered into force on 1 July 2016 and Member States are required to withdraw authorisations for plant protection products containing Isoproturon by 30 September 2016.

It should be noted that meanwhile, a **CLH dossier** for Isoproturon was submitted by Germany on **4 November 2015**. Following the Commission's decision on non-renewal of approval of the active substance Isoproturon, RAC adopted its opinion on **3 June 2016** on the proposed harmonised classification. RAC concluded that no classification is warranted for reproductive toxicity of Isoproturon.

Annex 5 Flutianil

Flutianil is a new active substance for which in accordance with Article 7 of the Plant Protection Products Regulation, the rapporteur Member State (RMS) the **United Kingdom** received an application from Otsuka AgriTechno Co., Ltd. on 23 February 2011 for approval. Complying with Article 9 of the Plant Protection Products Regulation, the completeness of the dossier was checked by the RMS and the application admitted on 21 October 2011.

The RMS provided its initial evaluation of the dossier on Flutianil in the **Draft Assessment Report (DAR)**, which was received by the EFSA on **19 June 2013**. The peer review was initiated on 2 July 2013 by dispatching the DAR for consultation of the Member States and the applicant. Following consideration of the comments received on the DAR, it was concluded that additional information should be requested from the applicant, and that the EFSA should conduct an expert consultation in the areas of mammalian toxicology and environmental fate and behaviour.

In accordance with Article 12 of the Regulation, EFSA should adopt a conclusion on whether Flutianil can be expected to meet the approval criteria provided for in Article 4 of the Regulation taking into consideration recital (10) of the Regulation. EFSA conclusions were published on **6 August 2014**³⁴. The conclusions were reached on the basis of the evaluation of the representative uses of Flutianil as a fungicide on grapevine and ornamental crops, as proposed by the applicant.

The conclusions of the EFSA peer review suggested classification as carcinogen category 2 and reproductive toxicant category 2. However the RMS remained of the opinion that classification regarding carcinogenicity was not appropriate. The DAR stated that the weight of evidence was insufficient to conclude that the test substance is carcinogenic for classification purposes.

Under Article 13 of the Plant Protection Products Regulation, within **6 months** of receiving the EFSA conclusions, the Commission is to present the review report and a draft Regulation, taking into account the DAR and the EFSA conclusions. The applicant is to be given the opportunity to submit comments on the review report. The Agenda for the Commissions Standing Committee on Plants, Animals, Food and Feed on 10/11 December 2015 included discussion of the Commission Draft Review Report and Regulation concerning the (non-) approval of Flutianil.

Meanwhile, a **CLH dossier** for Flutianil was submitted by the UK on **23 February 2015**. The 18-month period for ECHA to adopt an opinion on harmonised classification ran from 11 May 2015. The RAC opinion was published on 10 March 2016³⁵. Taking into account that there is not sufficient evidence of a carcinogenic effect in rats and mice, and considering the lack of genotoxicity of Flutianil, RAC is of the opinion that Flutianil does not warrant classification as carcinogenicity. RAC however, did not agree with the RMS that Flutianil warranted classification for reproductive toxicity. The conclusions of RAC are different from EFSA and in part from the DAR of the RMS. As the CLH dossier was submitted after the EFSA conclusions, there is no way for EFSA to reopen the process and therefore this will be the first case where ECHA and EFSA may have to produce a joint opinion for the Commission, explaining their views and why they have different interpretations on classification.

³⁴ EFSA (2014): Conclusion on the peer review of the pesticide risk assessment of the active substance Flutianil, available at: <http://www.efsa.europa.eu/en/efsajournal/pub/3805>

³⁵ ECHA (2016): Opinion proposing harmonised classification and labelling at EU level of Flutianil (ISO); (2Z)-[[2-fluoro-5-(trifluoromethyl)phenyl]thio] [3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene] acetonitrile, available at: <http://echa.europa.eu/documents/10162/6bf6db8a-862f-4e89-bdd5-ca45fde8d23e>

**Case Study 4: Relevance and coherence as
regards the introduction of new test methods
within chemicals legislation**

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1. Introduction

1.1 Overview of the issue

Hazard assessment traditionally relies on endpoint information from animal testing. There are several points of criticism related to the use of animal test data from a scientific perspective (e.g. poor reproducibility, ability to predict risks from life-long low dose exposures), from an economic point of view (time and resource intensive) and not least an ethical point of view (protection of animal health and welfare).

Many endpoint data from animal tests are now available on hazardous and non-hazardous substances. These data are used to develop hazard prediction models, grouping and read-across approaches as well as to validate any non-animal test methods for generating hazard data, including *in vitro* test systems. Furthermore, research has progressed to create extensive knowledge in the fields of mechanistic toxicology¹, toxicokinetics and toxicodynamics of substances. In order to be useful in the regulatory context, the results from non-animal test approaches need to allow classification according to the CLP regulation as well as deriving safe exposure levels for risk assessment (DNELs, PNECs, occupational exposure limit values, acceptable daily intakes, etc.).

New approaches to safety assessment (new assessment methods; NAMs) based on adverse outcome pathways (AOPs) aim at the identification of interactions between chemicals and biological systems that trigger an adverse effect. A variety of methods including *in silico*, *in chemico* and *in vitro* are used to predict substance hazards.

The main question this case study aims to answer is what barriers and opportunities exist in the current regulatory system for the use of new testing methods. In identifying indications of barriers and opportunities, among others the possibilities to use data from new testing methods for classification are analysed as well as the influence of data quality requirements.

The case study focuses on human toxicity, because:

- New testing methods do not apply to physical – chemical properties, as no animal tests are necessary and existing methods are in place, accepted and work well; and
- For environmental classification and risk assessment few animal tests are required².

¹ For example, Adverse Outcome Pathway Knowledge Base (<https://www.aopkb.org/>).

² Standard information requirements include testing on fish (aquatic toxicity and bioaccumulation). Efforts to replace these tests are ongoing and discussions about the validity and/or acceptance are likely to follow similar patterns as for human health. ECHA recommended the use of the OECD guideline 236 on Fish Embryo Acute Toxicity (FET) in a weight of evidence approach together with other, reliable and independent information to determine fish toxicity. The use of test results as solely to fulfil REACH requirements is not regarded as sufficient due to limitations of the test. ECHA recommends registrants to follow the discussions of a designated OECD working group (ECHA Weekly, September 21st, 2016: https://echa.europa.eu/documents/10162/21650280/oecd_test_guidelines_aquatic_en.pdf/2548af92-ffe1-4e38-a42a-463103b1586f).

1.2 Case study objectives

This case study aims at identifying the potential and implications of using new, non-animal testing methods for hazard assessments, thereby ascertaining whether the classification criteria in the CLP Regulation and the objectives of the related chemicals legislation regarding the protection of animal health are coherent.

The application of the evaluation criteria would raise the following questions:

- **Coherence:** To which extent are the current provisions on required hazard information and the data needs for classification and risks assessment coherent?
- **Effectiveness:** To which extent is it possible to use alternative hazard information and evaluation methods for classification and risk assessment and (how) would this influence the level of protection?
- **Efficiency:** Is the use of alternative methods to animal testing efficient?
- **Implications:** What implications would the introduction of alternative classification triggers³ based on results from non-testing methods have on the roles and responsibilities of all EU stakeholders, the regulatory framework as well as the international context?

The legislation included in the case study is the CLP Regulation⁴, the Cosmetic Products Regulation⁵, the REACH Regulation⁶, the Biocidal Products Regulation⁷ and the Plant Protection Products Regulation⁸.

1.3 Methodology of the case study

Information for the case study was collected from literature, the internet, the Fitness Check Stakeholder Workshop in April as well as targeted stakeholder consultation. Table 1-1 provides an overview of the consultation.

³ This new approach would include the development of classification triggers that correspond in particular to outcomes of (a set of) *in vitro* tests that identify key events in the development of an effect, thereby considering results from research on adverse outcome pathways.

⁴ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

⁵ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

⁷ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

⁸ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Table 1-1: Overview of stakeholder consultation				
Stakeholders	Number contacted	Interviews	Written input	No response
Authorities / Committees	9	3	1	5 (2 Committees)
Companies	4	0	3	1
Association	6	0	4	2
NGO	4	1	2	1
Other (labs, consultants)	3	2	0	1
Total	26	6	10	10

2. Detailed Description of the Issue

2.1 Hazard identification methods considered in the study

In this case study, “new testing methods” cover *in vitro* and *in silico* testing. In addition, data generation via grouping or read-across are included in some aspects as “alternative approaches” to testing that generate new information from existing data. The following understanding of methods underlies the case study:

- *In vitro* testing: experimental methods not involving the use of animals to obtain substance property information, including high throughput screening and ‘omics’;
- *In chemico* methods: identification of hazard data for a substance based on chemical properties or tests;
- *In silico* testing: computerised use models, including (qualitative) structure activity relationships (QSARs) to predict substance properties / hazards based on molecular structures or other information, such as physical-chemical properties; and
- Read-across (analogues and categories): the process of using data from one (set of) substance(s) to characterise another based on qualitative argumentation on the analogy / similarity of the substances / categories justifying the approach.

Classification and hazard assessment frequently allow a weight of evidence (WoE) approach that should consider all available data. This enables concluding from the combination of existing data, which would be insufficient for classification or hazard assessment if used in isolation. The WoE approach is one option allowing the use of data from new testing methods. It is not an information generation method in itself. Similarly, integrated approaches to testing and assessment (IATA) are instruments supporting the use of new testing methods. IATA aim to avoid animal testing by guiding testing sequences and providing support for interpreting results.

The use of new hazard assessment methods (NAMs) based on adverse outcome pathways and using *in vitro* and *in silico* methods to generate information on how substances interact with biological systems is also briefly discussed in the case study.

2.2 Status quo on the development of alternative methods

2.2.1 Availability of methods

The JRC compiled a state-of-the-art review on alternative methods for regulatory toxicology⁹. The report shows that several non-standard methods are available for most of the human health

⁹ European Commission, Joint Research Centre (2014): ‘Alternative methods for regulatory toxicology – a state-of-the-art review’.

endpoints¹⁰ for classification. However, many of these have limited applicability domains, do not provide quantitative information or are associated with high levels of uncertainty.

At present, the following *in vitro* testing methods are available as OECD guidelines:

- Skin corrosion/irritation: TG 430, 431, 435, 439¹¹;
- Serious eye damage/eye irritation: TG 437, 438, 460, 491, 492¹²; and
- Skin sensitization: TG 442C, 442D, h-Clat¹³.

In addition, several *in vitro* methods are available to test genotoxicity.

The JRC manages the DataBase service on ALternative Methods (DB-ALM)¹⁴, which provides information on alternative testing methods. The database is free of charge and gives access to ready for use, quality controlled method descriptions, but which are mostly not officially validated, standardised or internationally accepted. The database contains a high number of alternative method descriptions for various endpoints or effects. These can be regarded as principally available for regulatory purposes, e.g. for use as a contribution to WoE approaches, to support existing information, etc.

Kienzler *et al* (2016)¹⁵ and the JRC in its report on methodologies assessing combined effects of chemicals¹⁶ point out that alternative and novel hazard assessment approaches have a high potential for the assessment of mixtures. Among others, these methodologies can provide a better understanding of the mode of action of individual substances or the mixtures as such and hence contribute to the assessment of combined exposure. However, guidance is needed to support the use of these methods in the context of mixtures.

Although *in vitro* methods are available for several endpoints, whether a full replacement of animal testing is possible (e.g. for classification or risk assessment) depends on several factors including the substance's properties, which determine the applicability of *in vitro* and *in silico* tests, and the

¹⁰ The report covers the following endpoints: skin irritation/corrosion; serious eye damage/eye irritation; skin sensitisation; acute systemic toxicity; repeated dose toxicity; genotoxicity and mutagenicity; carcinogenicity; reproductive toxicity (including effects on development and fertility); endocrine disruption relevant to human health; and toxicokinetics.

¹¹ *In vitro* Skin Irritation: Reconstructed Human Epidermis Test Method; *in vitro* Membrane Barrier Test Method for Skin Corrosion; *in vitro* Skin Corrosion: Transcutaneous Electrical Resistance Test (TER); *in vitro* Skin Corrosion: Reconstructed Human Epidermis (RHE) Test.

¹² Fluorescein Leakage Test Method for Identifying Ocular Corrosives and Severe Irritants; Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants; Isolated Chicken Eye Test Method for Identifying Ocular Corrosives and Severe Irritants, Short Time Exposure *In Vitro* Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage, Reconstructed human Cornea-like Epithelium (RhCE) test method.

¹³ *In chemico* skin Sensitisation, *In vitro* Skin Sensitisation; the h-Clat method was approved in April 2016

¹⁴ DB-ALM (<http://ecvam-dbalm.jrc.ec.europa.eu/beta/>).

¹⁵ Kienzler et al. (2016): 'Regulatory assessment of chemical mixtures: Requirements, current approaches and future perspectives', Regulatory Toxicology and Pharmacology Volume 80, October, Pages 321–334.

¹⁶ European Commission, Joint Research Centre (2015): 'Scientific methodologies for the assessment of combined effects of chemicals – a survey and literature review.

availability of “other” information, including on structural analogues that could be used for read-across / grouping.

2.2.2 Inclusion of new testing methods in legislation

The use of non-animal approaches (i.e. the use of existing information, computational methods, read-across/grouping as well as *in vitro testing*) are encouraged by all legislation. In general, data generation should suffice for the regulatory requirements to either classify and/or conduct risk assessments, which the respective legal frameworks foresee.

The REACH Annexes VII and VIII include *in vitro* methods for the endpoints:

- Skin corrosion/irritation;
- Serious eye damage/eye irritation;
- Skin sensitisation; and
- Mutagenicity

The Cosmetic Products Regulation bans the use of animal tests for the purpose of placing on the market of cosmetic ingredients or products, hence only non-animal testing approaches may be used. However, information generated for the purpose of other legislation may be used.

Under the Plant Protection Products Regulation, the information hierarchy for the endpoints skin corrosion/irritation and eye corrosion/irritation explicitly refers to the use of *in vitro* methods, whereas this is not the case for skin sensitisation. *In vitro* tests are standard information requirements for mutagenicity.

The Biocidal Products Regulation refers to the appendices of the Test Methods Regulation (EC 440/2008) and their sequential testing strategies, which prioritise the use of existing data using WoE and the conduction of *in vitro* tests over animal testing for the endpoints skin corrosion/irritation and eye corrosion/irritation. For skin sensitisation the Local Lymph Node Assay is specified as the preferred test method.

2.2.3 Research activities¹⁷

There are many research projects ongoing in the area of developing new *in vitro* testing methods, QSAR models and adverse outcome pathways. Whereas most of them relate to the development of one specific method, some larger initiatives adopt a broader perspective, in particular related to the new assessment methods (NAMs). Three exemplary projects and activities are briefly introduced in the following.

SEURAT is a large EU research public private partnership aiming at developing a non-animal testing hazard assessment framework for repeated dose toxicity to evaluate chemical safety. This includes the development of mode-of-action frameworks and related *in chemico*, *in silico* and *in vitro* methods to predict hazards.

¹⁷ The information on research projects was extracted from the report: EU Commission, Joint Research Centre (2015): ‘EURL ECVAM Status Report on the Development, Validation and Regulatory Acceptance of Alternative Methods and Approaches’.

The Horizon 2020 project “EU ToxRisk”¹⁸ started in January 2016 with the aim of further developing scientific methods and tools for the prediction of repeated dose toxicity. The project builds, among others, on SEURAT 1, the adverse outcome pathways approach and combines various hazard prediction methods.

The US research programme “Toxicology testing for the 21st century”¹⁹ (Tox 21) is a collaboration between several national institutes, which will screen approximately 10,000 substances for their potential to disrupt biological pathways, which may lead to toxic effects. The programme includes activities on the development of new *in vitro* assays, the actual testing of substances, use of computational methods and software development as well as the use of data on the interaction of substances with biological functions, as represented in the various test systems for the development, further improvement and/or validation of hazard prediction models and tools. According to a recent publication in *Chemical Watch*²⁰ the prediction performance of models based on a combination of structure and assay activity is better than those using one parameter alone. The author states that these models partly perform better in predicting human toxicity than animal toxicity, due to the use of *in vitro* data from human cell tests.

2.3 Information quality

Information provided to fulfil the requirements under various legislation should be of sufficient quality to enable hazard and risk assessment. It is challenging to identify and measure “sufficient quality” due to the various information generation methods: human evidence, animal data, *in silico* methods, *in vitro* tests, read-across, etc.

REACH, the CLP Regulation, the Biocidal Products Regulation, the Plant Protection Products Regulation and the Cosmetic Products Regulation require new tests be performed applying Good Laboratory Practice (GLP). In addition, quality criteria mentioned include the use of scientific principles and methods or the validity of data.

If existing data are used in a WoE approach, or if read-across and (Q)SARs are applied, the quality of the related justification is decisive for regulatory acceptance of the data. Hazard assessments and justifications of approaches are case-by-case and may be largely differing, depending on the type of the substance, the availability of data and models, etc. ECHA’s guidance documents provide information on the regulatory expectations on justification and documentation of approaches. This aspect is not further discussed in the following, as it is not of core relevance for this case study.

¹⁸ An Integrated European ‘Flagship’ Program Driving Mechanism -based Toxicity Testing and Risk Assessment for the 21st Century (<http://www.eu-toxrisk.eu/>).

¹⁹ See US Environmental Protection Agency (<http://www.epa.gov/ncct/Tox21/>).

²⁰ Davies, E. (2016): 'Tox21 computer models predict human toxicity', in *Chemical Watch*.

2.3.1 Good laboratory practice for non-clinical safety studies

The main aim of good laboratory practice²¹ as defined by the GLP Directives²² is to ensure the reconstructability of non-clinical safety studies that should be used for regulatory purposes in order to verify their integrity. GLP principles require a sufficiently detailed documentation to review, assess and interpret a study. Furthermore, quality management procedures and responsibilities are to be in place. GLP does not require the use of OECD guidelines.

In analogy to GLP for laboratories, a consensus document²³ exists for *in silico* methods; i.e. if hazard information based on computer modelling is used for regulatory purposes, the GLP principles should be in place. The GLP for *in silico* methods, among others, defines specific requirements, such as on qualification and training of personnel, facilities and equipment as well as their maintenance, principles for storing and securing (raw) data, and the validation of the computerised system²⁴. Finally, the consensus document outlines documentation requirements and archiving.

2.3.2 Good *in vitro* method practice

The European Union Reference Laboratory for alternatives to animal testing (EURL-ECVAM) initiated a project at OECD level to develop a guidance document on good *in vitro* method practice. The aim of this activity is to increase acceptance of *in vitro* data by collecting and consolidating scientific, technical and quality practices related to the development of respective guidelines, their implementation and the interpretation of results for regulatory purposes.

2.3.3 OECD test guidelines

OECD test guidelines are internationally accepted and their application conforms to the quality requirements in any EU legislation. Deviation from the methods are possible, if justification is provided (e.g. due to the physical-chemical nature of the substance). OECD guidelines are normally

²¹ Good laboratory practice (GLP) is described as “a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported”; Directive 2004/10/EC, Annex I, Section 2.1.

²² Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances and Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP).

²³ OECD (2016): ‘OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring Number 17 Advisory Document of the Working Group on Good Laboratory Practice Application of GLP Principles to Computerised Systems. The development of *in silico* systems should include software validation, software verification (faithful implementation of algorithms to form a predictive model) and model validation (i.e. are the predictions correct). An OECD guidance document exists e.g. on QSAR model validation: <http://www.oecd.org/chemicalsafety/risk-assessment/validationofqsarmodels.htm>

²⁴ The latter includes a demonstration that the system is suitable for the intended purpose, for which several aspects should be considered, such as: acceptance of a system (involving for example a controlled system development, testing of conformity with acceptance criteria, and documentation of the system and testing); retrospective evaluations in case systems are used, which were originally not GLP based; change control, in case the computerised system should be modified; and the existence of support systems to ensure proper use.

adopted in the EU (e.g. in the EU Test Methods Regulation²⁵). Designated working groups develop and update the testing guidelines at OECD level, according to scientific progress. The guidance updates take account of inputs from all stakeholders²⁶.

2.3.4 Scientifically validated methods

Scientific validation in general comprises the assessment that a particular method is fit for its purpose. This includes the assessment of its representativeness, repeatability and reproducibility. At EU level, ECVAM scientifically validates non-animal testing methods as a preparatory step to regulatory acceptance. ECVAM published guidelines for the validation of methods, which allow any actor to conduct evaluation studies corresponding to EU standards (non-official validation). The method descriptions in the JRC's database DB-ALM include a section on their validation status.

2.4 Compatibility of *in vitro* test data with the classification triggers

The classification triggers of the CLP regulation are based on the GHS and have ultimately been derived in relation to animal test results. In the following sections, the results of an analysis of the CLP legal text and findings from experts from the Netherlands and the UK are presented, which have been submitted to the UN Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals²⁷. The information compiled for the following analysis is provided in Annex 3 and Annex 4 in table form.

2.4.1 Classification endpoints for which no *in vitro* tests are available

There are no OECD test guidelines for *in vitro* methods available for the endpoints acute toxicity, respiratory sensitisation, carcinogenicity, reproductive toxicity, and specific target organ toxicity (single and repeated exposure).

The classification trigger for the endpoint acute toxicity refers to LD50 or LC50 values. Neither the classification criteria nor the explanatory guidance mentions the possibility of using *in vitro* data for classification. Respiratory sensitisers are classified using WoE taking account of human or animal test data. Human data may include evidence from *in vitro* immunological tests. There is no animal test available for respiratory sensitisation. Carcinogens and reproductive toxicants are classified using WoE, which may take into account information from *in vitro* testing. The classification endpoint specific target organ toxicity (single and repeated exposure) is determined by WoE. However, neither the classification criteria, nor the guidance in the regulation's annex include any indication that *in vitro* test data may be used.

²⁵ Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

²⁶ An analysis of the "age" of OECD guidelines and the updating process is included in Annex 2.

²⁷ United Nations (2015): 'Use of non-animal testing methods for the classification of health hazards' submitted to the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals, Thirtieth session Geneva, 9–11 December 2015; ST/SG/AC.10/C.4/2015/13

2.4.2 Classification endpoints for which *in vitro* tests are available

Skin corrosion/irritation

The definition and the classification triggers of skin corrosion/irritation refer to damage of the skin observed in animals. The explanation in the CLP Regulation's Annex I indicates a hierarchy for using data, which does not include *in vitro* data. However, it is stated (c.f. Annex I, Section 3.2.2.1) that "*in vitro alternatives that have been validated and accepted may also be used to help make classification decisions*". The CLP guidance document clarifies that *in vitro* data may be used, including as the sole basis for classification of absence of effects, if tests are demonstrated to be sufficiently predictive and applicable to the test substances.

Four *in vitro* methods are available for testing skin corrosion/irritation (TG 430, 431, 435, 439). They differently discriminate between sub-categories and therefore, it is case dependent if a sub-category can be assigned or not. However, according to the OECD guidance document²⁸, sub-categorisation should generally be possible. The sub-categories 1A, 1B and 1C all have the same generic concentration limit (GCL) triggering classification of a mixture and are labelled with the same labelling elements. Therefore, a lack of sub-categorisation within cat. 1 due to the use of *in vitro* test data would not affect the level of protection. A lack of differentiation between cat. 1 and 2 would most likely increase the level of protection as cat. 1 would be chosen, which has higher GCL than cat. 2.

Serious eye damage / eye irritation

The classification endpoint and the classification triggers for serious eye damage/eye irritation refer to damage to the eye tissue after application to an experimental animal. The classification guidance of Annex I explicitly refers to *in vitro* data (c.f. Annex I, Sections 3.3.2.1 and 3.3.2.3). WoE approaches should take account of all information, including from *in vitro* tests. The guidance document also explains the use of data from *in vitro* tests.

OECD test guidelines are available for five *in vitro* tests. The test results allow determining serious eye damage or lack of effects but do not allow identifying eye irritants, hence a substance is either classified as cat. 1 (severe eye damage), or not classified at all. Absence of eye damage/irritation can be classified only based on results from two of the methods²⁹. If other methods are used, absence of effects must be verified with further data. Classification in cat. 1 is possible based on positive results from four of the tests.

Due to the lack of possibilities for sub-categorisation, *in vitro* testing could lead to an overly conservative classification when eye irritants are classified as causing severe eye damage. The GCL is lower for cat. 1 and the labelling requirements differ for the two categories. Therefore, a more stringent classification based on *in vitro* data might lead to a more stringent classification of mixtures containing the substance compared to a classification based on animal data. This would also change the precautionary statements that have to be attached to substances and mixtures. The Dutch and UK OECD experts state in their input to the UN that it is challenging to develop better/discriminating tests, as their validation is difficult due to "reversibility of effects" being part of the classification

²⁸ OECD (2014): 'New guidance document on an integrated approach on testing and assessment (IATA) for skin corrosion and irritation', ENV/JM/MONO(2014)19.

²⁹ ICE and BCOP test.

criterion. Furthermore, they state it very challenging to develop testing strategies and testing combinations (with the existing tests) that could be used for sub-categorisation.

Skin sensitisation

Skin sensitisers are defined as substances causing allergic reactions after skin contact. The classification triggers include “evidence from human data or animal testing”. Annex I to CLP does not specifically address the possibility to use *in vitro* test data. The CLP guidance document contains no information on the use of *in vitro* data, except that no validated methods are available, which is outdated information³⁰. It can be expected that the provisions and the guidance documents will be updated.

Three validated *in vitro* methods targeting the three key events of the AOP for skin sensitisation are available that may be used to classify substances for skin sensitisation. These methods can be used only in combination, not as standalone methods and the results can be used only in the weight of evidence approach in the frame of CLP. The negative results can be used in the decision whether a substance is skin non-sensitiser. However, positive results only allow categorising of a substance as Cat. 1. Sub-categorisation as strong sensitiser (Cat. 1A) or weak sensitiser (Cat. 1B) remains a challenge.

The GCLs of the sub-category 1 correspond to the sub-category 1B (1%), as opposed to sub-category 1A, which has a much lower concentration limit (0.1%). Hence, if a substance that would be classified as 1A based on animal test results is classified as cat. 1 (based on the *in vitro* tests), higher concentrations of that substance in a mixture (0.1-1%) would be possible without triggering classification of the mixture for that effect. This would be a loss of level of protection resulting from the use of *in vitro* data. According to the recently amended Annex VII of REACH³¹, data is required allowing for “a conclusion whether the substance is a skin sensitiser and whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A)”. Therefore, as long as the *in vitro* method fails to provide information on the potential for strong sensitisation, an *in vivo* test should be conducted.

Germ cell mutagenicity

Mutagenic substances are described as substances that cause mutations that are passed on to the next generation. Classification is based on WoE, taking into account information from various sources, including *in vitro* tests. Cat. 1A is mainly based on human evidence, cat. 1B on animal tests and cat. 2 include substances for which indications of heritable damage exist, which are not strong enough for classification in 1A or 1B.

Annex I of the CLP regulation clearly indicates that in determining mutagenic and/or genotoxic effects *in vitro* tests shall be considered. The CLP guidance document specifies that substances can be classified as mutagens cat. 2, if unequivocal positive *in vitro* test results are available and supportive information from structurally similar substances indicate mutagenic properties.

³⁰ Three OECD guidelines exist for *in vitro* methods to test for skin sensitisation.

³¹ Commission Regulation (EU) 2016/1688 amending Annex VII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards skin sensitisation

If a substance is classified as cat. 2 mutagen based on *in vitro* data and information from similar substances, a decrease of the level of protection would occur if, based on *in vivo* data, it were to be classified in cat. 1A or 1B. This is because: a) generic restrictions as well as specific risk management measures under different legislation (e.g. workers protection legislation) apply to substances classified as mutagenic 1A which do not cover substances in cat. 2; and b) GCLs are lower by a factor of 10 for substances in cat. 1A as compared to cat. 2. Consequently, mixtures would be classified at higher concentrations of the substances as mutagenic (with similar consequences as indicated under point a).

2.5 Compatibility of non-test data with the classification triggers

2.5.1 Endpoints which are straight-forward

For the endpoint acute toxicity, the possibility to use structural information (grouping, read-across, (Q)SARs or expert systems based on structural information) is not mentioned in the CLP regulation's Annex I. However, the CLP guidance document clarifies that this type of data may be used for classification.

Classification for skin corrosion/irritation and eye corrosion/irritation is possible based on structural information according to CLP Annex I and as explained in the CLP guidance document. Models can be used for positive classification, if they have been shown to sufficiently well predict the absence of the effect. No specific conditions are defined for the use of structural information.

The endpoint target organ systemic toxicity (single and repeated exposure) is determined by WoE, involving the use of any data, including structural information, as specified in Annex I of the CLP regulation and the CLP guidance document. There are no obvious conditions or inconsistencies in these provisions.

2.5.2 Inconsistencies related to the use of structural information

Structural information may be used in WoE assessments for carcinogenicity and reproductive toxicity according to CLP Annex I and the related guidance document. Classification for both endpoints in sub-categories is based on, among others, the type of data used, i.e. whether human data are available or not. Hence, it could be questioned if a substance could be classified in the categories 1A and 1B if only structural information is used (although potentially based on human or animal test data). Whereas the CLP guidance includes an explanation that categorisation as 1A, 1B and 2 is possible for carcinogens, the guidance document does not explicitly clarify this for reprotoxic substances.

2.5.3 Conditional use of structural information

Annex I of the CLP regulation and the related guidance specify that classification of respiratory and skin sensitisation may consider structural information in a WoE approach: a substance need not be classified if structural information, in conjunction with other data, suggests so (three types of information out of five need to be available). For respiratory sensitisers the REACH guidance

document on information requirements and chemical safety assessment³² specifies that hardly any information is available that could be used for read-across, grouping or (Q)SARs.

To classify substances as germ cell mutagens, structural information can only be used in combination with *in vitro* data, according to Annex I of the CLP Regulation and the CLP guidance document. In addition, it is possible to use structural data in a WoE approach to support classification based on other information, i.e. human or animal test data.

³² ECHA (2015): Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7a: Endpoint specific guidance, Version 4.1, October 2015.

3. Assessment and Evaluation

3.1 Overview

The relevant objectives of legislation considered in this case study, namely the CLP regulation, the Biocidal Products Regulation, the Plant Protection Products Regulation, the Cosmetic Products Regulation³³ and REACH are to ensure a high level of protection of human health, ensuring an efficient functioning of the internal market and enhancing competitiveness and innovation of EU industries. In addition, all legal acts include provisions requiring that animal testing should be avoided or reduced³⁴.

3.2 Coherence of legal requirements

3.2.1 Understanding of coherence

The objective of ensuring a high level of protection is implemented in three steps: hazard identification, consideration of risks and risk management. The identification of hazards of a substance (or mixture) can be differentiated into two steps:

- Compilation and/or generation of data on substance / mixture properties; and
- Comparing property data to classification criteria for classification or use of property data to derive safe exposure levels (e.g. derived no effect levels – DNELs).

Legal requirements could be considered coherent if:

- The legal provisions regarding the use of new testing methods to fulfil information requirements under different legislation are consistent; and
- The guidance documents for implementation of the legal provisions are consistent.

3.2.2 Coherence of legal provisions

All legislation includes provisions for the use of non-animal test data with different methods being acceptable, including read-across and grouping, *in vitro* testing and *in silico* methods. Studies on toxicokinetics and toxicodynamics can be used according to legislation as supporting evidence.

All legislation suggests an overarching tiered approach to the use of data aimed at avoiding animal testing and limiting efforts for new data generation: it suggests starting with the use of existing information, i.e. human evidence and animal test data, then using alternative methods. A WoE approach should be applied if individual data are insufficient for classification but viewing different pieces of information would allow classification. Animal tests are the last resort. The Cosmetic Products Regulation is the most stringent legislation because it prohibits the use of animal testing data (and thereby makes the use of alternative approaches obligatory).

³³ The Cosmetic Products Regulation only lists a high level of protection of human health in its aims and the functioning of the internal market.

³⁴ Under REACH the “promotion of alternative methods for assessment of hazards of substances” is included in section 1 on the aim and scope of the regulation.

References to test methods refer to the Test Methods Regulation, the OECD guidelines or scientifically validated methods. While the type of data required under REACH, the Biocidal Products Regulation, the Plant Protection Products Regulation and the Cosmetic Products Regulation are partly different, the methods on how to provide that data are in most cases similar. The wording in the legal texts is converging with the Biocidal Products Regulation and includes references to REACH Annex XI, with explanation on data quality for non-animal test methods. Table 3-1 provides an overview of data generation and use under REACH, the CLP Regulation, the Cosmetic Products Regulation, the Plant Protection Products Regulation and the Biocidal Products Regulation.

Table 3-1: Summary of provisions on the use of non-standard data / new testing methods

Legis-lation	Provisions related to animal testing	Requirements for data generation	Data for hazard assessment
REACH	Animal testing should be the last resort, waiving based on hazard or exposure data possible (Column 2; Annex XI). Annexes IX and X animal tests must be approved by ECHA (after public consultation). Data to be used in a WoE approach. Annex XI: guidance and rules for the use of non-standard data.	Substances registered above 1 t/a; the higher the tonnage the more data	Classification PNEC DNELs
CLP	Avoid animal tests if other methods generate adequate information. QSARs, read-across, grouping and WoE possible, if “adequate for classification”. Endpoint definitions and trigger values refer to animal test data	None	Data comparable to the trigger values to decide on the classification
Cosmetic Products Regulation	Prohibition of placing on the market of cosmetic products and/or ingredients for which animal tests have been performed for the purpose of that regulation.	Annex 1: “full toxicological profile”	MoS
Plant Protection Products Regulation	Approval requires toxicological and eco-toxicological information, specified in a separate regulation. Steps taken to avoid animal testing are to be described in the dossier.	Core and additional data for substance approval	Classification ADI, AOEL and ARfD; PNEC
Biocidal Products Regulation	Animal testing should be the last resort. Annex II specifies information requirements alluding to the test methods and species to be used	Core and additional data for substance approval	PNEC, AEL

For skin and eye corrosion/irritation, the Biocidal Products Regulation and Plant Protection Products Regulation refer to *in vitro* methods (information hierarchy). The REACH Annexes explicitly require *in vitro* tests before any *in vivo* studies. The CR prohibits animal testing and hence, *in vitro* testing is the only option for hazard assessment, if new data needs to be generated. For skin sensitisation, the Biocidal Products Regulation and the Plant Protection Products Regulation do not refer to *in vitro* tests, REACH will be updated and the Cosmetic Products Regulation prohibits the use of animal test methods for data generation via testing. Consequently, in the specific references to *in vitro* testing the legislation is not consistent with regard to how strongly these are prioritised.

3.2.3 Coherence of guidance

The overall requirement to avoid animal testing can frequently not be implemented, due to a lack of methods, in particular *in vitro* methods (c.f. Section 2.2). The degree to which existing information can be used and/or read-across, grouping or *in silico* methods be applied depends on the substance and the experience of the person compiling and evaluating information.

There is a lack of alignment of guidance documents due to different speed and timing of adaptations to technical / scientific progress. Whereas ECHA has established well-functioning and quick routines for guidance updates, under other legislation, such as plant protection products, respective processes are slower and for some aspects and endpoints, no guidance exists at all.

The main pieces of guidance on the use of alternatives to animal test methods are provided under REACH, i.e. by ECHA. There are guidance document on the use (and reporting) of (Q)SARs and read-across / grouping and *in vitro* methods. Guidance and explanations on how to implement the animal testing ban under the Cosmetic Products Regulation are available too. No detailed guidance on how non-animal test methods could be applied under the Biocidal Products Regulation and the Plant Protection Products Regulation is available.

Stakeholders discussing at the Fitness Check workshop in April as well as those responding to the consultation generally described the requirements for data generation as clear and understandable, including the related guidance documents. The application of GLP was questioned by some stakeholders and not regarded as relevant for the scientific quality of a study. Guidance and scientific publications³⁵ on assessing data quality are considered useful and supportive by stakeholders.

3.3 Effectiveness

The effectiveness of current provisions could be expressed as the degree to which alternative data:

- Are actually used by the stakeholders and accepted by regulators; and
- Can be used for regulatory purposes from a technical perspective; i.e. in how far data match the requirements for classification without decreasing the level of protection.

3.3.1 Information on the actual use of alternative hazard information

Across the different endpoints, the degree to which non-animal test methods are actually used differs. In general, the use of read-across and grouping is predominant, according to ECHA's evaluation reports³⁶. *In vitro* information is the least frequently used method.

REACH registration dossiers

According to an analysis of available registration dossiers in ECHA's report on alternatives to animal testing³⁷, an increase in the use of alternative data is observed. Grouping and read-across are the most widely used approaches, in particular for higher tier endpoints, followed by WoE, (Q)SARs and, where available *in vitro* methods (eye and skin irritation and skin corrosion). ECHA states that registrants use these methods even though they are in an early stage of implementation (particularly skin sensitisation). They commented that these methods have been used more to prove a substance

³⁵ No specific documents were pointed out.

³⁶ C.f. the most recent report: ECHA (2016): Evaluation under REACH: Progress report 2015 (<http://echa.europa.eu/web/guest/about-us/the-way-we-work/plans-and-reports>) (and the earlier reports).

³⁷ ECHA (2014): 'The use of alternatives to testing on animals for REACH - Second report under Article 117(3) of the REACH Regulation', Helsinki, 2014.

not being hazardous than to the contrary. Furthermore, (Q)SARs seem to be hardly used for environmental property predictions.

ECHA's evaluation report provides little detail on the extent to which registrants used alternative data of sufficiently high quality. However, their observations and recommendations indicate that the quality of documentation and partly the justification of read-across / grouping and (Q)SARs are not regarded as sufficient, as has been described in earlier evaluations. According to ECHA, registrants hardly ever use information from *in vitro* tests on toxicokinetics and toxicodynamics or omics data. ECHA interprets this as a sign that these methods are not sufficiently well developed and little experience exists on how to interpret and use these data as supporting evidence³⁸. Guidance documents and scientific publications state that this type of data is generally useful to support a better understanding of (the mechanisms of) effects and hence, to gather information on the relevance of effects for humans.

ECHA states that non-acceptance of read-across in REACH registrations is frequently due to a lack of supporting information, of scientific plausibility, or insufficient description of substance identity. ECHA's RAAF guidance³⁹ explains the use of read-across and grouping, including a description of methods, documentation requirements and practical examples. The use of alternative methods is stated acceptable, if the hazard predictions are reliable and useable for classification and risk assessment. There are several publications in existence that aim at facilitating the use of alternative methods, e.g. through elaborating how to evaluate the methods and document results⁴⁰. The RAAF explains how to structure the justification for the use of (Q)SARs and read-across. It also provides more clarity on the level of confidence and hence usefulness of the information for classification and risk assessment³⁸.

ECHA's guidance document⁴¹ on the reporting of data from *in vitro* methods specifies that only data from validated and pre-validated methods can be used for classification and risk assessment. In addition, this type of data can contribute to elucidating the effect mechanisms and hence support other evidence.

Stakeholder opinions

The degree to which non-animal test methods in general and *in vitro* methods are actually used to fulfil information requirements, to conduct risk assessment, and to classify substances was not discussed at the Fitness Check stakeholder workshop. The respondents to the stakeholder questionnaires did not have an overview in this regard and therefore could not comment in detail.

With regard to the use of *in vitro* methods, one stakeholder commented that there is currently a deadlock: industry states that authorities have too little experience in interpreting such data and would therefore not accept it. They would prefer using accepted (animal) test methods, thereby preventing that more experience is gained on the side of authorities. According to this stakeholder, industry should resolve this deadlock by submitting *in vitro* data and investing in discussions on its

³⁸ Norbert Fedtke (2016): Presentation on 'Critical aspects in the assessment of adaptations based on read-across: The role of supporting evidence' held at the ECHA Read-across Workshop in April 2016.

³⁹ ECHA (2015): 'Read-Across Assessment Framework (RAAF)', Helsinki.

⁴⁰ C.f. e.g. Schultz et.al (2015): 'A strategy for structuring and reporting a read-across prediction of toxicity', in *Regulatory Toxicology and Pharmacology*, 72, 586-601.

⁴¹ ECHA (2012): 'How to report *in vitro* data Practical Guide', Helsinki, September.

acceptance. This stakeholder regarded efforts to pre-define interpretation logics of (a combination of) tests as cumbersome and not very effective.

The effectiveness of the ban on animal testing under the Cosmetic Products Regulation was questioned by some stakeholders (NGO, other). One point of criticism regards the possibility of using animal test data conducted to comply with other legislation and data generated in countries outside the EU. This would undermine the goal of preventing animal testing. Another point of criticism relates to the (frequent) occupational occurrence of sensitising effects of cosmetic products. This might be prevented, if animal tests had been conducted and respective hazards been identified, according to one stakeholder⁴².

According to one industry association, avoiding animal tests for the classification of mixtures is possible and works well using provided substance data and the bridging principles foreseen in the CLP Regulation.

The use of *in vitro* methods would increase, in particular by SMEs, if respective integrated approaches for testing and assessment existed. This was underlined at an ECHA Workshop for the endpoint skin sensitisation, where respective methods exist but guidance on the sequence of applying them and interpreting their results is missing⁴³. The current work at OECD level on IATAs, which includes intelligent testing strategies, was seen as important as it could support those actors, which have less experience in (alternative) testing methods and increase the certainty that non-animal test data are accepted.

Confirming the findings of the analysis of available alternative testing and non-testing approaches, several stakeholders commented that the more complex hazard classes such as reproductive toxicity or chronic toxicity cannot be assessed using *in vitro* tests. They also confirmed that (non-validated) tests may be and do contribute data to an overall assessment of a hazard using WoE approaches, in particular by providing information on the modes of action and/or the transferability of results from animal to human health.

Many stakeholders were of the opinion that it would still take a long time until (combinations of) alternative methods are developed, which were sufficiently reliable and validated, so they could replace the animal tests currently used.

3.3.2 Reliability of data from new testing methods

Several stakeholders emphasised that the results from animal studies show a high variability, causing uncertainty about the meaning of test results. Any alternative tests developed and validated based on animal test data would therefore integrate this degree of uncertainty, plus that introduced by the

⁴² It was not assessed in the study if animal tests would have identified the substances in hairdressers' products as sensitisers and this statement could therefore not be verified. An example by the JRC on the classification of sensitisers using different approaches indicates that the use of alternative methods would increase rather than decrease the number of substances classified as sensitisers. However, as sub-categorisation might not be possible, the level of protection from individual substances could decrease if it is allocated in cat. 1 (rather than 1A) with a higher GCL. The stakeholder statement can also be questioned as for many cosmetics ingredients animal data from other legislation are available.

⁴³ C.f. Philip Lightowlers (2015): 'Experts discuss testing approaches for skin sensitisation', in Chemical Watch, April 2015, viewed May 2nd, available at: <https://chemicalwatch.com/23653/experts-discuss-testing-approaches-for-skin-sensitisation>

method itself. Due to this and uncertainties in transferring effects from animals to human health, some stakeholders questioned the overall usefulness of testing, thereby addressing animal-tests and non-animal methods alike. These stakeholders suggested relying on human data and models based on structural information rather than animal test data.

According to stakeholder opinions, the level of uncertainty and the number of false positives and false negatives for existing *in vitro* tests do not significantly differ from those of animal tests. Hence, the reliability of data is similar. Some stakeholders stated that *in vitro* and other methods that are also based on human data and/or human cells are even more reliable than animal tests. In agreement with the analysis on sub-categorisation of endpoints (c.f. Section 2.4 and 2.5), some stakeholders expressed the view that *in vitro* tests may provide less information than the corresponding animal test (e.g. sensitisation). One authority commented that the need to develop and validate new *in vitro* test methods needs to be balanced against the risk of decreasing the level of protection.

One stakeholder was concerned that non-animal test methods, in particular (Q)SARs and read-across, would lead to an increase in “expert judgement”. This could open opportunities to manipulate the outcome of assessments, which could lead to a decrease in the level of protection. This concern relates to the interpretation of test results rather than the methods as such. The need for expert judgement is obvious for all complex endpoints where WoE approaches are implemented; however the more methods are used, the more different competences are needed.

3.3.3 Barriers to the use of alternative methods

The following list of barriers to the use of new testing methods and alternative data for regulatory purposes have been deduced from the literature analysis and the stakeholder opinions provided during either the Fitness Check workshop or the consultation for this case study.

- Validated and (internationally) accepted *in vitro* testing **methods are missing** for many endpoints and partly need to be used in combination, which requires expertise and might lead to higher costs than animal tests (e.g. sensitisation). Whether or not full replacement of animal tests is possible for the complex endpoints is unclear.
- Negative results from new testing methods, **may not be sufficient evidence for classification** if contradicting (positive) indications also exist, and hence would have to be complemented by additional data, e.g. from animal testing. Negative results would generally be acceptable for non-classification from non-testing methods, if they are unambiguous or are in conformity with other data and in the case of *in vitro* test methods, if their scientific validity has been established by a validation study, results are adequate for the purpose of classification and labelling and/or risk assessment and adequate and reliable documentation of the applied method is provided.
- It is more difficult to get **regulatory acceptance** of data from non-validated (new testing) methods⁴⁴ and there is a high degree of uncertainty about the regulatory acceptance of non-animal test data⁴⁵, even if based on validated methods. In addition, some company

⁴⁴ According to authority stakeholders the use of data from non-validated (*in vitro*) methods as contributing information, e.g. to identify modes of action, is well received by regulators.

⁴⁵ No analysis could be made of rejections of alternative data for regulatory purposes to verify this statement. ECHA clearly states that the quality of justifications for (Q)SARs, grouping and read-across is not sufficient and it is likely that these data are rejected, if evaluated under REACH. ECHA does not specify the quality and related acceptance of data from *in silico* or *in vitro* methods. We did not identify any corresponding

representatives stated that **acceptance** of alternative methods, in particular based on WoE or read-across, **outside the EU is much lower** than inside the EU. This would require conducting additional animal tests for approval or authorisation procedures in other countries.

- The **level of expertise** needed to conduct and interpret new testing methods is higher than for animal tests. This is seen as a significant obstacle by all industry and authority consultees.
- Opinions were divided on whether or not the existing **guidance** is sufficient or not. While the OECD testing guidelines provide information on testing strategies and data interpretation, for other new testing methods these do not always exist. In addition, not all stakeholders are aware of the existence of interpretation guidelines for test results in the OECD testing guidelines, as can be deduced from stakeholder comments. Sufficient training opportunities are available according to stakeholder comments to build up expertise⁴⁶.
- If a number of different (*in vitro* for skin sensitisation) tests targeting key events on the AOP are necessary, e.g. for classification, stakeholders lack (agreed) guidance on how to evaluate **test results in combination** (e.g. two negative and one positive result from *in vitro* testing) and even if this is possible the results do not allow for assessing the potency of the toxicological effect. Therefore, stakeholders would rather rely on methods, with which they are familiar and for which the interpretation of results, in particular to conclude on classification, is straightforward.
- The use of data from non-animal tests often needs “**case-by-case**” consideration, which requires a high level of expertise and resources and creates uncertainties regarding the regulatory acceptance of the chosen approach. This may be even more important in relation to the use of (Q)SARs, read-across and existing data in WoE approaches than for *in vitro* testing.
- Companies (were) stated to **lack sufficient experience** with the use of alternative data for classification and hazard assessment, in particular where the information “format” does not correspond to the classification triggers and/or points of departure for risk assessment. Translation of information from e.g. skin sensitisation test to DNELs for risk assessment was considered challenging by industry representatives and *in vitro* tests would not provide e.g. EC values needed for risk assessment procedures in other legislative frameworks.
- According to statements from all stakeholder groups, (Member State) **authorities** are **uncertain** about how to interpret non-animal test data and fear accepting false negative results. They have different approaches to accepting data from new testing methods among themselves and across different or for the same legislation. Reasons for differences could be differences in legal interpretations and the experience of the assessors.
- Member State authorities would be not sufficiently trained to identify options to use alternative methods, due to which they could provide little support to enterprises. Even more, the requirement to **avoid animal testing is not sufficiently enforced**⁴⁷.
- The current classification triggers and the provisions to use data from new testing methods lack alignment and consistency (c.f. section 2.4 2.5) in some cases. This is a barrier to the

reports on the acceptance / acceptability of new testing information under e.g. the Plant Protection Products Regulation or the Cosmetic Products Regulation.

⁴⁶ This statement was not verified by an assessment of training needs and available training capacities.

⁴⁷ Several consultees from different stakeholder groups were of this opinion, including a Member State authority representative. No evidence on the enforcement of avoiding animal tests could be collected during the study to verify the statement.

use of all alternative data that are not provided in the required “format” (e.g. NOAELs or LD50 values).

Chemical watch reports⁴⁸ from the ECHA Read-Across Workshop in April 2016 that the “*major barriers preventing registrants from using new approach methodologies (NAMs) in read-across are cost, expertise, time and uncertainty of acceptance by the regulator*”.

3.3.4 Influence of quality requirements on the use of new testing methods

Legislation requires information used for classification and risk assessment to be of “sufficient quality”. Guidance documents provide interpretation of this requirement. All legal acts specify that performance of any new tests should follow internationally accepted standards. However, exemptions are possible but need to be justified. In addition, new tests need to be conducted according to GLP. REACH Annex XI includes criteria for the acceptance of alternative data.

In general, company and authority stakeholders regarded the provisions on data quality sufficiently clear, including in relation to new testing methods, both in legislation and related guidance documents. The discussions at the Fitness Check workshop in April confirmed that the legal provisions are sufficiently clear and understood. Nevertheless in the practical implementation, (Q)SARs and read-across / grouping under REACH frequently lack sufficient documentation and justification, according to ECHA’s evaluation report. Some stakeholders, in particular from the civil society organisations, fear that, in particular, data from read-across and conclusions from WoE are of insufficient quality or biased and would be challenged if new information were generated, potentially leading to different hazard conclusions⁴⁹.

Most stakeholders supported the principles that information from validated methods should generally be accepted and that data from non-validated methods should be accepted on a case-by-case basis.

According to a few stakeholders, guidance documents do not sufficiently well explain some of the terms related to the use of new testing methods, such as the term “sufficient for classification” leading to uncertainty. These stakeholders found the development of more guidance, in particular related to the use and interpretation of *in vitro* test methods, including at international level an important support activity to increase the (efficient) use of new testing methods.

The classification and labelling inventory includes numerous substances, for which notifiers have come to different conclusions on the classification. To what extent these differences are due to the use of non-animal test data and/or the inherent variability between animal studies is difficult to judge.

⁴⁸ Philip Lightowlers (2016): ‘New approach methodologies face huge barriers in supporting read-across’, in Chemical Watch, viewed May 2016, available at: <https://chemicalwatch.com/47030/new-approach-methodologies-face-huge-barriers-in-supporting-read-across>

⁴⁹ It could not be assessed in this case study if this is actually the case. However, the notion from ECHA’s evaluation report supports the statement of insufficient quality, although it is not clear if different hazard conclusions would be reached if other (animal test) data were generated / used.

At the Fitness Check workshop in April, opinions were divided on the benefits and drawbacks from requiring GLP in new testing⁵⁰. Some participants said that GLP is “outdated” because all laboratories now operate to high management and documentation standards. Others strongly supported the existence of the requirement as a general quality assurance mechanism, in particular regarding the study documentation. Several stakeholders do not see a relation between the use of GLP and the quality of testing results at all. Although there were some stakeholders that regarded GLP as not necessary, the requirement to implement GLP principles in conducting new tests for regulatory purposes appears to be generally accepted.

Drawbacks mentioned by the stakeholders in the individual consultation and at the stakeholder workshop related to GLP were: higher laboratory costs, fear of a shortage of laboratory capacities, and fear that studies from academia and independent institutions, which may be of high scientific quality but not conducted according to GLP, are not considered⁵¹.

An analysis of testing costs and laboratory capacities conducted in nine Member States⁵² in 2007 showed a large variation of costs for tests required according to the REACH Annexes. More importantly, it was determined that more than 95% of the testing capacities in the surveyed Member States are supplied by large (GLP) laboratories. However, the study does not specifically address *in vitro* methods and is based on the situation at the start of REACH implementation.

Two laboratories interviewed on the costs of tests according to GLP and non-GLP specified that the prices would differ by 10% to 30%. The overall additional costs merely result from the documentation requirements, because the overall costs for GLP (e.g. training of staff, certification) would be included in the costs of any tests⁵³. The representatives from the laboratories also specified they believe that any laboratory on the market providing tests for regulatory purposes operates at GLP standards. They stressed that GLP is an important factor for the international acceptance of data. Companies would normally want to use the data in any country they are active in and would hence demand GLP, because that guarantees acceptance also in the US or China or other regions, whereas e.g. the use of OECD guidelines could not be sufficient.

⁵⁰ The requirement for GLP for physical chemical hazards was unanimously considered as creating unnecessary burdens without improving the information quality. As physical-chemical endpoints do not involve new testing approaches, this is not further discussed here.

⁵¹ According to other stakeholders, there is no automatic dismissal of non-GLP studies in classification and risk assessment procedures. It could not be checked in this case study to which extent non-GLP studies, which are scientifically valid and relevant, are disregarded when fulfilling data requirements, classifying and/or conducting risk assessments. The fears were mainly raised by NGO representatives, who expect a bias in industry conducted studies. This could not be fully levelled out by authorities, in particular under REACH, where only dossier evaluation and substance evaluation include a data quality control mechanism. Several stakeholders commented that non-GLP data can be and are used at least in all procedures involving authorities. In a publication by NGOs (Buonsante *et al.* (2014): ‘Risk assessment’s insensitive toxicity testing may cause it to fail’, in *Environmental Research* 135, 2014 pp. 139-147), several sources are quoted which state that academic studies were not considered in risk assessment, among others due to lack of GLP.

⁵² Fleischer, M. (2007): ‘Testing Costs and Testing Capacity According to the REACH Requirements – Results of a Survey of Independent and Corporate GLP Laboratories in the EU and Switzerland, 2007.

⁵³ Costs for operating a laboratory at GLP standards in general are included in prices for testing as “general overhead costs”. The documentation efforts of GLP studies only occur when a study is requested according to GLP.

Due to the existence of the GLP-requirement for generating new data, laboratories offering toxicity testing as a commercial service comply with GLP in order to get access to the market for toxicity testing of substances for regulatory purposes. While laboratories operated by universities may develop and/or conduct *in vitro* tests, their interest is more of a scientific nature and only few are likely to provide toxicity testing as a commercial service. No statistics could be identified on the numbers of laboratories with and without GLP compliance that conduct *in vitro* tests and the capacities they can offer. Similarly, no overview of the demand for *in vitro* tests for regulatory purposes could be identified from literature. Consequently, it is neither possible to determine if there is an overall lack of testing capacities (for *in vitro* tests) and if this is aggravated by the fact that testing should be conducted according to GLP.

3.3.5 Stakeholder proposals to increase the use of non-animal test data

Stakeholders see several opportunities to increase the use of non-animal test data. These suggestions match the barriers listed in Section 3.3.3. We could not assess during the study if and to what extent these proposals are suitable and effective in reducing the barriers to the use of new testing methods.

Improvement options suggested by stakeholders included:

- Investment in the development of non-animal test methods, a more accessible and better resourced validation process, e.g. at OECD level, including acceleration of efforts;
- Changes in classification criteria to allow comparison of non-animal test results with the classification criteria (c.f. Section 2.4 and 2.5 as well as Annex 3 and Annex 4);
- Development of guidance on the interpretation of test results for *in vitro* methods (at the level of the OECD). More and better guidance on how the use of non-animal methods and respective data can be identified as “adequate for classification” and how sufficient documentation can be provided to support acceptance;
- Increased enforcement of the prevention and reduction of animal testing at Member State level and in ECHA;
- Capacity building in industry and for authorities to ensure a better understanding of new testing methods, including their limitations and advantages regarding human health; and
- A checklist or reporting format for new testing methods to assess their quality, including completeness and reliability of data⁵⁴.

One authority stakeholder emphasised that development of new methods and hazard assessment approaches strongly needs to take the regulatory context into account, e.g. the need for sub-categorisation with hazard classes, in order to be compatible with the overall framework. The EPAA network concluded similarly⁵⁵ and recommended, in order to increase regulatory acceptance of alternative approaches to animal testing:

- Early involvement of and close collaboration between all relevant stakeholders and across all sectors, in particular scientists developing new methods and users of alternative approaches

⁵⁴ Note: the OECD already provides templates, for example: [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO\(2014\)35&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2014)35&doclanguage=en)

⁵⁵ Ramirez *et al.* (2015): Knowledge sharing to facilitate regulatory decision-making in regard to alternatives to animal testing: Report of an EPAA workshop, Regulatory Toxicological Pharmacology, Oct;73(1):210-26. doi: 10.1016/j.yrtph.2015.07.007.

as well as regulators in the process of planning, developing, validating and implementing alternative approaches;

- International harmonisation of legal requirements, including rules and criteria for interpreting and accepting negative and positive results;
- Consideration of whether the validation of methods could be streamlined (case-by-case); and
- Investments in training and education, creation of additional incentives for the use of non-testing methods.

3.4 Efficiency

3.4.1 Benefits and disadvantages of new methods

Advantages of *in silico* models, read-across and grouping are that new data is generated without testing. Different types of input information could be combined to derive conclusions on analogies in hazards. The development of *in silico* models is time and resource consuming but the later actual testing is quick and of low cost. Grouping and read-across have a comparatively limited scope but may be very cost-efficient, depending on the extent of justification and data used.

Advantages of *in vitro* tests compared to animal testing are that specific interactions can be studied under controlled conditions, excluding interference with other external stressors. Furthermore, a high number of tests can be performed quickly and using low amounts of the test materials. Disadvantages include that the effects in complex biological systems cannot be reproduced/simulated and a combination of test results is normally needed to draw conclusions on potential adverse effects. This also means that information from some *in vitro* methods has to be “translated” into apical endpoint information.

The sensitivity of ‘omics’ methods is comparatively high, but it is challenging to relate the genetic reactions to chemical exposures to concrete outcomes. The method is useful, for example, to clarify modes of action at the molecular level, but is not applicable to classifying a substance.

The information derived from the different methods and approaches differs depending on the respective methods. Some *in vitro* tests are validated against animal tests and hence result in data types comparable to the results of animal tests. Other *in vitro* tests or omics data address different effects or indicators of effects and hence cannot be directly related to animal test results. The type of data generated by (Q)SARs, read-across and other (computational) methods depends upon which type of data they are based on and how the output information is designed.

Stakeholders named the following benefits from the use of non-animal test methods:

- Saving of animal lives;
- Short duration of data generation;
- Potentially lower costs⁵⁶; and

⁵⁶ Some stakeholders expect lower costs for the use of alternative data (not *in vitro*) for complex endpoints with long experiments, e.g. carcinogenicity or chronic toxicity testing. Others believed alternative methods to be more costly, as more experience and competences are needed. We did not identify information comparing the overall costs for classifying substances using different methods that would take account not only prices for testing but also administrative costs. Furthermore, the costs of classification are dependent on many factors, such as the availability of existing information and the physical-chemical properties.

- Potentially better predictability and understanding of the relevance of effects to human health if models or tests are also based on human data.

These have to be viewed against the advantages named for conducting animal tests:

- Long experience with generating and interpreting information;
- Potentially lower costs⁵⁶;
- Certainty for industries that data will be accepted by regulators and trusted by NGOs/the general public;
- Availability of standardised methods and laboratories that can conduct respective testing;
- Compatibility to classification criteria and risk assessment methodologies; and
- International acceptance of data.

Representatives from authorities and industry pointed out that both over- and under-classification would cause substantial costs to society and market actors. Therefore, also non-animal test methods that have a high number of false-positives, although potentially being protective, are not considered useful in the overall context⁵⁷.

The “procedures” of the legal framework in relation to non-animal test methods are interpreted in this case study as “the manner of applying non-animal test data” for classification or risk assessments. Classification and risk assessment could be implemented by industry actors (self-classification, risk assessment in applications for substance approval / registration) or at EU level by authorities, including stakeholder involvement via committees (harmonised classification, assessment of dossiers for substance approvals or scientific opinion forming e.g. in SCCS). Overall, the benefits and disadvantages mentioned for individual classification and risk assessment were the same as for the classification and risk assessment procedures (c.f. above).

3.4.2 Time and resources for using alternative approaches

Stakeholders did not provide detailed information on the (potential) time or resource savings from the use of non-animal testing data. No consistent, overall statement on the efforts for hazard identification appears possible, because they depend on the substance, the availability of existing information, the availability of applicable testing methods as well as the experience of the person assessing the data. However, there seems to be a tendency to believe new testing methods as being more resource-efficient, once they are established and all stakeholders sufficiently trained. However, there are also comments from company representatives indicating that *in vitro* testing is more expensive for skin sensitisation (three *in vitro* tests vs. one LLNA) and that resources for providing justification for read across could be higher than conducting an animal test.

Overall, most stakeholders believe that of all methods, *in silico* testing is most likely to save time and resources. For endpoints where validated *in vitro* tests are available, their use is generally regarded as cheaper than animal testing, except when a combination of several methods is necessary. Many stakeholders stressed that the use of any new method requires capacity building and training, which would make these methods “more costly”. Training facilities would be available, however.

⁵⁷ The JRC’s example on the consequences of classification based on alternative methods shows an overall higher share of substances classified based on non-testing methods than is currently the case according to the CLI. However, no sub-categorisation would be possible. Therefore, this is only an indication that non-testing methods would lead to over-classification rather than to under-classification.

Stakeholders indicated that the identification of the hazard class “skin sensitisation” by *in vitro* testing might be as costly as conducting, for example, a local lymph node assay, due to the need to combine several test results and the low costs of the LLNA. As the LLNA has a short duration, time savings were regarded as of minor importance for this endpoint.

The metals industry states that its bioelution test is 40 times less expensive than a toxicokinetics study that would be necessary for use in classification, where lack of bioavailability of a substance would change the classification (alloys).

A comprehensive evaluation of changes in testing costs for classification comparing animal testing with the use of non-animal test data could not be identified from literature. The Humane Society International⁵⁸ published a comparison of prices of *in vivo* and *in vitro* studies that shows generally lower costs of *in vitro* tests compared to *in vivo* tests. However, as data from one *in vitro* test may not always provide the same information as an *in vivo* test, this information cannot be directly compared. An evaluation of testing costs for skin sensitisation concludes that overall costs would decrease⁵⁹.

3.5 Implications of new assessment methods

The OECD runs a programme on the development of Adverse Outcome Pathways⁶⁰ (AOPs) including a guidance document and template to develop AOPs, a knowledge base on AOPs, which is developed and managed jointly with the EU JRC and the US EPA, and opportunities to make project proposals for AOP development. The OECD work is coordinated with the activities of the WHO/IPCS on chemicals risk assessment. Most of the projects working on alternative testing methods, as well as the US Tox21 project relate to AOPs as the framework for using respective information.

New assessment methods comprise a set of different data generation types, including high throughput screening or ‘omics’ data, which are used to derive hazard conclusions of a substance. The output of these methods is not oriented towards the traditional endpoints used in classification and risk assessment. Stakeholders commented that:

- AOPs are useful to understand toxicological effects;
- AOPs may contribute to the targeted development of further alternative methods;
- AOPs currently support hazard assessment at a qualitative level;
- To identify hazards for more complex endpoints, several AOPs may have to be developed and combined, resulting in complex methods and tools to predict effects; and
- AOPs could be used for an initial screening of the potential hazards of a substance but should not be used for risk assessment purposes (in the near future) due to a lack of information on the uncertainties and predictability of the approach.

All of these statements reflect the discussions in grey and scientific literature.

⁵⁸ Humane Society International, ‘Costs of Animal and Non-Animal Testing’, available at http://www.humanesociety.org/assets/pdfs/animals_laboratories/cost_animal_testing.pdf; accessed September 2016.

⁵⁹ Leonataridou et al. (2016): ‘Evaluation of Non-animal Methods for Assessing Skin Sensitisation Hazard: A Bayesian Value-of-Information Analysis’, in *Altern Lab Anim.* Jul; 44(3):255-69.

⁶⁰ See OECD (<http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm>).

The description of the effect chains and key events of adverse outcome pathways already contribute to classification and risk assessment as additional information⁶¹. All stakeholders who commented on the issue considered the development of AOP hypothesis and tests relating to the key events as a long process⁶². Challenges for the implementation of new assessment methods, as presented by Rusty Thomas at the ECHA Read – Across Workshop in April 2016 include:

- Technical limitations associated with each technology;
- Moving from an apical to a molecular paradigm and defining adversity;
- Predicting human safety vs. toxicity;
- Combining new approaches to have adequate throughput and sufficiently capture higher levels of biological organisation;
- Systematically integrating multiple data streams from the new approaches in a risk-based, weight of evidence assessment;
- Quantifying and incorporating uncertainty and variability;
- Defining a fit-for-purpose framework(s) that is time and resource efficient;
- Performance-based technology standards vs. traditional validation; and
- Role of *in vivo* rodent studies and understanding their inherent uncertainty, legal defensibility of new methods and assessment products.

According to George Fotakis⁶³, tools and methods are available for the use of information from new assessment methods in regulatory science, such as reporting formats and guidance. The main use of related data is seen in their contribution to WoE approaches to increase their acceptability and/or reduce uncertainty.

⁶¹ C.f. Presentations by Mark Cronin, Liverpool John Moores University England, 'Case Study from SEURAT-1 β -Unsaturated Alcohols: Indirect Acting Toxicant Category Supported by SEURAT-1 Data' and Schultz *et al.*, 'Read-Across for 90-Day Rat Oral Repeated-Dose Toxicity for Selected Perfluoroalkyl Acids: A Case Study' at the ECHA Read-across Workshop, 19-20 April 2016, Helsinki.

⁶² Romualdo Benigni (2016): 'How to overcome limitations of new approach methodologies in the context of regulatory science', at the ECHA read-across workshop in April 2016.

⁶³ George Fotakis (2016): 'Using new Approach Methodologies in Regulatory Science: Tools and Methods for Integration of Evidence', presented at the ECHA Read-Across Workshop in April 2016.

4. Conclusions

All methods generating hazard information, other than animal testing are considered new testing methods in this case study. This includes *in vitro* testing, *in silico* methods (including (Q)SARs) and the use of read across and grouping. The use of WoE of existing data and IATA are regarded as instruments supporting the use of alternative data.

Overall, the case study shows that efforts to replace animal testing are ongoing and that all stakeholders committed to contribute.

4.1 Coherence

At a general level, the provisions on the possibilities to use data from new testing methods and to avoid animal testing are coherent in the CLP Regulation, the Biocidal Products Regulation, the Plant Protection Products Regulation, the Cosmetic Products Regulation and REACH. The degree to which animal tests are prohibited and non-animal test methods are binding is inconsistent, with the Cosmetic Products Regulation's ban being the most stringent requirement.

The information requirements in the annexes in legislation on the use of data from new testing methods are partly inconsistent. For example, the requirements on *in vitro* tests for skin sensitisation are different. In addition, each piece of legislation has its own guidance explaining which data (from which method) could be used to fulfil an information requirement. No mechanism exists that ensures guidance harmonisation across legislation.

The following observations relate to the possibility to classify substances based on *in vitro* data and structural information / *in silico* methods:

- For the endpoints carcinogenicity, reproductive toxicity, target organ systemic toxicity, respiratory sensitisation and acute toxicity, no *in vitro* test methods are available. Except for acute toxicity, classification should consider any data, including from *in vitro* testing in a WoE approach. None of the provisions for acute toxicity relate to *in vitro* data;
- The use of *in vitro* data is in principle possible for skin corrosion/irritation, eye corrosion/irritation, skin sensitisation and germ cell mutagenicity. However, the provisions in the CLP regulation's Annex I for these endpoints are partly ambiguous and the guidance is partly outdated; and
- The use of structural information ((Q)SARs, grouping, read across, expert systems etc.) is possible for all classification endpoints. However, the legal provisions in the CLP Regulation's Annex I are not always fully clear and partly not explained in the guidance document. Inconsistencies are observed, if classification sub-categories are related to particular data types, i.e. human data for CMR. In addition and across different endpoints, the opportunities to use structural information are not constant because for some endpoints it is unconditional and for others certain conditions apply, i.e. that it may only be used in conjunction with other information.

4.2 Effectiveness

In principle, all legislation allows and partly promotes the use of alternative hazard information. The following influences from the use of *in vitro* data or structural information on the level of protection are identified:

- Classification based on *in vitro* data may be stricter than if based on animal tests for the endpoint eye corrosion/irritation due to the lack of possibilities for sub-categorisation⁶⁴. In this case, the default classification of cat. 1 applies, which has a stricter GCL than cat. 2. Hence, mixtures would be classified at lower concentrations of the respective substance and related risk management measures would apply in downstream legislation.
- The use of *in vitro* test results could cause a decreased protection level for the endpoint skin sensitisation due to a lack of possibilities for sub-categorisation (a substance that would be cat. 1A based on animal test results would be classified as cat. 1) and the related application of higher GCLs. However, as REACH requires data to be sufficient for determining whether the substance can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A), there should be sufficient data available.
- A potential decrease in the level of protection could also occur for germ cell mutagenicity due to the provision that only the category 2 can be assigned to substances classified based on non-animal test data (*in vitro* plus structural information). A different classification may be identified for the same substance if animal test information were available (i.e. cat. 1A and 1B). Here, both downstream legal consequences as well as mixture classifications would be less stringent if alternative data are the basis for classification.

The actual use of new-testing data is hindered by a number of barriers, in particular the lack of *in vitro* testing methods, a lack of competences of all stakeholders and uncertainty about the regulatory acceptance of new-testing data.

4.3 Efficiency

The benefits and drawbacks of new testing methods are obvious to all stakeholders, with all supporting the aim of preventing animal tests.

No clear information could be obtained on the cost-efficiency of alternative approaches, neither from literature nor from the stakeholders. This is due to the many factors influencing classification costs. Overall, stakeholders and the identified literature sources suggest that testing costs as such are likely to be lower for new testing methods (including *in vitro* and *in silico* methods) than for animal tests. Although the costs for individual tests may be cheaper, it is not clear if the overall costs for classification based on *in vitro* tests would be significantly lower than if animal tests were used. The use of *in silico* methods, read-across and grouping are, however, generally considered as cost efficient, in particular for complex endpoints.

There are differing opinions regarding the benefits and drawbacks from requiring GLP for new testing. Some stakeholders suggest that the GLP is outdated as all laboratories operate to high standards, whereas others support the existence of GLP requirements to ensure the quality of tests (particularly in relation to study documentation). However, although some stakeholders regard the GLP as unnecessary, the requirement to implement GLP principles in conducting new tests for regulatory purposes appears to be generally accepted. Discussions with testing laboratories also indicate that GLP is an important factor for the international acceptance of data, as well as the use of data across EU legislation.

Stakeholders suggest that the drawbacks related to GLP include higher laboratory costs, and fear that studies from academia and independent institutions, which may be of high scientific quality but not conducted according to GLP, are not considered. Discussions with laboratories suggest that the

⁶⁴ Sub-categorisation for skin corrosion/irritation should generally be possible.

costs of tests according to GLP are generally higher than those not undertaken in accordance with GLP (with this resulting from the GLP documentation requirements). Statistics could not be identified on the numbers of laboratories with and without GLP compliance that conduct *in vitro* tests and the capacities they can offer. Similarly, an overview of the demand for *in vitro* tests for regulatory purposes could not be identified from the literature. Therefore, it has not been possible to determine whether there is an overall lack of testing capacities (for *in vitro* tests) and whether this is affected by the fact that testing should be conducted according to GLP.

4.4 Implications

Information from new testing methods is already applied in the regulatory context, in particular, as supporting information in WoE approaches and to identify a substance's mode of action as well as the relevance for humans of effects observed in animals. However, the use of new testing methods as the sole approach to classification and risk assessment with the definition of corresponding classification triggers was not regarded as a reasonable short-term or mid-term perspective. This was justified by the lack of sufficient scientific expertise and the lack of stakeholder competences.

Annex 1 Legal Analysis

A1.1 CLP Regulation

A1.1.1 Type of required information

The CLP Regulation does not require but allows for data generation (Article 8) for classification purposes. All available information should be considered if it conforms with the applicable requirements of REACH Annex XI for the classification of substances (Article 5) and mixtures (Article 6). The information sources may include epidemiological data, information generated according to REACH Annex XI, scientific information and information from recognised chemical programmes.

A1.1.2 Options to use alternative methods

Article 7 of the CLP Regulation prohibits testing on humans and non-human primates and requires that animal testing is only performed if no alternative methods can be used which provide reliable data of sufficient quality.

For classification of substances and mixtures, hazard data are to be compared with the classification triggers. If individual data are insufficient for classification or a direct comparison of the available data with the classification triggers is not possible, a WoE approach may be taken (Art. 9 and Annex I, Section I). Accordingly, non-animal test data can principally be used for classification of substances and mixtures, if they are adequate, reliable and scientifically valid.

A1.1.3 Quality requirements

New tests for the purpose of classification and labelling should be conducted using Good Laboratory Practice and according to the Test Methods Regulation⁶⁵ or internationally recognised / validated scientific principles or methods.

A1.1.4 Use of data

The definitions of many toxicological and ecotoxicological hazard classes as well as the related classification trigger values refer to information from animal testing. For example, the CLP Regulation (Annex I, Part III, 3.1.1.1) defines acute toxicity as:

"[...]those adverse effects occurring following oral or dermal administration of a single dose of a substance or a mixture, or multiple doses [...]."

The trigger values are expressed as LD50 or LC50. Consequently, both the hazard definition and the trigger values are based on animal data. Several other hazard classes are defined similarly.

In the specific provisions for classification in the CLP Regulation's annexes, information on the use of non-animal test data is explicitly included for the endpoint serious eye damage / eye irritation:

⁶⁵ COUNCIL REGULATION (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

before animal tests are applied, existing information and hazard predictions should be used in a WoE approach. This provision (and the type of information included) is not explicitly required for other endpoints.

A1.2 REACH

In the REACH text as well as the guidance document(s) on information requirements and chemical safety assessment it is expressly stated that any existing information should be used to fulfil the data requirements under REACH (e.g. Art. 13 and Annex XI). This would include the application of WoE approaches.

In general, non-animal test methods should be preferred over animal tests as long as they provide appropriate results that can be used for classification and risk assessment. If a registrant plans to conduct tests according Annexes IX or X, he is first to make a testing proposal, which is assessed by ECHA, submitted for public consultation and decided by ECHA after evaluating the information provided by stakeholders.

The ECHA guidance document(s) on information requirements and chemical safety assessment include integrated testing strategies and provide endpoint specific information on the generation and use of hazard data. This includes an indication of availability of OECD test guidelines for *in vitro* methods.

Testing methods are described in the Test Methods Regulation based on published OECD guidelines. Other methods than those described in the Test Methods Regulation may be used (if recognised by the Commission or ECHA), however.

A1.2.1 Type of required information

The REACH information requirements for a given substance depend on the registration tonnage and are listed in the Annexes VII to X. It is possible to waive data requirements based on other information (column 2 of the Annexes) or exposure consideration (Annex XI, Section 3).

A1.2.2 Options to use alternative methods

In general, the prevention of animal testing is strongly promoted under REACH, by recommending the use of existing information or alternative methods for generating new data (under certain conditions). This is also implemented in the guidance document on information requirements and chemical safety assessment, where respective hierarchies for the use of data are established. Regardless of the general provisions the following allusions to animal tests are included in the REACH Annexes:

Annex VII explicitly requires in-vivo tests for skin sensitisation (8.3). An amendment is proposed replacing the current provisions specifying the following hierarchy of data use:

- Information allowing conclusions on skin sensitisation, including significant sensitisation in humans (Cat. 1A) and on risk assessments;
- *In vitro* / *in chemico* methods⁶⁶; and

⁶⁶ These methods should address the following key events on the Adverse Outcome Path (AOP): molecular interaction with skin proteins or inflammatory response in keratinocytes or activation of dendritic cells.

- *In vivo* testing.

Annex VIII specifies that *in vivo* tests for eye and skin irritation may only be conducted, if *in vitro* tests are not applicable. Other *in vivo* tests are suggested by the way requirements are worded for acute and repeated dose toxicity, reproductive toxicity, as well as acute aquatic toxicity.

Article 13 specifies that the Test Methods Regulation be regularly reviewed with the aim to avoid animal testing by integrating other, suitable methods as well as amending the respective REACH annexes.

A1.2.3 Quality requirements

REACH Annex XI Section 1 defines quality requirements / conditions for the use of existing (non-standard) data to fulfil the information requirements. Criteria for determining equivalence / adequacy of existing data are defined (Section 1.1) as well as rules for using WoE, (Q)SARs, *in vitro* methods and grouping / read-across. In general, the data should be adequate for the purpose of classification or risk assessment and the method adequately and reliably documented. In addition, the following is specified:

- WoE: if sufficient evidence is available from existing data, no new animal tests shall be performed; the term “sufficient evidence” is not further defined;
- (Q)SAR: scientifically validated data may be used to ascertain presence or absence of a property, if the substance falls into the applicability domain of (Q)SAR in question;
- *In vitro* methods: data may be used to indicate the presence of a property or contribute to the mechanistic understanding of an effect under the condition that the test is developed according to respective standards. Indications of absence of a property need to be confirmed by further testing, except when the *in vitro* methods are validated, adequate for purpose and adequately and reliably documented; and
- Grouping and read-across: data may be used if they cover the key parameters and the exposure durations of the corresponding test method adequately and reliably; these provisions are further explained in the guidance document.

According to REACH Article 13, all new tests on toxicological and ecotoxicological information shall be performed according to GLP. They should be generated with methods listed in the Test Methods Regulation or other, internationally accepted methods regarded as appropriate by the Commission or ECHA.

The IR/CSA guidance suggests using the Klimisch code or similar systems to evaluate and characterise the reliability of data.

A1.2.4 Use of data

Information collected and generated under REACH is to be used in the context of chemical safety assessment for: a) classification (c.f. section on classification) and b) the derivation of safe exposure levels for risk assessment (i.e. Derived No Effect Levels (DNELs) and Predicted No Effect Concentrations (PNECs)).

The points of departure for DNEL / PNEC derivation normally are “dose descriptors”, i.e. study results expressed as doses or concentrations below which no effects are observed (e.g. no observed (adverse) effect levels NO(A)ELs)). According to the IR/CSA guidance, these data may be generated

using any method, including (Q)SARs and *in vitro* tests, where these deliver adequate and relevant information.

A1.3 Cosmetic Products Regulation

A1.3.1 Type of required information

Substances that require authorisation for use in cosmetic products (inclusion in Annexes) are reviewed by the SCCS, based on the principles of regulatory chemicals safety assessment (hazard identification, dose-response assessment, exposure assessment and risk characterisation). Respective notes for guidance⁶⁷ exist that are in use by the SCCS and are equally applicable to safety assessors of substances not requiring authorisation.

Article 10 (1) of the Cosmetic Products Regulation requires the product manufacturer or placer on the market to provide a product safety report in accordance with Annex I prior to placing on the market. It should include a full toxicological profile of the contained substances covering all relevant endpoints. No specific tests or information requirements are listed in the regulation.

The guidelines on compliance with Annex I⁶⁸ define the safety assessor responsible for the identification of relevant hazard data for the product. Relevance depends, among others on the product type and possible exposures. The following endpoints are specified as potentially relevant:

- Acute toxicity via relevant routes of exposure;
- Irritation and corrosivity;
- Skin irritation and skin corrosivity;
- Mucous membrane irritation (eye irritation);
- Skin sensitisation;
- Dermal/percutaneous absorption;
- Repeated dose toxicity;
- Mutagenicity/genotoxicity;
- Carcinogenicity;
- Reproduction toxicity;
- Toxicokinetics (ADME studies); and
- Photo-induced toxicity.

The guidelines refer to the REACH endpoint specific guidance documents for further information.

A1.3.2 Options to use alternative methods

The Cosmetic Products Regulation generally prohibits animal testing to comply with the regulation as well as the placing on the market of products and ingredients, for which animal tests were conducted solely for the purpose of compliance with the Cosmetic Products Regulation. Results from animal testing conducted for compliance with other legislation are admissible.

⁶⁷ The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation, 9th revision

(http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_190.pdf).

⁶⁸ Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products.

The Annex I guidelines and notes for guidance of the SCCS specify that the following data types can be used for the toxicological profile:

- *In vivo* or *in vitro* test data according to the Test Methods Regulation or international guidelines or standards and performed according to GLP;
- Test data not according to the Test Methods Regulation, other standards and GLP but considered as valid;
- *In vitro* or alternative data from validated test systems;
- Existing human data and/or experience, human (clinical) data, human data from post-marketing surveillance and/or human volunteer compatibility studies; and
- Read-across approaches, grouping of substances, and non-testing data from QSAR model outputs.

The data should be assessed using a WoE approach regarding the likelihood of adverse effects in humans (Article 10, Annex I, and guidelines).

The SCCS notes for guidance specify that alternative methods do not yet exist (and no proposals are in pre-validation or validation stage) for acute and repeated dose toxicity, including reproductive and developmental toxicity, and carcinogenicity. It is also stated that information from non-validated methods and tools (including omics data) may be used on a case-by-case basis if regarded acceptable due to a “sufficient” amount of experimental data proving their relevance and reliability including positive and negative controls.

The Commission is to monitor progress in the development of *in vitro* methods and may, if technical challenges are identified, prolong the timetables for phasing out animal tests. In addition, derogations from the prohibition of animal tests are possible in “exceptional cases”.

A1.3.3 Quality requirements

Any information may be used for safety assessment according to the guidance on Annex I, provided that it is relevant, valid and of sufficient quality. Although studies conducted according to international guidelines are qualified as most useful, the use of other information is only restricted to the extent that its quality should be considered. Reference is made to the endpoint specific REACH guidance documents, which makes it plausible that similar quality standards should be followed for the safety assessment of cosmetics ingredients and products as under REACH.

New experimental studies have to be carried out in accordance with the principles of Good Laboratory Practice and possible deviations are to be scientifically justified.

A1.3.4 Use of data

Substance hazard information is to be used in the product safety assessment to develop a toxicological profile consisting of an identification of hazards and a characterisation of the dose response curve. In addition, margins of safety (MOS) should be derived.

The hazard assessment aims at deriving the likelihood of an adverse effect and is conducted using a WoE approach. No cut-off criteria or threshold values are defined.

The margin of safety is calculated based on the NO(A)ELs and the Systemic Exposure Dosage (SED). NO(A)ELs are usually derived from human or animal data.

A1.4 Plant Protection Products Regulation

The Plant Protection Products Regulation requires an authorisation of active substances, safeners and synergists for use in plant protection products at EU level. Producer or placers on the market are to compile relevant (eco)toxicological information to apply for substance approval. The data requirements are set out in a separate regulation⁶⁹.

Plant protection products must be authorised based on data compiled in a respective application dossier. The producer or placer on the market is to submit an application for product authorisation to all Member States where it shall be placed on the market. The data requirements are set out in a separate regulation⁷⁰.

A1.4.1 Type of required information

For the approval of active substances, safeners and synergists, a full toxicological and ecotoxicological profile shall be submitted, requiring information on an extensive number of endpoints, including those necessary for classification.

For product approval, data on the active substances, safeners and synergists contained in the product are to be provided.

A1.4.2 Options to use alternative methods

Recital 40 and Article 8 of the Plant Protection Products Regulation requires that animal testing be minimised.

Section 1.7 of the regulation setting out data requirements for active substance includes a list of applicable test methods that should be published and regularly updated in the Official Journal. If no validated test guidelines exist, the use of other methods accepted by the EU competent authorities is recommended.

The regulation also reiterates that vertebrate animal tests shall be avoided and only conducted in the absence of validated other methods. *In vitro* and *in silico* methods should explicitly be considered. Tests involving human and non-human primates are prohibited.

The regulation specifies the endpoints, for which data are to be submitted, which partly include indications as to the type of test (*in vivo*, *in vitro*, oral 28 day study). In the explanation of test data and requirements, references to effects on animals and their body parts are frequent, suggesting that animal testing and referencing to effects in animals is a preferred option to provide safety data.

For the endpoints skin and eye irritation, a WoE assessment of existing data shall be performed before conduction of *in vivo* tests. Furthermore, the testing strategy explicitly suggests starting the assessment with *in vitro* tests. However, confirmation of results by animal testing is still included.

⁶⁹ COMMISSION REGULATION (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

⁷⁰ COMMISSION REGULATION (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

For skin sensitisation a LLNA is prescribed. For the assessment of genotoxicity, at least one *in vivo* test in somatic cells is required to confirm a negative result (absence) for mutagenicity determined by *in vitro* tests. For positive *in vitro* test results further (*in vivo*) testing should be tailored on a case-by-case basis.

A1.4.3 Quality requirements

All tests and analyses related to human health or the environment for active substances not consisting of micro-organisms or viruses are to conform to standards of Good Laboratory Practice and related principles. Exemptions are made in relation to data for minor crops, where the accreditation of laboratories according to the EN ISO standard for the respective method is accepted as sufficient. In addition, existing data on vertebrate species, not according to GLP may be used if the competent authorities regard them as scientifically valid.

A1.4.4 Use of data

The information should be sufficient, among others, to conduct risk assessments and classify the active substance in accordance with the CLP Regulation, including the derivation of acceptable daily intakes, acceptable operators' levels and acute reference doses, if relevant.

Sufficiency for classification suggests that animal test data are used in order to allow direct comparison with the classification criteria.

The derivation of safe exposure levels, such as the acceptable operator exposure, is based on toxicity data, such as NO(A)ELs, which suggest the use of animal test results as a starting point. The guidance document⁷¹ suggests a 90-day study as the starting point for the oral exposure route, for example.

A1.5 Biocidal Products Regulation

According to the Biocidal Products Regulation, active substances must be approved for use based on a dossier submitted by the active substance manufacturer or placer on the market. Biocidal products require authorisation, for which an application must be made to the Member States or at EU level.

A1.5.1 Type of required information

Annex II of the Biocidal Products Regulation specifies the information requirements for the active substance dossiers. Reference is made to the Test Methods Regulation with regard to the methods and deviations from these that are possible, if methods are missing in the Test Methods Regulation or if they are regarded as inappropriate. Deviations must be justified.

No new information needs to be generated on the biocidal product, if information is available for all components. Otherwise, requirements to testing correspond to those for active substances.

⁷¹ European Commission (2006): Draft Guidance for the Setting and Application of Acceptable Operator Exposure Levels (AOELs), Health & Consumer Protection Directorate-General Directorate E – Safety of the food chain E3 - Chemicals, Contaminants, Pesticides, SANCO 7531 - rev.10 7 July.

A1.5.2 Options to use alternative methods

The BPR includes a provision that animal testing should be the last resort for generating data to fulfil the regulation's information requirements.

The list of information requirements partly includes options to waive data requirements based on available (other) information (column 3 of Annex II and Annex III).

For acute local effects, use of existing data and a testing strategy prioritising *in vitro* tests is foreseen. If all *in vitro* tests for gene mutation are negative, and in the absence of indications to a mutational effect, no animal test needs to be performed to confirm this finding.

Annex IV of the Biocidal Products Regulation includes provisions for waiving data requirements, including based on the use of alternative methods. The annex resembles the REACH Annex XI in structure and content. *In vitro* tests may be used if they are developed according to internationally accepted principles of test development. If they show positive results, *in vivo* tests need to be conducted to confirm the finding. When the *in vitro* tests are validated, the method is documented and the results are sufficient for classification and risk assessment.

The provisions for using (Q)SARs and read-across are almost the same as under REACH, as are those relating to the use of existing data in a weight of evidence approach.

A1.5.3 Quality requirements

Tests should be conducted according to validated and/or internationally accepted methods (reference to REACH / the Test Methods Regulation, international standards) and in conformity with Good Laboratory Practice (data on toxicology and/or ecotoxicology).

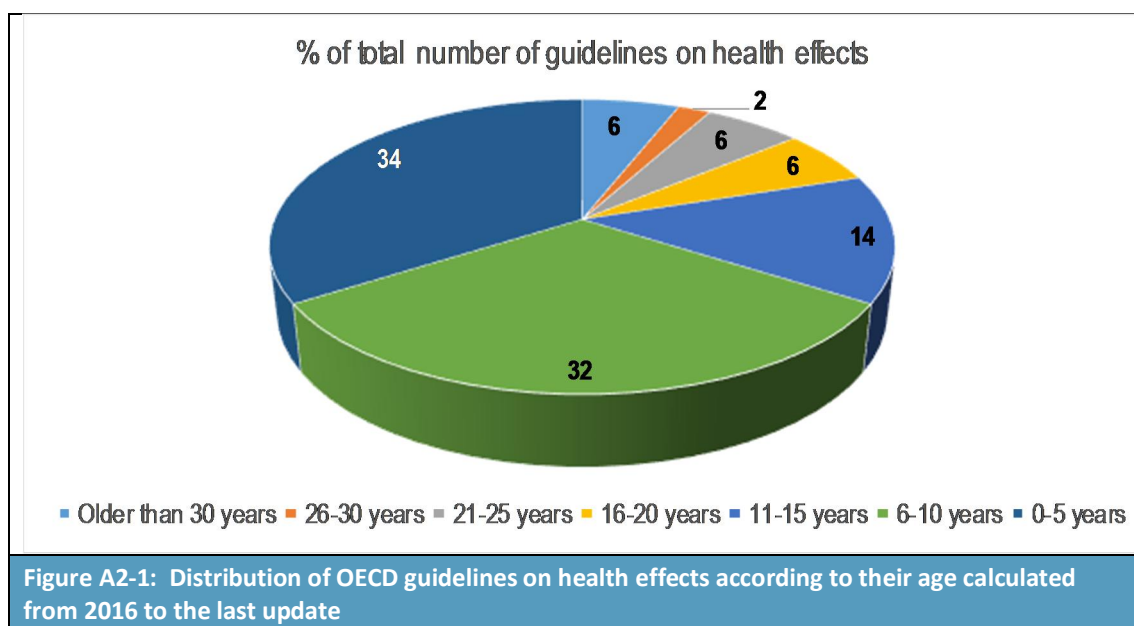
The acceptability of existing data, which were generated before September 2013 and not according to the Test Methods Regulation, is decided by the evaluating Member States on a case-by-case basis.

A1.5.4 Use of data

The information on hazardous properties is used for classification and labelling as well as risk assessment. The latter includes the derivation of safe exposure levels for human health and the environment.

Annex 2 Age and Updates of OECD Guidelines

An analysis of the time of adoption and the date of the last revision of the OECD testing guidelines for human health effects shows that the updating process is not systematic (different time periods for updates for different guidelines) and that there are some rather old test guidelines which are very old. The majority of guidelines for health effects are between 0 and 10 years old, counting the “age” from the date of the last review of the guidelines. The percentage of all guidelines falling into different age classes is shown in the following figure.



Annex 3 Compatibility of In Vitro Data with Classification Triggers (Human Health)

Table A3-1: Overview of information requirements

Endpoint	Classification trigger	Sub-categories	Provisions in CLPR on <i>in vitro</i> data	Guidance on <i>in vitro</i> methods	Guidance	Sub-cat. based on <i>in vitro</i> data	Labelling	Challenges
3.1 Acute toxicity	LD50 / LC 50	1, 2, 3, 4	None		None	Not applicable		No method available
3.2 Skin corrosion / irritation	Corrosive: 1A: response < 3 min; 1 hour observation; 1B: response 3 min - 1 hour; observation up to 14 days; 1C: response 1 hour to 4 hours; observations up to 14 days. Irritation: 2 of 3 tested animals have a mean score of $\geq 2,3 - \leq 4,0$	Corrosion: 1A, 1B, 1C; GCL 5% Irritation: 2; GCL 10%	“3.2.2.1 <i>In vitro</i> alternatives that have been validated and accepted may also be used to help make classification decisions” 3.2.2.4. Data hierarchy does not mention <i>in vitro</i> testing	Positive results can be used for classification; absence of effect must be verified with other data	TG 430, 431, 435, 439	Sub-categorisation should generally be possible	Corrosion: all same label	Sub-categorisation not possible for some methods
3.3 Serious eye damage / irritation	Irreversible or reversible damage or decay of tissue	1 (damage); GCL 3% 2 (irritation); GCL 10%	3.3.2.1 [...] tiered testing and evaluation scheme, combining pre-existing information [...] as well as the output of validated <i>in vitro</i> tests [...]. 3.3.2.3 <i>In vitro</i> alternatives that have been validated and accepted can be used 3.3.2.4 WoE of all evidence to decide on the need for testing	<i>In vitro</i> tests to be used; results from some tests may be used as sole basis for classification. No tests available to classify for eye irritation. Results from some tests should be subject to further evaluation	TG 437, 438, 460, 491, 492	Category 1 or not classified	Different labels	Combination of methods needed to replace animal tests, two ECVAM validated methods, validation of <i>in vitro</i> tests challenging, sub-categorisation

Table A3-1: Overview of information requirements								
Endpoint	Classification trigger	Sub-categories	Provisions in CLPR on <i>in vitro</i> data	Guidance on <i>in vitro</i> methods	Guidance	Sub-cat. based on <i>in vitro</i> data	Labelling	Challenges
3.4 Respiratory sensitization	Evidence from human data or animal testing (no specific tests available) WoE	1A (human evidence); GCL = 0.1% 1B (animal data); GCL = 1% 1 (insufficient to sub-categorise); GCL = 1%	Immunological tests as part of human evidence		None	Not applicable	All same label elements	No method available
3.4 Skin sensitization	Evidence from human data or animal testing. WoE	1A (strong); GCL = 0.1% 1B (sensitiser): GCL = 1% 1 (if insufficient for sub-categorisation); GCL = 1%	No <i>in vitro</i> tests quoted	Hardly any information provided; guidance outdated regarding validation status of <i>in vitro</i> tests	TG 442C, 442D	Sub-categorisation normally not possible	All same label elements	Combinations of methods may enable classification; normally no sub-categorisation.
3.5 Germ cell mutagenicity	Primarily substances causing mutations in human germ cells that can be transmitted to the progeny. Results from mutagenicity or genotoxicity tests <i>in vitro</i> and in mammalian somatic and germ cells <i>in vivo</i> are also considered; WoE	1A, (known, human data); GCL = 0.1% 1B (known <i>in vivo</i> data); GCL = 0.1% 2 (suspected; various data); GCL = 1%	3.5.2.3.1 Mutagenic and/or genotoxic effects determined in <i>in vitro</i> tests shall also be considered. Category 2 mutagens may be solely identified via <i>in vitro</i> tests	Structural data are necessary to enable classification as muta Cat. 2 if based on <i>in vitro</i> data only	several	several	Same pictogram, different warning, same phrases	No issues mentioned

Table A3-1: Overview of information requirements								
Endpoint	Classification trigger	Sub-categories	Provisions in CLPR on <i>in vitro</i> data	Guidance on <i>in vitro</i> methods	Guidance	Sub-cat. based on <i>in vitro</i> data	Labelling	Challenges
3.6 Carcinogenicity	Allocation to categories acc. To strength of evidence and additional considerations (WoE). May be route-specific, if no other route of exposure exhibits the hazard. WoE	1A (known; human data); GCL = 0.1% 1B (presumed; mainly animal data); GCL = 1% 1 (suspected); GCL = 1%	<i>In vitro</i> data from ADME studies or determining mode of action at cellular level to support WoE	Information from <i>in vitro</i> germ cell and somatic cell mutagenicity studies, <i>in vitro</i> cell transformation assays, and gap junction intercellular communication (GJIC) tests	None	Not applicable	Same pictogram different warning (1 and 2), same phrases	No method available
3.7 Reproductive toxicity	Effects on sexual function and fertility, and on development, are considered separately. In addition, effects on lactation are allocated to a separate hazard category. WoE approach	1A (known; human data); GCL = 0.3% 1B (presumed; animal data); GCL = 0.3% 2 (suspected); GCL = 3%	3.7.2.5.4 Evidence from <i>in vitro</i> assays, or non-mammalian tests [...], can contribute [...] expert judgement must be used to assess the adequacy of the data.	Little guidance is provided; reference to IR/CSR guidance; no clarification as regards sub-categorisation	None	Not applicable	Same pictograms , different t signal word (1 and 2), same phrases	No method available

Table A3-1: Overview of information requirements								
Endpoint	Classification trigger	Sub-categories	Provisions in CLPR on <i>in vitro</i> data	Guidance on <i>in vitro</i> methods	Guidance	Sub-cat. based on <i>in vitro</i> data	Labelling	Challenges
3.8 Specific target organ toxicity single exposure	WoE considering level of evidence and severity of effects	1 (significant; human & animal data); GCL = 10% 2 (harmful; animal data); GCL = 10% 3 (narcotic effects and respiratory irritation); GCL = 20%	none	Lack of <i>in vitro</i> studies for acute toxicity results in lack of possibilities to use <i>in vitro</i> data.	No specific methods	Not applicable	1&2: torso and 3: exclamation 1: danger; 2&3 warning Different P-statements	No method available
3.9 Specific target organ toxicity repeated exposure	[...] use of expert judgement (see 1.1.1), on the basis of the weight of all evidence available, [...], and are placed in one of two categories, depending upon the nature and severity of the effect(s) observed [...]	1 (significant; human & animal data); GCL = 10% 2 (harmful; animal data); GCL = 10%		Lack of <i>in vitro</i> methods; however potential value of <i>in vitro</i> information as part of WoE is acknowledged.	None	Not applicable	1&2: torso 1: danger; 2&3 warning Different P-statements	No method available
3.10 Aspiration hazard					TG 114 (physical chemicals)	Not applicable		None

Annex 4 Compatibility of Non-Test Data with Classification Triggers (Human Health)

Table A4-1: Overview of information requirements					
Chapter	Definition	Use of read-across	Relevant paragraph read across	Challenges and inconsistencies for read across	Guidance QSAR
3.1 Acute toxicity	Acute toxicity means those adverse effects occurring following oral or dermal administration of a single dose of a substance or a mixture, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours	Not stated	Use of structural information not explicitly mentioned in the CLP regulation's Annex I		Information from QSARs and structural analogues may be used. LD50/LC50 values derived from these methods should be used to identify the respective ATE
3.2 Skin corrosion/irritation	Skin corrosion means the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to 4 hours. Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discolouration due to blanching of the skin, complete areas of alopecia, and scars. Histopathology shall be considered to evaluate questionable lesions. Skin irritation means the production of reversible damage to the skin following the application of a test substance for up to 4 hours.	Unconditional	3.2.2.1 In some cases enough information may be available from structurally related compounds to make classification decisions	None	Use is possible, non-classification if model is shown to well predict absence of an effect

Table A4-1: Overview of information requirements					
Chapter	Definition	Use of read-across	Relevant paragraph read across	Challenges and inconsistencies for read across	Guidance QSAR
3.3 Serious eye damage irritation	Serious eye damage means the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application. Eye irritation means the production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application	Unconditional	3.3.2.1 [...] tiered testing and evaluation scheme, combining pre-existing information [...] as well as considerations on (Q)SAR and the output of validated <i>in vitro</i> tests [...]. 3.3.2.3. In some cases sufficient information may be available from structurally related substances to make classification decisions	None	(Q)SARs etc. may be used on a case by case basis
3.4 Respiratory sensitization	Respiratory sensitiser means a substance that will lead to hypersensitivity of the airways following inhalation of the substance	Conditional	3.4.2.1.2.3 The evidence referred to above could be: (a) clinical history and data from appropriate lung function tests related to exposure to the substance, confirmed by other supportive evidence which may include: (i) <i>in vivo</i> immunological test (e.g. skin prick test); (ii) <i>in vitro</i> immunological test (e.g. serological analysis); (iii) studies that may indicate other specific hypersensitivity reactions where immunological mechanisms of action have not been proven, e.g. repeated low-level irritation, pharmacologically mediated effects; (iv) a chemical structure related to substances known to cause respiratory hypersensitivity; (b) data from positive bronchial challenge tests with the substance conducted according to accepted guidelines for the determination of a specific hypersensitivity reaction	Read across could only be used as supportive data, if other evidence is available but not as only information for classification	Reference is made to the IR/CSR guidance which specifies that hardly any models are available and structural alerts are based on asthmagens rather than sensitisers

Table A4-1: Overview of information requirements					
Chapter	Definition	Use of read-across	Relevant paragraph read across	Challenges and inconsistencies for read across	Guidance QSAR
3.4 Skin sensitization	Skin sensitizer means a substance that will lead to an allergic response following skin contact.	Conditional	3.4.2.2.4.3 If none of the above mentioned conditions are met, the substance need not be classified as a skin sensitizer. However, a combination of two or more indicators of skin sensitization as listed below may alter the decision. This shall be considered on a case-by-case basis. (a) Isolated episodes of allergic contact dermatitis; (b) Epidemiological studies of limited power, e.g. where chance, bias or confounders have not been ruled out fully with reasonable confidence; (c) Data from animal tests, performed according to existing guidelines, which do not meet the criteria for a positive result described in 3.4.2.2.3, but which are sufficiently close to the limit to be considered significant; (d) Positive data from non-standard methods; (e) Positive results from close structural analogues	Read across only as part of WoE to alter a non-classification as one out of at least two conditions applying from a list of 5	Structural alert data or data to show that the chemical structure of a molecule is similar to that of known sensitizers (e.g. QSARs or expert systems) may form part of the weight of evidence
3.5 Mutagenicity	[...] The term 'mutagenic' and 'mutagen' will be used for agents giving rise to an increased occurrence of mutations in populations of cells and/or organisms. The more general terms 'genotoxic' and 'genotoxicity' apply to agents or processes which alter the structure, information content, or segregation of DNA, including those which cause DNA damage by interfering with normal replication processes, or which in a non- physiological manner (temporarily) alter its replication. Genotoxicity test	Conditional	Table 3.5.1 Note Substances which are positive in <i>in vitro</i> mammalian mutagenicity assays, and which also show structure activity relationship to known germ cell mutagens, should be considered for classification as Category 2 mutagens	Read across only, if positive in <i>in vitro</i> mammalian mutagenicity assay (condition) and in any case of indication of mutagenicity, classification in category 2, regardless of the category of the structural analogue	Structural data is necessary to enable classification as muta Cat. 2 if based on <i>in vitro</i> data only

Table A4-1: Overview of information requirements					
Chapter	Definition	Use of read-across	Relevant paragraph read across	Challenges and inconsistencies for read across	Guidance QSAR
	results are usually taken as indicators for mutagenic effects				
3.6 Carcinogenicity	Carcinogen means a substance or a mixture of substances which induce cancer or increase its incidence. Substances which have induced benign and malignant tumours in well performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumour formation is not relevant for humans	Unconditional, expert judgement	3.6.2.2.6. Some important factors which may be taken into consideration, when assessing the overall level of concern are: [...] (g) structural similarity to a substance(s) for which there is good evidence of carcinogenicity; [...] 3.6.2.2.7 A substance that has not been tested for carcinogenicity may in certain instances be classified in Category 1 or Category 2 based on tumour data from a structural analogue together with substantial support from consideration of other important factors such as formation of common significant metabolites, e.g. for benzidine congener dyes	Classification as 1A requires human data for a substance. If read across is applied, human data relates to the structural analogue. Hence, classification via read across could only result in 1B (OECD) The ECHA guidance document specifies that classification is possible for 1A, 1B and 2 based on structural information	Information from QSARs and structural analogues may be used in the WoE approach; guidance is provided on justification but no details on evaluation
3.7 Reproductive toxicity	Reproductive toxicity includes adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring. In this classification system, reproductive toxicity is subdivided under two main headings: (a) adverse effects on sexual function and fertility; and (b) adverse effects on development of the offspring	Unconditional, expert judgement	3.7.2.3.1 [...] Evaluation of substances chemically related to the substance under study may also be included (<i>in WoE</i>), particularly when information on the substance is scarce. [...] 3.7.2.5.4 Evidence from <i>in vitro</i> assays, or non-mammalian tests, and from analogous substances using structure-activity relationship (SAR), can contribute to the procedure for classification. In all cases of this nature, expert judgement must be used to assess the adequacy of the data	Classification as 1A requires human data for a substance. If read across is applied, human data relates to the structural analogue. Hence, classification via read across could only result in 1B	Little guidance is provided; reference to IR/CSR guidance; no clarification as regards sub-categorisation

Table A4-1: Overview of information requirements					
Chapter	Definition	Use of read-across	Relevant paragraph read across	Challenges and inconsistencies for read across	Guidance QSAR
3.8 STOT single exposure	Specific target organ toxicity (single exposure) is defined as specific, non-lethal target organ toxicity arising from a single exposure to a substance or mixture. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in sections 3.1 to 3.7 and 3.10 are included	Unconditional, expert judgement	3.8.2.1.10.3 A substance that has not been tested for specific target organ toxicity may in certain instances, where appropriate, be classified on the basis of data from a validated structure activity relationship and expert judgement based extrapolation from a structural analogue that has previously been classified together with substantial support from consideration of other important factors such as formation of common significant metabolites.	None	The use of structural information / (Q)SARs is possible but stated to be limited to specific cases and in particular Cat. 3 due to the relation to specific effects
3.9 STOT repeated exposure	Target organ toxicity (repeated exposure) means specific, target organ toxicity arising from a repeated exposure to a substance or mixture. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed are included. However, other specific toxic effects that are specifically addressed in sections 3.1 to 3.8 and 3.10 are not included here	Unconditional, expert judgement	3.9.2.10.3 A substance that has not been tested for specific target organ toxicity may in certain instances, where appropriate, be classified on the basis of data from a validated structure activity relationship and expert judgement based extrapolation from a structural analogue that has previously been classified together with substantial support from consideration of other important factors such as formation of common significant metabolites	None	Use of QSARs, structural information and read across as contribution to WoE possible but stated as limited and case by case
3.10 Aspiration hazard		Not stated	Not applicable	Not applicable, read-across not mentioned	

**Case Study 5: Coherence of classifications,
definitions and labelling requirements for
detergents**

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1 Introduction

1.1 Background

The aim of this case study is to ascertain the coherence of classifications, definitions and labelling requirements for detergents. In addition to coherence, this case study also contributes to the study report's evaluation of relevance, effectiveness and efficiency as defined by the Better Regulation evaluation criteria, with the emphasis here on those evaluation questions set for the Fitness Check relevant to the subject of this case study.

The case study considers coherence and inconsistencies between the labelling requirements for detergents under the Detergents Regulation and CLP, and also examines requirements under the Biocidal Products Regulation and the Cosmetic Products Regulation. The intention is to gauge how such requirements have affected the coherence, effectiveness and efficiency of EU chemicals legislation in the field of detergents and the administrative burden for industry. In addition, issues arising regarding definitions and differences in relation to transport legislation are examined. This case study will consider the detergents industry across the EU. It will also indirectly assess the effectiveness of the CLP Regulation at communicating hazard information, contributing to a second consumer-focused case study (Case Study 9 on consumers' comprehension of and relevance of safety information on product labels).

Note that the definitions of "placing on the market" and "manufacturer" were identified as possible issues to be researched in this case study. However, it became clear during the interviews that there are no issues around the definition of "manufacturer" for detergents stakeholders and alignment of the meaning of "placing on the market" has been achieved.

In the case of detergents, the classification of the mixture is reflected directly on the label and it is the label which, for retail products in particular, is the primary route of user/consumer communication. It is also the classification and labelling of retail products that is now (a year after the deadline for introducing mixture classification under the CLP Regulation) where the majority of issues encountered by authorities and industry alike are found. Hence, the focus of this case study is primarily retail products, rather than maintenance products for use by workers and/or professionals.

1.2 Overview of the issues

For all case studies undertaken as part of this study, the purpose is to explore in detail some of the more pertinent issues associated with EU chemicals legislation, both in relation to the impacts of implementing the CLP Regulation and the interface between this and other chemicals legislation.

To put the contribution of the detergents sector to improved public health in context, it is well known that during the last 150 years in Europe, there has been a significant improvement in public health and successes in the fight against infectious disease have played a major role. However, less frequent acknowledgement is given to the socio-cultural transformation in personal hygiene and domestic cleanliness (Aiello *et al.*, 2007). Today it is impossible to imagine hospitals, clinics, schools and restaurants without a primary focus on cleanliness and hygiene. Similarly, on the domestic front, personal hygiene and household cleanliness are very important. Detergents play an important role in all of these public and domestic hygiene activities and therefore can be seen to play a vital role in maintaining and improving public health.

The Detergents Regulation ((EC) No 648/2004) establishes common rules to enable detergents and surfactants to be sold and used across the EU, while providing a high degree of protection to the environment and human health. Key objectives include (Eur-Lex, 2016):

- Harmonised testing methods to determine the biodegradability of all surfactants used in detergents. These cover primary and ultimate biodegradability;
- Information on detergents' packaging must be legible, visible and indelible. This includes contact details for the manufacturer and the datasheet; and
- Labels on detergents sold for public use must give details of recommended dosages for different washes in a standard washing machine.

In 2012, the legislation was amended to harmonise rules on limiting the content of phosphates and other phosphorus compounds in detergents for household laundry and dishwashing machines.

The Cumulative Cost Assessment found that the greatest costs to the detergents sector arising from chemicals legislation are linked to administrative requirements (Technopolis, 2016). As is detailed in the Cumulative Cost Assessment Report (2016), "Administrative burden is mainly related to the cost of the preparation and submission of information for registrations and the issue of permits, as well as for the information of product users (e.g. labelling).[...] Overall, it amounts to 10% of the total regulatory cost. [...] The highest administrative burden is observed in soaps and detergents, where it represents almost 28% of the legislation cost and 3.2% of the subsector's value added."¹ Labelling requirements are an important component. As administrative burden represents a large share of regulatory cost, it is a first target to look at in terms of the EU's REFIT programme.

For the detergents sector, this administrative burden can stem from information obligations to public authorities or third parties, changes in labelling requirements and the need for reclassification of substances under the CLP Regulation. It may also result from differences across Member States in interpretation of certain definitions and of legislation.

The labelling of detergents is always subject to the Detergents Regulation and the CLP Regulation. Some detergents may also be subject to the Biocidal Products Regulation, but only if they contain a biocidal active substance and the detergent product has a biocidal claim. In addition, the Detergents Regulation makes reference to the Cosmetics Products Regulation for the labelling of allergenic fragrances. Hence, a change in the Cosmetic Products Regulation list of allergenic fragrances will have consequences for the labelling of detergents. All detergents are subject to transport legislation for transport packaging.

Labelling in the detergents sector is the pivotal point of the application of all EU legislation to the sector. Firstly, all detergents mixtures need to be classified. The outcome of these classifications manifests itself in the labelling on industrial and institutional (maintenance and medical) products and also on consumer products. These labels are the major source of communication to users and consumers, which means this subject (considered in further detail in case study 9) is particularly important to this sector. The detergents sector is the third biggest in the chemicals sector and is one of the few sectors where the products are sold directly to consumers (retail) and to professionals (maintenance products).

The detergents sector undertook considerable preparation for the introduction deadline of 1 June 2015 for the classification of mixtures (introduced by the CLP Regulation). However, case study

¹ Cumulative Cost Assessment for the EU Chemical Industry, p.9.

findings and expert feedback across the range of stakeholder groups who participated in this case study indicate that classification rules for mixtures are considered to be not (yet) fit for purpose for consumer products in this sector, as is discussed in this case study report.

Firstly, the choice of classification method is an issue. The correct classification of mixtures under CLP, particularly for SMEs, was predicted by Cefic to be “complex”² and this prediction is being confirmed. Stakeholders’ perceptions are that detergents mixture classifications are not necessarily consistent, being based on the use of existing or new test data, on expert judgment or on calculations. As a result, the outcome of the mixture classification process depends on the method used, so the same mixture will be classified differently depending on the method used. SMEs in particular are more likely to depend on calculations to classify mixtures resulting in more conservative hazard classifications than companies that can undertake the necessary testing themselves (e.g. for laundry detergents, using the modelling approach can lead to the need to use a corrosive pictogram whereas testing will result in a classification requiring only an exclamation mark).

Early findings from industry stakeholders indicated that Member States are not all consistent in their acceptance of expert judgement or bridging principles for classifying mixtures, with different views and interpretations on what is permitted, with some accepting only the most conservative approach to classification, the calculation method. This was researched in more detail in the following phase of the study and further research supported the early findings. These are reported in detail in this case study report.

For the detergents sector, the key outcome of classification of mixtures is the labelling of consumer products. However, consumer detergent products are also subject to (different) labelling requirements under the Detergents Regulation. The various requirements of labelling under CLP and the Detergents Regulation lead to complex labels, provision of confusing information (some duplicate data such as ingredients and composition) or too much information for consumers and are not seen to be effective in communicating safe use or other essential information. Due to lower thresholds under CLP than under the previous Dangerous Preparations Directive (DPD), known and trusted consumer products previously not labelled as hazardous may now have a hazardous label, causing further consumer confusion.

Other consumer confusion issues include the likelihood of misrepresenting the intrinsic hazards of a detergent to consumers, based on classification requirements. For example, it is difficult to explain to consumers why a laundry detergent especially intended for washing a cashmere sweater has a corrosive pictogram.

Finally, it can be noted that due to the relatively recent deadline for the compulsory classification of mixtures under CLP, some of these issues could be expected to be satisfactorily dealt with in due course, subject to the willingness of stakeholders to work together to achieve agreement.

1.3 Objectives

The aim of this case study is to investigate the coherence, consistency, gaps and overlaps related to classification and labelling requirements for detergents under the Detergents Regulation, the Biocidal Products Regulation, and the CLP Regulation. Issues arising regarding definitions and

² Cefic (2016): Implementing a new, complex system, The European Chemical Industry Council. Available at: <http://www.cefic.org/Policy-Centre/Environment--health/Classification-Labeling-and-Packaging/>

differences in relation to transport legislation are also be examined. This case study considers the detergents industry across the whole of the EU. Furthermore, it indirectly assesses the effectiveness of the CLP Regulation at communicating hazard information, contributing to a second consumer-focused case study (case study 9).

1.4 Methodology

The information required for this case study has been gathered through a series of interviews with key stakeholder groups, including regulators, national detergents associations and detergents companies. Where relevant, comments made in the interviews undertaken as part of case study 9 (on consumer understanding of labels and pictograms) are also included. In addition, other relevant information gathered from Member States and industry for the purposes of the study as a whole is referred to where relevant.

As the title of this case study is the coherence of classification, definitions and labelling of detergents, coherence is considered first. Based on the roadmap questions, coherence is discussed in terms of (in)consistent interpretations, implementation and approaches, gaps and overlaps, as well as unintended results and data quality requirements.

2 Gaps, Overlaps and Inconsistencies in Detergents' Classification and Labelling Requirements

2.1 Overview

The purpose of this section is to ascertain whether and to what extent gaps, overlaps and inconsistencies exist in the classification and labelling requirements for detergents under the Detergents Regulation, the CLP Regulation, the Biocidal Products Regulation and the Cosmetic Products Regulation. It briefly considers the key issues faced by the sector and the importance of detergents classification and labelling, which can have consequences for many aspect of the detergents business.

The issues faced by companies in the detergents sector ultimately manifest in labelling issues because the sector is subject to different legislation (e.g. Biocidal Products Regulation, Cosmetic Products Regulation, CLP, transport) with the associated overlaps between these. This can result in inconsistencies such as dual labelling, where the same ingredient is listed twice, which adds complexity for detergents manufacturers, regulators and consumers.

Questions put to regulators by the detergents industry indicate that industry is challenged by issues including double labelling, overlapping and practical issues regarding the amount of information to be fitted onto labels. Regarding classification of mixtures, approaches used by the detergents industry are not always agreed to by the authorities. For example, the use of bridging principles by the detergents sector has generated considerable discussion and a number of aspects need clarification. Stakeholders noted that in order for the CLP Regulation to function properly, the use of bridging principles needs to be clarified, at the international level if necessary.

The main issues highlighted during the consultation process that directly or indirectly impact the labelling of detergents are as follows:

- Inconsistencies in interpretation: the use of historical data, expert judgement and weight of evidence approaches to mixtures classification by companies is not considered to be consistent; Member States are considered to be inconsistent in accepting the use of non-calculation approaches to the classification of mixtures;
- As a result, the labelling of detergent products, and therefore the communication to consumers on safe use, is not consistent (see Section 3), and inconsistencies also arise from labelling requirements under other legislation);
- As mixture classification under the CLP Regulation only came into force in June 2015 it was, at the time of the case study interviews, still relatively new. At the time of preparing for this deadline, there were inconsistencies in Member States' interpretation of some definitions, for example 'placing on the market' (although this has now been resolved); and
- The length of time required to get a biocidal detergent product to market is not considered proportionate compared to that of non-biocidal products.

2.2 Definitions

During the initial stages of this case study concerns were raised regarding the possible inconsistency in the definitions of “placing on the market” and “manufacturer” in the Detergents Regulation with the definitions under other legislation within the legislative framework.

The definition of a manufacturer under the Detergents Regulation is much broader (and more inclusive) compared with the definition included in the CLP Regulation because manufacturers, importers and packagers are all classified as manufacturers (and subject to the relevant requirements) under the Detergents Regulation, whereas manufacturers and importers are considered separately under the CLP Regulation. Whilst this difference could be considered an inconsistency, evidence obtained during the consultation process indicates that no issues/impacts have been identified.

Discussions with stakeholders revealed that the definition of “placing on the market” under the Detergents Regulation was an issue when the CLP Regulation was first introduced. The definition of “placing on the market” is different under different pieces of legislation and it became clear that different Member States interpreted it differently with regards to detergents. This issue apparently took a long time to solve (it was still being discussed sometime after the 1 June 2015 deadline), which caused considerable uncertainty.

2.3 Coherence and consistency considerations

2.3.1 Consistency between legislation (relevant to labelling of detergents)

Detergents are subject to numerous pieces of legislation, e.g. Detergents Regulation, Biocidal Products Regulation, CLP, and transport legislation; in addition, the Cosmetic Product Regulation must also be taken into account where relevant in terms of classification, ingredients listing and labelling. One of the objectives of this case study is to consider the interplay of the different pieces of legislation concerned and identify how consistent this interplay is, particularly as regards labelling.

CLP, the main regulation driving classification and labelling of detergents, is purely hazard based, whereas the Biocidal Products Regulation, Cosmetic Products Regulation and transport legislation are all, in varying ways, risk-based. Stakeholders contacted as part of this case study noted that the inconsistency of interpretation between regulations is a significant issue. It was noted that it is becoming more problematic in the area of CLP and the Biocidal Products Regulation guidance.

2.3.2 Classification of detergents - examples of inconsistencies for consumer (retail) detergents

As regards classification and labelling of consumer products, a number of examples of inconsistencies resulting from different legislative requirements were identified during the consultation process (note that labelling and consumer communication issues are dealt with in more depth in case study 9).

An example of inconsistencies cited by industry is the case of shampoo and hand washing-up liquid, which are almost identical formulations falling under different pieces of legislation. Shampoo is a cosmetic product and therefore falls under the scope of the Cosmetic Products Regulation; shampoo products do not require hazard pictograms (as cosmetics are exempt from the CLP labelling requirements), but are required to be accompanied by safe use instructions. Washing-up liquid is

very similar to shampoo but falls under the scope of the Detergents Regulation and therefore is subject to CLP labelling requirements. Washing-up liquid can (via the calculation route) be classified as being corrosive to the eyes resulting in the need for either a 'corrosive' pictogram meaning "causes severe burns or eye damage", or (where demonstrated by test results) the 'exclamation mark' pictogram, which means "causes serious eye irritation" and "harmful in contact with skin", as well as relevant P statements. This therefore highlights the different classification and labelling requirements that apply (and potential inconsistencies in how products are treated) for very similar products that are regulated under different pieces of legislation.

Concrete examples of the potential for the same detergents mixture to be classified and consequently labelled in two different ways depending on the classification approach used, include the following:

1. A test mixture was tested and confirmed not to be classified for skin effects. Applying bridging principles and expert judgement, a substantially similar hand dish wash liquid would also not be classified for skin effects. However, this detergents product would be classified as hazardous to the skin if the CLP calculation method were applied instead.
2. Superwash is a detergent that is made by mixing three different pre-mixtures (e.g. bleaching agents, enzymes and perfume). Different classification outcomes are obtained via the calculation method if either a) each of the three pre-mixtures is considered as a single ingredient with its own ingredient concentration and classification or b) each substance in each pre-mixture is considered a single substance and its own classification and final concentration are used in the classification. In the first approach, the final classification is more severe since the calculation method overestimates the presence of hazardous components.

In the case of environmental hazards, stakeholders note that the chronic environmental toxicity classification endpoint which came into place with the introduction of the 2nd ATP to CLP, before mixtures fell under CLP, has resulted in detergent surfactants being classified. All surfactants are readily biodegradable because they must be so by law under the Detergents Regulation, but surfactants in the environment also have some toxic effect on aquatic animals, which leads to a classification under CLP (see also the discussion below on unintended consequences). In terms of labelling, surfactants with an aquatic toxicity cat. 3 classification require "harmful to aquatic environment" and "don't dispose of down the drain" statements on the labels. As detergents contain biodegradable surfactants which will degrade in the WWT Plant, they cannot be considered harmful to the aquatic environment. As to the second labelling statement, consumer understanding is not helped when products, that by definition are meant to go down the drain, contain a statement on the label affirming "don't dispose of down the drain".

These are therefore considered to reflect inconsistencies in the legislation with regards to the classification and subsequent labelling of products (including detergents), which can lead to consumer confusion as inconsistent messages are being given.

2.3.3 To what extent are the classification rules for mixtures fit for purpose

The extent to which classification rules for mixtures under CLP are fit for purpose for detergents mixtures is a key question for this sector, and stakeholders perceive that they are not fit for purpose. The main issue here is lack of clarity in the legislation. The rules should in principle be quite clear and should apply equally to all.

Although calculation rules will not be 100% accurate, it was noted that a precautionary approach which may lead to over classification may be considered justified where there is no testing. The problem is that the classification of a mixture can be difficult when there is the potential for surfactants and substances to interact, such that the calculation rules may not lead to the same result as if the mixture itself was tested.

The extent to which bridging principles should be applied is also a grey area. The use of bridging principles in the classification of detergent mixtures is recognised by stakeholders as being a key point where clarification, at international level if needed, is urgently required. This is because different interpretations of the permissible application of bridging principles are leading to multiple inconsistencies in approving mixture classification and consequent labelling.

The example of the eye cat. 1 issue is very relevant for this sector. All main surfactants, when tested in pure form, are classified as eye cat. 1. According to CLP rules, classification of mixtures can be calculated based on ingredients, and if a mixture contains more than 3% of a substance classified as eye cat. 1 then the mixture automatically will become eye cat. 1. However, if the mixture were tested, it would not be. There are test methods available, for example BCOP and ICE methods, which are both non-animal tests. They are validated and distinguish between a classification as eye cat. 1 and non-classified, but there is no validated test for the intermediate cat. 2 (eye irritant). This is an issue³. It is necessary to rely on bridging to historical data, expert judgement and weight of evidence, but this can lead to different results and may be challenged by authorities.

Member States also vary in terms of acceptance of weight of evidence for mixtures. Different Member States have different opinions as regards the classification of mixtures. Some mixtures may be classified based on testing and others on calculation, and the question is whether one can use the results of testing in classification of new formulations. It was noted that in the case of a product that contains five chemicals, where the producer wants to understand the CLP implications, firstly, they look to see if the required information is available from test or other CLP data. They then use the SDSs from the supply chain (which themselves are not consistent) and then cross reference with the Classification and Labelling Inventory (CLI) and find huge differences. Thus, almost from the start, the producer has to make technical interpretations, taking an expert position on classifying the formula.

DetNet is an example of an industry approach based on the principles set out in CLP to develop an industry network for classifying and labelling detergent and cleaning products for skin and eye effects. It was developed to act as the Detergent Industry Network for CLP Classification (“DetNet”) in response to the classification challenges for detergent and cleaning product mixtures. DetNet is a collective approach for sharing toxicological data on mixtures and on classifying detergent and cleaning products for skin and eye effects. The overall aim of DetNet is to provide a means whereby all manufacturers/suppliers of detergents and cleaning products can have access to shared test data and expert judgment to allow for a science-based process for CLP classification of products with respect to skin/eye effects⁴. DetNet includes the use of weight of evidence, which the detergents sector considers appropriate, and is appropriate under CLP provided adequate and specific justifications and documentation are included.

³ Note that the sector is working to get OECD support for an additional test (Histopathology to the ICE test) which would more clearly discriminate between eye cat. 1 (eye damage) and eye cat. 2 (eye irritant).

⁴ <http://www.det-net.eu/about-detnet/what-is-it.html>

A number of Member States have also expressed concern regarding the inconsistencies and differences in classifications that they see across companies; they suggest these may be due to a lack of expertise or sufficient resources in the SME sector. They also note that downstream users often use the CLI which is known to contain substances with different classifications, which may be leading to confusion. As bridging principles and weight of evidence are applied differently by different companies, the result is inconsistency. Likewise both the classification criteria and toxicity data are interpreted differently by companies. The access to relevant data may also vary between companies. The different interpretations possible due to the different methods of classification (expert judgement, bridging principles) result in the same formulation being classified differently by different companies. This can have particular significance where classification impacts further regulation, e.g. Seveso. As a result, the choice of classification of certain mixtures can also lead to uneven competition in the marketing of similar mixtures with differing classifications (e.g. detergent products that are either corrosive or irritant).

Finally, it was noted that, under the CLP Regulation, formulators should use the information provided by suppliers as input for the classification of mixtures. However, if RAC or EFSA or another scientific body's experts make a decision on a classification, this often means SDS formulation manufacturers need to use the Committee's interpretation rather than that on the SDS provided by the supplier, which may be different.

2.3.4 Testing and data interpretation

The detergents-related issues that have arisen with the move to the classification of mixtures under CLP include both human health and environmental testing and data quality issues. For human health, there are no validated tests accepted by some of the Member States that demonstrate the difference between light and serious eye and skin irritation. In particular, as noted above, there is no validated test method for eye irritant cat. 2, in the absence of which some Member States insist on the more conservative classification (cat. 1, which requires the use of the corrosive symbol). While the regulators indicate that it is difficult to have a system which covers "everything", and it takes time to resolve issues that arise, some Member States require the use of the corrosive symbol. This is mainly an issue for SMEs and for tested mixtures where (some) Member States do not approve the testing approach.

In addition, there is the issue of a change in classification of the same formulation due only to a change in the legislation. Under the CLP Regulation, triggers for eye and skin irritation have been lowered so an increasing number of products are classified as irritants. This is recognised by both industry stakeholders and Member State authorities. Industry stakeholders note that some products went from having zero classification (under the previous system) to being classified as corrosive under CLP. These stakeholders suggest that there is a need for reliable *in vitro* methods for testing irritants to be developed and accepted in a harmonised way, as it is no longer possible to do an animal test to clarify the actual hazard. As noted earlier, there is concern that overly conservative hazard labelling can lead to confusion and potentially result in consumers no longer paying appropriate attention to hazard labels.

In terms of quality requirements for testing (for example GLP or ISO), the use of old data can be an issue. It is suggested by stakeholders that the quality of data could also be looked at in a relative way; for example, the precedent could be set that as long as the research is repeatable with the same results, the data are considered suitable. However, it is also noted that this can be difficult to determine because repeating tests is expensive. From an industry perspective, it was noted that if *in vitro* data (probably (slightly) over predictive) are not accepted and animal testing is not possible, this may be problematic for global companies. With centralised R&D departments developing

formulations for global use, because animal testing is possible in some jurisdictions but not in the EU, this in turn potentially impacts the ability of the global company to use the new formulation globally.

With regard to the use of DetNet, industry stakeholders report positive opinions with respect to classifications based on the DetNet approach from a number of Member States, including Germany, Italy, Benelux, Poland, with others (France, Sweden, Ireland, and especially Greece) having concerns about, or not supporting the approach. The position of authorities in other countries is not yet clear⁵.

Those that expressed concerns typically support the DetNet principles in general, but reflect concerns over the use of non-validated test methods as part of weight of evidence within the approach, specifically the use of tests such as the Human Patch Tests and Low Volume Eye Tests in the context of a weight-of-evidence approach, as they are not listed in Regulation 440/2008/EC (Test Method Regulation). However, industry notes that Regulation 440/2008/EC explicitly does not exclude the use of such test methods. By references to REACH Annex XI, 1.2., the weight of evidence approach may include test methods not (yet) listed in Regulation 440/2008/EC.

From the above, it is concluded that the inconsistencies between Member States in terms of the classification approaches and justifications they accept relate more to acceptance of test methods than quality requirements, where the (lack of) availability of generally accepted tests for endpoints critical to detergents formulations results in inconsistent acceptance of classification approaches and/or of test data by the Member States.

2.3.5 Consistency in interpretation, implementation and enforcement

Consistency and clarity of language used in Regulation and Guidance

Industry and some Member State consultees noted that differing interpretations across Member States exist in part from the legal text, which is not always clear enough to ensure that there is little room for interpretation. In this respect, the transport legislation was mentioned as a good example of clear language which results in consistent interpretation. It was also noted that some Member States regard and use Commission guidance as a guide, while others see it as what *must* be followed. This difference in interpretation of the rules for classifying mixtures can result in the same formulation being classified differently in different Member States.

In addition, where issues in interpretation do arise, it is noted by stakeholders that they can be discussed at a range of different venues, which may itself lead to inconsistencies (e.g. currently, CLP issues are discussed at the Forum, Helpnet, Caracal and the Detergents Working Group, all of which may discuss the same issues).

Another aspect that is considered to require improvement is the need for clear language in Q&A's drafted by the Commission and legal services in order to facilitate consistent interpretation.

⁵ At end June 2016, based on Member States' input to this study.

Inconsistency in (some) Member States' interpretation

As noted above, one of the key interpretation issues is with regard to the use of bridging principles and weight of evidence approaches. Clarification on the way in which these should be used is therefore very important to increasing harmonisation across the single market.

As regards specific Member States, some countries such as France, Greece and Ireland are noted to read the law more strictly than others when it comes to issues such as eye irritancy. It was also noted across a range of stakeholder groups that Greece is very meticulous and very active in the area of labelling, not just for detergents but for all chemicals, with a particular approach to the classification and labelling of detergent mixtures. Due to the lack of harmonisation of interpretation in the EU, detergents products can end up with unique labels for Greece.

Differences in Member States' approach to enforcement

Industry indicates that approaches to enforcement can also be inconsistent at the Member State level, with this leading to inconsistent implementation and hence a lack of harmonisation across the single market. This is not surprising given that enforcement policy is determined at the national level and will vary given differences in national approaches and resources. Countries that were specifically mentioned as being very active in terms of enforcement include Greece, the Balkans, the Scandinavian countries, Germany and Poland.

More generally, the following issues were raised by industry stakeholders:

- Because goods move freely on the EU market, the recipient is often targeted by the enforcement authorities rather than the producer, for example, regarding compliance with CLP labelling and SDSs;
- Inconsistent enforcement leads to an increase in administrative burden for detergents manufacturers;
- There are differences in the extent to which Member States consider issues regarding accuracy in classifying and labelling detergent products: some work on education (active in giving training) at the detergent manufacturer level, others issue warnings, while others are more likely to impose fines, including criminal fines, or demand product withdrawal; and
- Some Member States appear to regard the purpose of labels as being primarily there for enforcement and compliance purposes, rather than primarily for user or consumer communication on safe use (see also case study 9).

Industry also noted differences between Member States in terms of acceptance of automated SDS text, which reflects differences to attitudes towards enforcement but also highlights the potential need for the detergents industry to communicate problems with its own suppliers. Formulators using an SDS IT tool have received varying comments on the same text for a given formulation sold in different countries. Some comments are relatively trivial, such as questioning a specific detail to be changed, a word omitted or why the exact wording of the guidance is not followed. The outcome of such discussions may be the need to change labels and update and re-circulate supporting documentation such as SDSs, with the timing of the change depending on agreement with the particular Member State concerned.

Across the Member States, Greece was highlighted as being the most active in enforcement terms, with measures including fines, product recalls and criminal prosecutions. Hence, companies putting detergents products on the market in Greece tend to take the most conservative route to classification. As a result, industry stakeholders note that classifications of products in Greece can differ from the rest of the EU. For example, in practice, products classified as a cat. 2 eye irritant

could be placed on the market (based on weight of evidence) across the EU, but this would not be possible in Greece.

2.3.6 Unintended consequences

The evaluation questions include consideration of unintended consequences, where these include: unnecessary regulatory burden, automatic mechanisms potentially triggering significant costs or benefits, obsolete measures or gaps in the legislative framework, etc. In practice, stakeholders interviewed for this case study generally commented on the overlaps, and therefore indirectly on unnecessary regulatory burdens.

One of the key issues raised by industry relates to biodegradability or degradability. CLP is updated under ATPs every two years for alignment with UN GHS and on average every year to adopt CLH changes or new harmonised classifications. Under the 2nd ATP to CLP, which came into play before mixtures fell under CLP, it is no longer possible to exclude ingredients that are readily (bio) degradable from classification for chronic toxicity to the environment. The consequences for detergents mixtures may have been unintended.

For detergents, this mainly affects surfactants. Although all are readily biodegradable, because they must be by law under the Detergents Regulation, surfactants in the environment have an effect on living species because they also impact the water/oil contact areas of membranes. Because surfactants also have some sort of a toxic effect on aquatic animals, this leads to classification of the detergent for aquatic toxicity. Even unstable substances can become classified as chronically toxic for the environment, as there is no way to officially define that these are rapidly degradable. For example, hypochlorite bleach is a very unstable product that reacts with many compounds, which makes it an effective cleaner. But it has quite a high toxicity for aquatic animals, and is classified as toxic for the environment, both acute and chronic under the 2nd ATP to CLP.

As a result of this classification, hypochlorite bleach falls under Seveso for both endpoints, and requires a specific derogation in Seveso III (see entry 41) to restrict Seveso sites to only those stocking higher quantities (200 tonnes or more) of hypochlorite and its products. From industry's perspective, this highlights the need to define (rapid) degradability of inorganic substances.

In 2015 the Netherlands proposed a change in harmonised classification for hypochlorite and, in 2016, the RAC concluded a final opinion, adding aquatic chronic 1 H410, acute M-factor 100 and chronic M-factor 10 to the existing classification. As a result, and as was pointed out during the public consultation on the proposed classification, there are consequences, for example for storage; these consequences are also relevant for companies and products in the detergents sector. Once this new classification is added to Annex VI of CLP, sites with products containing more than 0.25% of hypochlorite and with more than 200 tonnes of product will be subject to Seveso. This consequence cannot be laid either at the door of CLP or of Seveso. As RAC pointed out in their response to comments to the public consultation⁶: "We are aware of the consequences given the Seveso directive but would like to point out that it should be of no influence for the derivation of the correct classification which should be purely based on the intrinsic properties ... of the substance. Hence, this argument is not relevant for the discussion." And, similarly, this change in classification cannot be blamed on Seveso, which directly links to the hazard classification of a substance.

⁶ <https://echa.europa.eu/documents/10162/e17f9569-0db3-47f5-a378-a9cc91bac87c>

This issue of the consequences of the automatic link between CLH and Seveso was raised in numerous interviews, by multiple industry associations (not only detergents) and by industry, with consequences noted as relevant in numerous countries, including the Netherlands and Greece. Industry stakeholders consider this consequence to be disproportionate to the risk, as there has been no change in the intrinsic properties of the products, only in the definition and therefore classification of the hazard. One example of an impacted SME is a company in the Netherlands, a long-standing small company which purchases and dilutes hypochlorite for onward sale, and which is located in a town which has a policy of not permitting Seveso sites. This means that due only to the change in hazard classification of hypochlorite, this SME could face severe consequences once the new harmonised classification is added to Annex VI.).

In addition, as more detergents products are drawn into Seveso III because of stricter environmental classifications, distribution centres are likely to be impacted. For big warehouses and production sites, it may not be a new issue, as most will already fall under Seveso III; but hypochlorite bleach provides an example where a new environmental classification may pose problems not only for smaller companies but also for warehouses of retailers, where these are not used to Seveso III measures for their storage.

This specific hypochlorite issue (which impacts the detergents sector in particular) exemplifies the linkage between CLP and automatic downstream legislation which uses CLP hazard classification as a trigger, in this case Seveso.

2.3.7 Gaps in legislative coverage of products or market initiatives

One emerging new issue is cleaning products that contain micro-organisms. These do not have a biocidal claim, however, are often considered to be biocidal products by Member States. If they contain soap or surfactants, they fall under the Detergents Regulation but the micro-organism aspect is not covered by the current Regulation and this has been identified by authorities as needing to be considered in the evaluation of the Detergents Regulation.

Industry stakeholders have also indicated that animal skin care products fall between sectoral legislations, as these are not defined as cosmetics (as are human shampoos for example) and do not fall under the scope of the Cosmetic Products Regulation, nor are they detergents. Although they fall under CLP, they believe that this is an inconsistent treatment of these products, representing a gap within the sectoral legislative framework.

Zero-waste shops⁷ or refill outlets, where bulk detergents are used for refilling domestic use containers, are a form of container recycling. The zero waste sustainability initiative aims to popularise eliminating waste, thus this can be seen as an example of legislation creating an opportunity for innovation. However, regulators are concerned that this results in a lack of control of proper labelling, and a lack of control on the use of proper containers. Although the Detergents Regulation specifies that certain information must be legible and visible on the packaging, it does not cover the refill situation. This could result in potential issues in terms of protecting human health and the environment if the correct labels are not included with the associated detergent products.

⁷ See for example: <http://zerowasteshop.uk/content/about-us>

2.3.8 Biocidal Products Regulation related issues for detergents

Detergent products are subject to the requirements of the Detergents Regulation, CLP, as well as in certain cases and for particular ingredients, the Biocidal Products Regulation and the Cosmetic Products Regulation. Of these, the Biocidal Products Regulation is reported to provide the most significant challenges to the detergent industry, which can be regarded as a coherence issue.

Information received from stakeholders indicates that, while the concept of mutual recognition is laudable, it does not seem likely that it will happen in practice under the Biocidal Products Regulation. It is noted that Member States use “specific local requirements” to justify not applying mutual recognition. Under the Biocidal Products Regulation, when product use is included under the mutual recognition principle, Member States determine how parts of the label should be worded, generating ambiguity, uncertainty and inconsistency between labels in different Member States.

The length of time required to gain approval is also a key challenge. The time to market used to be a matter of months between an industry request for substance approval and placing of a product on the market; this can now take a number of years (over 5 years in some cases). An example was given of a company that submitted a large number of detergent (with biocide active substances) product dossiers in 2012, with the active substance having been approved. The Rapporteur Member State was expected to provide an assessment within two years, however, this was extended by one year (when BPD changed to Biocidal Products Regulation), at the same time some of the guidance changed. For the dossiers that had already been submitted, the company was asked to submit new data in line with the new guidance (thus leading to additional costs). Almost four years later, the company does not have an initial authorisation from the Rapporteur Member State, and will move to mutual recognition. If other countries do not accept the approach taken then there could be further delays and possible rejection of mutual recognition resulting in different safe use instructions and different labels in different Member States. This is considered to be contrary to single market principles.

It was also noted during stakeholder discussions that Member States authorise biocidal products and maintain the power of labelling those products for use in their country. When there is a change in classification of raw materials, there is a high administrative burden because the product manufacturer has to re-apply for authorisation.

3 Other Detergents Issues Impacting Effectiveness, Efficiency and Relevance

3.1 Labelling issues

3.1.1 Summary of issues

As has been noted before in this case study, the classification of detergents mixtures directly impacts the labelling. This section considers the clarity of legislative requirements on communication via labelling of detergents products as well as the single market objectives, to be achieved through harmonisation.

Industry stakeholders highlighted a number of issues relating to clarity of legislation, inconsistent interpretation of legislation, and changes in classification leading to changes in pictograms and labelling, which negatively impact the harmonised application of information requirements throughout the EU:

- While the CLP Regulation is clearly hazard based, other key regulations for chemicals, such as PPPR and Biocidal Products Regulation, are risk-based approaches where exposure is taken into account. However in the Detergents Regulation, there is much less of an assessment of ingredients that go into the detergent, with only the environmental part related to characteristics of surfactants being assessed. The Biocidal Products Regulation and PPPR also restrict the use of certain surfactants;
- Most detergents products are now classified as hazardous under CLP. Under the DPD there were fewer classifications because of higher thresholds. For retail consumer products that are not acutely hazardous, consumers used to see them as not hazardous at all but now the same products are labelled as hazardous, typically carrying the 'exclamation mark' symbol indicating eye irritant;
- A major issue is the consistent labelling of products, which will depend on consistency in classification. As discussed in the previous section, this is an issue for the sector and both companies and some authorities note that non-test approaches are more likely to lead to the need for a 'corrosive' symbol on labels rather than the less severe 'exclamation mark' symbol. At UN level, it has been agreed that it is not necessary to use the 'corrosive' symbol for detergents, only the 'exclamation mark' symbol, but the words 'corrosive to metals' are still included on certain products;
- From the classification and labelling perspective, one area that is complex is the Biocidal Products Regulation because at Member State level the Member States have all the say on labelling in their Member State. For detergent mixtures, if not in the remit of Biocidal Products Regulation, the label content required can fall under various regulations (such as CLP and Detergents Regulation, and for allergens the Cosmetic Products Regulation). Labels are therefore quite full and not easy to read or understand from the perspective of downstream users and consumers. It is suggested that simplification of product labels should be considered to ensure that the most relevant and important information is communicated. In principle, there are double requirements from authorities under the Detergents Regulation and CLP;
- In terms of communication to downstream users, under the Detergents Regulation they require an ingredient data sheet but other regulations use SDSs. Stakeholders have indicated that it is unclear why there is this difference and that the same SDS could work for detergents too; and

- Surfactants are biodegradable (as required by the Detergents Regulations) but classified as “may be harmful to aquatic environment”. This is clearly, or at least potentially, confusing communication from a consumer perspective.

A big pressure point for industry is the issue of labelling in multiple languages. Some Member States require their language to top the list of multilingual information, meaning different labels for different Member States; some Member States have different interpretations of a formulation classification to others, meaning specific labels for that Member State. This latter point is an issue for detergents and also for biocidal products where Member States give instructions for the labels to be used in their country. From the perspective of communicating to consumers on safe use and risk management, there is no guarantee that, for example, a French label on a product sold in France will be comprehensible to all consumers. Given the right of freedom of movement of individuals in the EU, it is clear that many users of domestic chemicals and, indeed, of professional products (in the construction and renovation sectors, for example), may not be fluent in the primary language of any single EU Member State. This means that the objective of communicating safe use to these detergent product users may not be met by a single language label. Even for multilingual labels, risk communication can only be successful if the consumer is able to understand one of the languages on the label. In Finland, for example, construction products are labelled in five languages including Russian and Estonian. This issue is also discussed in case study 9.

As part of the consultation process undertaken for this study, Member States also noted issues as regards non-compliance with labelling requirements (not necessarily detergents specific, but nevertheless detergent labelling relevant). Some of the key issues identified include the following:

- Incorrect classifications;
- Labelling not in the language of the country being placed on the market;
- Label did not identify substances in a mixture that contribute to the classification of the mixture as set out under Art 18(3) (b) of CLP;
- Labelling and hazard pictograms did not reflect the actual classification of the substance/mixture – with there being differences in classification of the same substance across Member States;
- Limited hazard information on the label particularly in relation to products imported from outside the EU;
- Inconsistency in the information provided on the label and SDS;
- Label not using the correct language, use of non-existent pictograms, misprinted and illegible labels; and
- Issues regarding the space dedicated to compulsory information versus marketing information, with labels sometimes overloaded, making it difficult to focus on essential information.

The above issues suggest that at present information requirements for detergents labelling are not sufficiently clear to allow harmonised application throughout the EU, affecting the extent to which single market objectives are being achieved. The key issues identified are discussed in greater detail in the following sections.

3.1.2 Conservative classification and the labelling consequences

As discussed in Section 2, compared with requirements under the Dangerous Preparations Directive (1999/45/EC (DPD)), general concentration limits for the classification of mixtures for serious eye damage/irritation have decreased significantly under CLP, e.g. for cat. 1 from 10% to 3%. As a result more mixtures are classified as Eye Dam. 1 using the conventional method based on concentrations of ingredient substances. For Eye Dam. 1 the ‘corrosive’ pictogram GHS05 is assigned, while in the previous legislation (DPD) it would have been the St Andrew’s cross. Therefore, based on

conventional methods, the hazard symbol of many household products such as several hand dishwashing detergents would change from St Andrew's cross to the 'corrosive' pictogram, making these products more difficult to distinguish from corrosive products such as drain cleaners. This may have resulted in over-labelling (or inflationary labelling), which can create problems for consumers as appropriate classification and labelling is essential for safe use.

With regard to the 'corrosive' label and detergent mixtures, it was noted that the criteria which are the basis for classification as 'corrosive' do not allow differentiation between slightly corrosive and strongly corrosive. Thus, consumers can be misled (for example, concentrates of hand dishwashing detergents are classified as 'corrosive' if classified on the basis of the calculation method (because of the high content of surfactants) and so are pipe cleaning products (because of the content of sodium hydroxide)).

An example provided by detergents stakeholders is vinegar, which is used in kitchens at a concentration of 5-7% typically, but can exceed 10% in some cases. Chemically, vinegar is acetic acid which is classified as corrosive (in its pure form) and as irritant when provided in concentrations above 10%. Thus, labelling kitchen vinegar with an 'irritant' pictogram would not help the consumer and instead create confusion. The point here is that a consumer knows very well how to use vinegar as part of food preparation, so any hazard symbol is likely at best to confuse as it does not match with the consumer's known and trusted experience. At worst, it could lead to the consumer ignoring the same hazard warning on other products and, at the very worst, this could lead the consumer to ignore other hazard pictograms defeating the objective of consumer communication.

Hence, industry argue that such labelling of detergent products does not necessarily increase consumer awareness of hazards associated with products and may lead to them ignoring labels and/or to increased confusion due to the difference between the label and consumer experiences. On this basis, it is suggested that classification under CLP does not allow for clear and consistent consumer communication regarding products with skin and eye irritation hazards, as hazards ranging from in severity are covered by a single CLP symbol (the 'corrosive' symbol).

Another example relates to the use of the serious health hazard (exploding chest) pictogram to indicate a respiration hazard on a toilet cleaner, which is not deemed very useful for consumers as it does not indicate the specific hazard warning. However, it is suggested that a hazard/precautionary statement of 'do not breathe in the vapour during cleaning' is a helpful guide for the consumer and provides clear details of what should be avoided during product use.

Member State authority respondents also note that the Detergents Regulation has its own additional labelling requirements beyond what is required according to CLP. It is suggested that these demands are too detailed and are in fact unnecessary since CLP entered into force and that they could be removed.

3.1.3 Listing of ingredients

A number of points were raised by Member States on inconsistencies between regulations and on lack of clarity on certain points of regulation. In the case of the Detergents Regulation and the CLP Regulation, Member States have indicated that there are inconsistencies and overlaps with regards to the listing of allergenic substances. It is also noted that with respect to the Detergents Regulation and the Cosmetic Products Regulation, there are labelling issues and potential overlaps, for example in relation to the use of INCI names and allergenic fragrances.

Compositional/ingredient labelling is compulsory for cosmetics in the EU and is useful for those who are allergic, for example. Chemical names (IUPAC names) are different in different languages, which

is a problem for consumers. Cosmetics therefore use an international nomenclature which does not need to be translated (INCI, i.e. International Nomenclature for Cosmetic Ingredients) so that a consumer can recognise the substance wherever it is bought (contributing to enhanced consistency and consumer comprehension of labels). INCI names derive from the U.S. system which is 95% the same as in the EU but with one difference. In the U.S. certain ingredients (e.g. milk, honey, and eggs) can be listed in their English names, whereas in the EU it is not permitted to use only one EU language. As a result, to avoid translating these names into all EU languages, the Latin name is used. However, stakeholders indicate that the use of Latin words is not necessarily understood in all EU languages, which means that only a proportion of consumers will be able to determine the ingredients used in these products.

With regards to allergens, there is a link between the Detergents Regulation and Cosmetic Products Regulation. In the case of fragrance allergens, the detergents sector must use the same listing required under the Cosmetic Products Regulation for all detergent products. This initially created an issue with regards to double labelling of certain ingredients under the Detergents Regulation (using IUPAC names) and the Cosmetic Products Regulation (using INCI), when detergent mixtures first became subject to the requirements of the CLP Regulation. After considerable discussion and with the pragmatic participation of all stakeholders concerned, this has been resolved and it is now accepted that it is only necessary to use INCI names. This is therefore a positive example of resolving issues that have been identified by stakeholders when classifying and labelling detergent mixtures under CLP.

Stakeholders have also noted that over the last 20 years the number of allergens needed to be listed on detergent products has remained relatively constant. Currently, there are 26 allergens with labelling requirements if present in a detergent at > 100 ppm (0.01%), and there is a requirement for fragrance or preservatives allergens ingredient declarations on detergent manufacturers' website. However this allergens list is currently under consideration by the Commission, who are looking at expanding the list to one of 80 or more substances. This will result in more allergens being listed on the pack, possibly leading to a tripling of the number of allergens listed on product labels. Whilst informing consumers of the allergens contained in products is useful for enabling informed choices, industry is concerned that this could result in too much information having to be provided on labels, which may be detrimental to consumer understanding.

3.1.4 Over-labelling and consumer understanding

Over-labelling is an issue frequently highlighted by industry stakeholders, including both the amount of information on a label and the need to include some mandatory information which leads to consumer confusion. Industry stakeholders note the following (over) labelling issues are currently being encountered:

- As noted above, double listing of ingredients under the various legislations, as CLP requires listing of allergenic perfumes and preservatives, the Detergents Regulation listing of perfume allergens and preservatives, and the Biocidal Products Regulation listing of preservatives;
- Labelling complexity leads to increased space demands, raising inventory complexity with more labels (SKUs) required to accommodate European language needs;
- There are higher costs with labelling multiple packaging layers; and
- Formulation changes not requiring artwork changes today should not require new artwork to manage the complexity associated with the introduction of a Unique Formula Identifier (UFI) under Article 45 of the CLP Regulation.

Figure 3-1 on the following page provides a practical illustration of the amount of space on a detergents product label given to regulatory and marketing or branding information as well as safe-use icons.



Figure 3-1: Example of types of information included on a detergent product label

As regards the various regulations that impact the communication of hazards to detergent consumers, it is clear that while stakeholders perceive the value of harmonisation to be a key aim, in practice differences occur in almost all countries (whether large or small) in implementation which have to be taken into account by detergents manufacturers when labelling. Part of the issue is that enforcement is undertaken at the local level. In this case, if an auditor in one country has a different view to an auditor in another country, there is a problem with harmonised communication on safe use to consumers. There are national differences and cultural differences, but the regulations are very complex, with a large number of guidance documents and the whole picture is very hard to understand for companies and Member State authorities.

Stakeholders note that the regulations and in some cases the accompanying guidance documents are not written clearly enough to be consistently interpreted. For example, there is ambiguity around CLP and pictograms and fold out labels. It is noted that the guidance can be read in one way but then the examples given may show something different.

Stakeholders also indicate that in general what is relevant for the safety of consumers is written text that can be easily read, however, issues occur whereby the text on labels is included in too small a font to be easily read and understood. Also, in some cases, the text can be difficult to read as the font is not included in a suitable colour.

It was noted that the fact that there is more and more information on the product label does not mean that this is good consumer communication. It was suggested that safe use instructions for detergents (as with cosmetic products) should be enough. However, it was also noted that, on the other hand, symbols can work as a warning if they are simple and intuitive as large amounts of text are generally not read and the burden of text and multiple languages can lead to information overload. The detergents industry is of the view that there could be better ways to inform consumers regarding the hazards associated with detergent products. For example, it was suggested that CLP for classification of mixtures should be kept, but meaningful and actionable safe use advice should be given to consumers, potentially with relevant pictograms, to ensure that they use the

products in the most appropriate way to ensure safe use. It was noted that the CLP labelling includes the wording advice but no specific pictogram to indicate what to do and how to use a product safely.

It was also noted that consumers do not know there are three levels of hazards – environmental, human health and physico-chemical hazards, and they may not know the difference between hazard and risk. As a result, CLP compliant labels may not communicate to consumers properly (it was not designed for consumer communication). Stakeholders across the different stakeholder groups agree that the hazard labelling under the CLP creates confusion and can lead to consumers disregarding hazard information, which in turn could lead to a misuse of products (e.g. consumers may put liquids down the drain that should not be disposed of in this way). It was suggested that educating consumers may assist in increasing their understanding of hazard labels.

Some stakeholders (and across different groups) noted that a system of communicating on the label of consumer products with clear and comprehensible information, for example, using simple pictograms and safe use instructions/icons complemented by all additional information being accessible via a bar code or QR code could be of real value to consumers (although this would need to be verified by research).

3.2 Innovation

This section considers innovation in the context of detergents. It should be noted that some stakeholders' comments on legislative impacts on innovation given here do not necessarily specifically relate to the classification and labelling of detergents.

When asked to what extent the chemicals legislative framework has contributed to innovation in the detergents sector, stakeholders were consistent in their message that CLP does not prevent but does not help innovation in this sector. It was also noted numerous times that the focus on compliance (which is critical for business continuity) may impact negatively on resource and budget availability for research and innovation. This cannot be expected to apply equally to all companies, with larger companies presumably experiencing this effect to a different degree to SMEs, for example.

Stakeholder comments on the impact of chemicals legislation are detailed below:

- It was noted that the way in which a company moves to new technologies or new activities is not always clear. In some companies, this is driven by corporate strategy. Ongoing innovation is at the heart of the detergents sector and new formulations are constantly being developed. The detergents sector was used to dealing with innovation under the DPD but as CLP is more conservative, it has a bigger impact on innovation in this sector;
- Within companies, innovators complain about the lack of clarity about the legislative situation in 10 years' time. There are only indications and no certainty. This leads to business uncertainty and situations where the company is asked to hold off on innovations that could be profitable because of the lack of regulatory certainty;
- It was noted that in terms of innovation and research, large companies develop formulations on a global basis, for global use. In the EU there is a more restrictive Detergents Regulation than in other regions, which impacts innovation and research. Also, due to the Biocidal Products Regulation's lengthy process and uncertain outcome, detergent manufacturers developing new products containing active biocide ingredients are asked to invest in innovating products that have no guaranteed future. Once there is certainty about what can be used in terms of active ingredients, a company can try to continue to innovate within a limited range of options. The increasing number of hurdles means innovation budgets are (more) severely constrained;

- CLP hampers innovation, for example, in terms of ingredient concentrations which can be used in the detergent mixture, whereas the Biocidal Products Regulation hampers innovation in terms of resources (e.g. time and money required to gain an approval of an active substance). For detergents with approved active substances, the time to market can be two to three years (due to the need for a full dossier submission and competent authority evaluation). In the Fast Moving Consumer Goods (FMCG) sector, a critical element of innovation is the speed at which products can enter the market. Larger companies are able to deal with the work that needs to be undertaken to submit a dossier under the Biocidal Products Regulation. However, it slows the process, because using an approved active substance means submitting a dossier which the authorities have two years to consider. The high costs of these dossiers can be an issue for SMEs;
- On the other hand, surfactant and phosphate requirements in the Detergents Regulation have meant that new ways of cleaning have had to be found and to this extent, it can be said that regulation has stimulated innovation;
- Legislation has put pressure on some products, leading to delisting, either because the required pictogram is one the company does not want to have on their product, or because some substances are no longer supplied in the EU. Stakeholders noted that the (possible) need to include a corrosive pictogram on a consumer detergent, for example, can stop a line of innovation. Many detergents companies do not wish to have the corrosive symbol on their products (which can be the outcome of a calculation-based classification, or the outcome in some Member States who effectively insist on a corrosive pictogram), so will not continue to develop an innovative formulation which could have multiple other benefits, purely because of the corrosive pictogram; and
- It was also noted that many really new innovations used to come from SMEs (who are now more focussed on compliance than innovation). There are always ongoing innovations and products are safer, but CLP has not contributed to innovation. However, at a higher and more general level, the framework has contributed to safer use.

In conclusion, new ways of cleaning are being developed in response to the Detergents Regulation, and in this respect the legislation can be considered to have stimulated innovation. However, with budget limitations many companies and particularly SMEs have had to focus on CLP compliance rather than research and innovation. This suggests that CLP may have set innovation back, perhaps for a number of years, and especially for SMEs, the section of the sector that generally makes a significant contribution to innovation. CLP's lower classification thresholds mean many more formulations are classified and a corrosive classification for some companies will be sufficient to stop research into an innovative formulation.

3.3 Transition times

Research undertaken for this study indicates that the CLP Regulation is not always efficient in terms of the transition times that are allowed, as all players in the downstream user supply chain have the same deadline for implementing change. This may not only increase the costs of compliance, but inadequate transition times could also have other knock-on effects, for example, in terms of enforcement.

This section considers the transition period of 18 months allowed under the GHS from the perspective of detergents labelling. Consultation undertaken as part of this case study indicates that it is not always clear what the 18 month transition period refers to. This can depend on the products affected and on the understanding of what the 18 months is meant to cover. It was questioned whether the 18 month transition period refers to all updated products on the market or all updates implemented into the company system ready for use at next opportunity. Therefore, if updates are

required to be visible on the market, this could mean implementation (into full production) within nine months, which is not considered feasible. Companies may need to use a disproportionately large amount of resources in order to keep up with the small changes (e.g. editorial changes or changes in raw material classification), even without significant/important re-writes of legislation or issuance of new guidance.

It was also noted during the two year transition period for the labelling of mixtures under CLP that one of the issues encountered was the lack of classification information from suppliers or, if the information existed, it was delivered too close to the 1 June deadline and could no longer be taken into account when re-labelling the products. This time delay in receiving information from suppliers will continue with new ATPs, unless a more pragmatic approach, such as varying deadlines for substances, intermediary mixtures (also called mixtures in mixtures) and end-use mixtures, is found.

The P105 phrase is a P-phrase originally recommended but omitted from labels because it was not compulsory. In December 2015 it was deemed by ECHA to be mandatory not just recommended which has significant consequences in terms of the number of labels affected. There is an 18 month transition period and most changes will be made in that time but many will not. The impact is costly both for changing labels and for putting a special project in place to deal with low-label-turnover products, such as shoe care products.

In conclusion, the EU approach of having an 18 month transitional period for applicability of GHS updates is generally perceived as being sufficient (depending on a company's position in the supply chain) but the constant need to re-label is a cost burden. Minor changes (such as editorial changes, e.g. wording clarification) have no real benefits but can have significant negative impacts due to re-labelling requirements. In this sense, a longer transitional period or longer delay in the EU adoption of minor changes would be desirable. Proportionality and assessment of the costs and benefits of proposed changes could support this analysis. Also, the situation is getting increasingly complex with many changes being required and overlapping transitional periods.

3.4 Safe-use icons and detergents labelling

The ECHA Study into communication on safe use of chemicals points out that “in certain cases, industry has undertaken voluntary information campaigns to increase users’ awareness and encourage the safe use of their products”. Yet such campaigns have largely not been based on the new CLP hazard pictograms and have focused on images and symbols that addressed certain types of behaviours or hazards; an example is the A.I.S.E. campaign on “safe use icons” (ECHA, 2012). However, it is important to note not just that the legislative framework allows for such additional communication but also that the addition of a system of safe-use icons can be seen as a result of the need to communicate more clearly to consumers on safe use in a way that is not enabled by the CLP system.

For this case study, it was noted that safe-use icons are routinely used as a means to communicate sensibly to consumers/users of products. Voluntary initiatives such as the safe-use icons used in the detergents sector, are generally (but not universally) regarded positively. Voluntary safe-use icons and statements may be used in particular Member States to deal with a particular issue, or by some industries, like the detergents industry, as a means to communicate to consumers on how to safely use a product.

As an example, in the Netherlands, there used to be a problem with hypochlorite where consumers were mixing this with acids. On a voluntary basis, a pictogram was introduced which stated: “do not mix this”. This pictogram was shown to be an effective communication tool as within a year, the

number of associated accidents had reduced. This demonstrates that symbols that clearly say what is meant and/or how to act do in fact work.

In the detergents sector, the set of A.I.S.E. safe-use icons are used consistently by members of the detergents industry association, increasing consistency and clarity of communication and increasing consumer awareness of safe use. Amongst the Member State responses, more stakeholders agreed that voluntary icons are effective in communicating to (downstream) users than not. However, some Member States noted that they are considered misleading and sometimes appear at first sight to say the opposite of CLP pictograms, and that voluntary measures may lead to confusion, especially visual confusion as very large icons can divert attention from the CLP information. More generally, concern has also been expressed that safe-use icons and marketing information take up space that could better be given to regulatory pictograms and statements. Member States were more or less split in opinions as to whether a reduction in labelling requirements to provide only the most important hazard information on the label may be appropriate, if additional information is available as part of use instructions.

In 2010-2011, A.I.S.E. conducted a second round of market research on consumers' understanding of the safe-use pictograms, which confirmed that consumers had a relatively good understanding of most of the icons, but recommended improvements to some of the icons. In addition, due to the growing use of liquid laundry detergents in the form of capsules, A.I.S.E. added four new pictograms in October 2012. The current set of safe use icons is illustrated in Figure 3-2.

The fact that A.I.S.E. has developed and introduced such icons for inclusion on labels alongside CLP pictograms and hazard phrases and statements indicates that the legislative framework does allow for a supplementary approach to hazard and safe use communication. It also suggests that industry itself will respond to such a need where it is important to ensuring safe use and where the labelling requirements do not meet the needs for communicating effectively with consumers.



Figure 3-2: A.I.S.E. safe use icons

3.5 New technologies (bar codes, QR codes) for detergents labelling

This section briefly considers comments made by stakeholders regarding the possibilities of using new technologies such as apps, QR codes or bar codes in addition to labels.

The use of new technologies to complement labelling and provide further information to consumers is clearly seen by stakeholders as providing opportunities. Such technologies include bar-codes, QR codes, apps, and all similar digital media. Comments received from stakeholders include:

- This could be a way to provide additional information, supplementary to ingredient and safe use information on the label;
- Any such move would require clear guidance in advance if the issue of inconsistent Member State acceptance is to be avoided;
- This could be of benefit if it helps to simplify the label;
- The necessary technology (e.g. an electronic device) would have to be available to all consumers as would an internet connection; and
- The use of any new technologies would need to be well developed before being introduced.

It was noted that it may be possible to gain advantages by using a smart tag to access information in all EU languages, for example. In the Detergents Regulation, there is this requirement to list label details on the manufacturers' websites but it was questioned whether producers do in fact then provide all information in all languages. However, it was also noted that not all detergents products are properly labelled in terms of the web address requirement.

Stakeholders are generally positive about the opportunities offered by new technologies for communication with consumers, in addition to labelling. In particular the use of these technologies could assist in reducing the amount of information on product labels, thus enhancing understanding by focussing consumer attention on the most important elements.

3.6 Maintenance products

Maintenance products in the detergents sector are sold to a variety of sectors for cleaning and maintenance. These products are used to clean and maintain a range of facilities including in buildings, hospitals, clinics, schools, restaurants and hotels, farm and industrial installations.

This is a dynamic sector employing over 3.75 million people in 2008 (OSHWiki, 2016), with more than 75% of these being women, and around 70% part-time workers⁸. As a significant number of these workers may be from other countries, there can be an issue of worker ability to read and understand labels that are only in the language of the Member State in which they are working. For this reason, in Finland for example, and in the construction products sector, products are labelled in five languages including Russian and Estonian. The subject of multilingual labels is discussed in more detail in case study 9.

The key difference between users of maintenance products and household detergents is user training. While maintenance products may be more hazardous than consumer detergents, employers have an obligation to provide appropriate occupational safety and health training for

⁸ Note that these numbers exclude domestic cleaning workers.

their workers (however, it was noted by stakeholders that there is little enforcement of this obligation). Some Member States, such as the Netherlands, have dedicated websites for workers, for example, there is a website for the professional cleaning industry, and another for transport. Several manufacturers provide training to workers as part of their services (one example mentioned was producers of maintenance products providing training to hospital cleaning staff). It was also noted that some maintenance product manufacturers are working together with cleaning equipment manufacturers to design equipment that is safer for workers and that is more environmentally friendly. At EU level, sites like OSHWiki, sponsored by the European Agency for Safety and Health at work, provides information that is easily accessible via internet search engines.

3.7 Transport vs. CLP for the detergents sector: overlaps and inconsistencies

ADR is the EU treaty (a one-on-one implementation) of the UN's Model Regulations on the Transport of Dangerous Goods. It is considered to be clear and consistent in terms of detailing how to determine which packaging group, labelling pictogram and UN code must be used for transport, also internationally. This clarity means in general that there is little room for significant differences in interpretation of the legislation. Also, ADR is easier because it concerns only industry and professionals whereas CLP is complicated by the application to consumer communication.

Road transport is the main mode of transport of detergents within the EU and is the focus here. Transport legislation considers the risk of exposure during transport and becomes relevant when transporting a good that is considered hazardous under the transport legislation. Transport legislation covers outer, and to a somewhat lesser extent, inner packaging.

The transport legislation requires the substance or mixture to be identified (assigned a UN code), the hazard class must be determined and then the relevant packing group (PG) assigned⁹. Packing group assignment is based on how dangerous (i.e. really corrosive) the mixture is. The different packing groups have different transport labelling, packaging and transport procedure obligations.

Labelling is mostly in the form of pictogram(s) combined with a UN code (4 digits) to identify the substance. The UN code determines the product identification and this is often simple to apply for substances, but more difficult for mixtures. For many substances and mixtures, a harmonised class and PG assignment exists in the so-called Dangerous Goods List, which is maintained by a UN sub-committee. The 'classification' for many substances in the dangerous goods list is different to that in CLP Annex 6, so the transport 'classification' is not consistent with GHS/CLP.

For mixtures, the transport class and identification is based on substances in the mixture. If there is only one substance in the mixture which is classified for transport, generally the UN identification and classification of that substance is used. When the mixture contains multiple substances classified for transport, a generic "not otherwise specified" (NOS) identification can be selected depending on which is considered the most appropriate, based on expert opinion. The PG of the mixture should then be determined either by testing the mixture itself or taking the 'worst-case' PG of the substance(s) in the mixture.

⁹ Group I, II or III where I is for really dangerous (hazardous) and III is for the least dangerous goods during transport.

For detergents, the main hazards that are relevant for transport are environmental, flammable liquids class 3 or corrosive substances. There is considered to be an inconsistency between the labelling requirements under the CLP Regulation and transport legislation. Under CLP, the classification for skin corrosion may be based on extreme pH, which can lead to a classification as skin cat. 1A. The testing criteria that would lead to skin cat. 1A are the same criteria that would lead to a Packing Group I assignment for transport. The same is true for skin cat. 1B (Packing Group II) and skin cat. 1C (Packing Group III). However, there are many substances in the Dangerous Goods List with a 'lower' PG assignment than a PG based on testing results. There are several substances which are classified as skin cat. 1A under CLP Annex VI, for example, that may have a Packing Group II assignment in the Dangerous Goods List. This difference is due to the fact that in transport legislation, elements other than pure hazard are considered for the Dangerous Goods List.

This difference also leads to difficult situations for detergents. For example, a drain cleaner based on sodium hydroxide may be classified as skin cat. 1A under CLP, which would suggest a Packing Group I assignment. This link between CLP and transport legislation is often easily made and was already used in practice under the DSD/DPD directives. Using the CLP classification, a formulator would be able to derive a suitable PG without having to test the mixture itself. However, in this case it needs to be considered that (pure) sodium hydroxide is Packing Group II according to the dangerous goods list. A Packing Group I assignment would therefore be a significant over-classification of the mixture itself. While the DSD/DPD and transport legislation generally worked well together, under CLP there are many cases where it would not lead to a correct transport PG assignment. This can also have knock-on consequences as the costs for transporting substances considered under Packing Group I are much higher than under Packing Group II.

To address this problem, a proposal has been made at UN level to introduce alternative PG assignment methods for mixtures; using bridging principles and a calculation method. The proposal will most likely be formally accepted by December 2016 (the alternative methods were agreed in June, though some textual discussions are still ongoing¹⁰). Thus, at UN level, transport legislation is being changed to deal with the indirect consequences of the CLP Regulation and its differences in classification when compared to transport legislation.

Stakeholders have also noted that in the case of transporting substances/mixtures, Article 33 of the CLP Regulation is a real issue. CLP requires all packaging to be labelled with a CLP label if there is no transport label required. However, if the CLP pictogram for corrosion appears on transport packaging because the product is classified as corrosive to eyes, this may lead to problems for distributors. Many warehouse workers are used to working with transport labelling; hence they may therefore mistake the CLP 'corrosion' pictogram with the 'corrosion' pictogram under the transport legislation. This can create an issue as distribution workers may consider there to be a need for storage according to the transport corrosive pictogram when this is not actually required. Such products cost more to store, as they need to be insured. So in practice, the lack of significant difference between the pictograms used on packaging under two different legislations is likely to cause problems.

In conclusion, an alignment between transport legislation and the CLP Regulation is currently in progress. The main issues that remain relate to the similarity in symbols used under both pieces of legislation. There are proposals to introduce a new transport symbol to deal with CLP classifications which are currently not considered relevant for transport, in order to reduce the potential for misinterpretation.

¹⁰ Please see the calculation method here:
<http://www.unece.org/fileadmin/DAM/trans/doc/2016/dgac10c3/UN-SCETDG-49-INF65-Corr.1e.docx>

4 Conclusions

The conclusions summarised here deal firstly with definitions, then discuss the coherence of classification and labelling of detergents, followed by concluding remarks on the findings relating to the relevant efficiency, effectiveness and relevance evaluation questions.

This case study examined the different definitions of particular terms, such as “manufacturer”, under the various legislation relevant to the classification and labelling of detergents. The one definition identified in the case study that had proven to be problematic was that of “placing on the market”. Initially, different Member States interpreted the term differently when CLP was first introduced, but this has since been resolved through discussion and negotiation and is no longer an issue.

Conclusions on the coherence of legislation related to the classification and labelling of detergents products for consumers are that the various pieces of relevant legislation (e.g. Biocidal Products Regulation, Cosmetic Products Regulation, CLP, transport) are not fully coherent, neither in terms of classification requirements nor in terms of labelling (safe use or risk communication). This results in a number of inconsistencies and overlaps, leading in some cases to unintended consequences. One of the key inconsistencies is the difference in Member States’ interpretations of the classification of mixtures rules and of labelling requirements. Member States also differ in their opinions on and acceptance of this sector’s approach for using expert judgement and weight of evidence approaches, including the use of historical data, as well as the bridging principles as part of mixture classification. This leads to different labels for the same product in different countries. From the competent authority perspective, companies are not consistent in their approaches to classification, nor in their interpretation of classification criteria and toxicity data.

On the coherence question relating to test data¹¹, stakeholders from various groups noted that, for human health, there are no validated tests accepted by some of the Member States that demonstrate the difference between light and serious eye or skin irritation. Skin and eye irritant models can only say if a mixture is corrosive or not, but cannot give a degree of irritancy. In particular, there is no validated test method for eye irritant cat. 2, in the absence of which some Member States insist on the more conservative classification (cat. 1, which requires the use of the corrosive symbol). It is concluded that the inconsistencies between Member States in terms of the classification approaches and justifications they accept relate more to acceptance of test methods than quality requirements, where the (lack of) availability of generally accepted tests for endpoints critical to detergents formulations results in inconsistent acceptance of classification approach and/or of test data by Member States.

Classification of mixtures under CLP has led to the detergents industry associations developing DetNet, a common industry approach to the use of bridging principles for classifying and labelling detergents. This approach is not equally accepted across all Member States. Clarification (at international level if necessary) on the way in which the bridging principles used in the classification of detergent mixtures should be interpreted and implemented is therefore very important to increase the consistency of interpretation across Member States and to improve harmonisation. This will also increase the consistent application of classification approach amongst detergents

¹¹ Question 4.2.9: Are there any inconsistencies as regards quality requirements for data?

companies. This is very important, because labelling is the outcome of hazard classification and the means of consumer communication.

For household detergents, many of the labels required due to the more conservative CLP concentration limits and the impacts of the new hazard class for hazardous to the aquatic environment would not match, or be consistent with, consumer experiences, for example: a cashmere sweater laundry product being labelled corrosive, or “avoid release to the environment” for cleaning products that by definition go down the drain, or “causes severe skin burns” on hand washing up liquid¹².

Due to detergents labelling being subject to multiple pieces of legislation (Detergents Regulation, CLP, Biocidal Products Regulation, Cosmetic Products Regulation, transport), and because these are not coherent in terms of labelling requirements, there is an increased administrative burden on the sector, as well as the potential for inconsistent consumer communication. For detergents, there seems to be little coherent attention paid to how the substance or mixture is used. During stakeholder consultation it was noted that what is key is how a substance is used, and what risks are manifested in practice.

For labelling in the detergents sector, the lack of coherence between Member State interpretations (impacting single market effectiveness) and between legislation leads to increased inefficiency and increased administrative burden. In terms of the effectiveness questions relevant to this case study, issues of consumer understanding of pictograms and labels are dealt with in depth in case study 9.

Dual labelling (or double listing of ingredients under different legislations), is an example of the lack of coherence of requirements for labelling of detergents: CLP requires listing of allergenic perfumes and preservatives, the Detergents Regulation listing of perfume allergens and preservatives, and the Biocidal Products Regulation listing of preservatives. In addition, varying requirements by different authorities on the use of (multiple) languages on a label are not consistent.

In terms of efficiency, it can be concluded that classification and labelling of detergents mixtures has not (yet) resulted in the harmonised communication of hazards to consumers, due in part to the fact that the information requirements are not sufficiently clear to enable consistent application throughout the EU. As a result, it can be concluded that the legislative measures for the communication of hazards and thus safe use to consumers are not (yet) effective in helping to ensure that single market objectives are met.

As regards innovation¹³ in the detergents sector, new ways of cleaning are being developed in response to the Detergents Regulation, so the legislation can be considered to have stimulated innovation. However CLP’s lower classification thresholds mean many more formulations are classified and a corrosive classification may be sufficient to stop research into an innovative new detergents formulation. Unfortunately, examples cannot be provided for commercial sensitivity reasons. Furthermore, some industry stakeholders note that corporate strategies may effectively prevent a consumer product with a corrosive label being launched newly onto the market.

The extent to which classification and labelling rules for mixtures under CLP are fit for purpose¹⁴ for detergents mixtures is key and stakeholders perceive that they are not (yet) fit for purpose. The rules should in principle be quite clear, should apply equally to all and should be interpreted

¹² Consumer understanding of labels is discussed in case study 9.

¹³ See evaluation question 1.1.3.4

¹⁴ See evaluation question 1.1.4.1

consistently by all. This would result in consistent labelling and enhanced consumer comprehension of safe use.

The Cumulative Cost Assessment found that the detergents sector has the highest administrative burden of all chemicals subsectors, with these costs representing “almost 28% of the legislation cost and 3.2% of the subsector's value added.”¹⁵ Labelling requirements are an important component of the administrative burden. This case study finds that part of the administrative burden for detergents manufacturers may be due to inconsistencies in the interpretation of requirements at Member State level. The variations in national level enforcement and interpretation include differences in the acceptance of different approaches and data for classifying and labelling detergent products, with some MSs working on education (active in giving training) at detergent manufacturer level and others more likely to impose fines, including criminal fines, or demand product withdrawal. Some Member States also reportedly (by industry) have no measures in principle unless there is a serious breach of the rules, whilst others prefer to start with a series of warnings in a process of encouraging compliance.

The efficiency of transition times relates to the adequacy of time allowed for duty holders to adapt when new risk management measures are introduced. The EU approach of having an 18 month transitional period for applicability of GHS updates is generally perceived as being sufficient in this sector but the constant need to re-label is costly and the situation is getting increasingly complex with many changes in too short a time period leading to overlapping transition periods. A longer transition period or a delay in the EU adoption of minor changes (e.g. word/editorial changes) would reduce these impacts.

New technologies are perceived to offer opportunities to deliver more relevant consumer information on hazards and safe use (see also case study 9 on consumer understanding of labelling information). The information currently available is not considered to help enable consumers to make informed choices although the use of voluntary industry icons is generally considered to promote safe handling and use of the products.

As regards the continued relevance of the Detergents Regulation, a number of stakeholders questioned the current and future relevance of the Detergents Regulation now that it has served its primary purpose of regulating the biodegradability of surfactants¹⁶.

Finally, this case study finds that for retail detergent mixtures the current system of classifying and labelling detergents is time and resource-intensive for industry and competent authorities alike and the resulting consumer communication on safe use is not optimal. It is clear from recent successes in resolving classification and labelling issues (such as the use of INCI names and the definition of placing on the market) that increased harmonisation and streamlining is feasible. Increased harmonisation will benefit all stakeholders, reducing time, resource and budgetary demands for regulators, Member States and industry, while helping to ensure more consistent consumer communication and more consistent enforcement throughout the EU.

¹⁵ Cumulative Cost Assessment for the EU Chemical Industry, p.9.

¹⁶ Stakeholders from different stakeholder groups noted this and were consistent in their ideas as to possible solution.

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**Case Study 6: Differences in assessment
procedures for PBT and vPvB as properties of
concern**

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1. Introduction

1.1 Background and overview

Several pieces of legislation, namely REACH¹, the Plant Protection Products Regulation², the Biocidal Products Regulation³ and the Directives on Medicinal Products for Human Use and for Veterinary Use⁴, include criteria and procedures to identify Persistent, Bioaccumulative and Toxic substances (PBT) and very Persistent, very Bioaccumulative substances (vPvB)⁵ substances. Also within the scope of the Water Framework Directive⁶, PBT/vPvB may be identified as priority hazardous substances (PHS). The CLP Regulation includes no requirements for the classification and labelling of substances as PBT or vPvB.

Due to the different context and time of adoption of the legislation, differences may exist regarding the PBT/vPvB criteria, the quality of evidence required to identify PBT/vPvB and the related procedures.

Following PBT/vPvB identification, different types of risk management measures may be implemented automatically, or based on risk assessment and/or requiring additional implementation steps. These measures may be included in the legislation under which the substances are identified, or in other downstream legislation.

The case study analyses the status quo of PBT/vPvB identification (criteria, data use and procedures) and PBT risk management (RMM triggers / decision procedures, types of RMMs, including communication) in the pieces of legislation relevant to this case study. It complements the legal analysis with information on the evaluation of these aspects from literature and stakeholder consultations.

REACH and the Directives on Medicinal Products are not subject to the fitness check. These legal acts are therefore analysed only for the purpose of allowing comparisons and because some legislation refers to the REACH provisions.

¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

² Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

³ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

⁴ Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

⁵ The EU Regulation on Persistent Organic Pollutants implements the provision of the Stockholm Convention but does not include any criteria for the identification of POPs but directly refers to the annexes of the Convention.

⁶ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy.

1.2 Case study objectives

This case study report on “PBT/vPvB identification and risk management” feeds into Task 2 (horizontal links; PBT identification) and Task 3 (vertical links; risk management). The aim of the case study is to answer the following questions:

- Are there inconsistencies, gaps or overlaps between the different pieces of legislation related to the identification or risk management of PBTs?
 - Which mechanisms and factors cause inconsistencies, gaps or overlaps?
 - Which impacts arise for competitiveness, health and the environment?
- How are risk management measures triggered after PBT/vPvB identification and which types of measures exist? What type of data is considered in the decision making on PBT/vPvB risk management?
- How are the different pieces of EU legislation adapted to scientific and / or technical progress?
- Which opinions exist on integrating PBT/vPvB as hazard class in CLP?

1.3 Case study methodology

The case study is based on desk research and stakeholder consultation (targeted interviews and written input). In addition, discussions from the Fitness Check Workshop⁷ conducted in the context of this study in April 2016 are considered. Table 1-1 gives an overview of the targeted consultation carried out for this case study.

Table 1-1: Overview of consultation				
Stakeholders	Number contacted	Interviews	Written input	No response
Associations	5	0	ECPA CEFIC	Concawe ⁸ Eurometaux ⁸ National organometals association
Company representatives	2	0	0	2
EU institutions / agencies	9	ECHA (PBT Expert Group) DG ENV (2)	DG GROW DG SANTE ECHA (BPC)	EFSA JRC
NGO	3	EEB PAN Chemtrust	0	0
Other (labs, consultants)	4	2	2	0
Total	23	8	7	8

⁷ Workshop on the regulatory fitness of chemicals legislation (excluding REACH), http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8696

⁸ Some information was provided in a short phone discussion but no structured input was obtained on the interview / consultation questions.

2. Legal Background

2.1 PBT/vPvB criteria

2.1.1 EU legislation

The CLP Regulation

The CLP Regulation currently does not include a hazard class for PBT/vPvB properties and hence lacks any respective criteria or references to other legislation, as well as any labelling provisions. Recital 75 provides for the possibility to include provisions on PBTs/vPvBs in the regulation and Article 53(2) tasks the Member States and the European Commission with promoting the harmonisation of the criteria for classification and labelling of PBTs/vPvBs at the level of the UN Globally Harmonized System (GHS).

The EU delegation in the Sub-Committee⁹ of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals submitted a respective proposal to consider harmonisation of the PBT/vPvB criteria¹⁰ to the meeting in December 2009. According to the meeting report, the participants were divided over the issue. Not being in a position to decide, provision of further information was welcomed. The issue has not yet been discussed again in the sub-committee.

At OECD level, it was planned to develop harmonised guidance for the assessment of PBTs/vPvBs as well as properties related to long range transport under the supervision of the OECD Working Group on Pesticides. However, this work has been stopped and neither draft guidance nor a commitment to finalise one exists.

REACH

Annex XIII of REACH specifies that PBTs/vPvBs are to be identified according to their numeric criteria and/or by a weight of evidence approach (WoE), in particular where a direct comparison of data with the numeric criteria is not possible or when additional, non-standard information is taken into account. Information sources could be results from *in vitro* testing, grouping and read-across or (Q)SARs, animal testing or human data, information on environmental exposure from monitoring or modelling, as well as information from epidemiological or clinical studies. Testing should be conducted under relevant conditions. Annex XIII also specifies that constituent substances and transformation and degradation products should be considered. Furthermore, it includes information for PBT screening, in case only information according to Annex VI and VII is available. The criteria apply to organic substances, including organo-metals but not to inorganic substances and inorganic metals or inorganic metal compounds.

⁹ Sub-Committee of the Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals.

¹⁰ UN/SCEGHS/18/INF.4

Biocidal Products Regulation

No PBT/vPvB criteria are included in the Biocidal Products Regulation but it refers to REACH Annex XIII (therefore, the criteria are identical).

The Plant Protection Products Regulation

Annex II of the Plant Protection Products Regulation includes criteria for the identification of PBTs/vPvBs, which are almost identical to those of REACH Annex XIII before its revision; i.e. it includes the same numerical thresholds¹¹ but does not explicitly include the use of “other information” by means of a WoE approach. However, the possibilities to use “other information” in a WoE approach are laid out in a working document by DG SANCO¹². Metabolites and degradation products are not considered in the PBT/vPvB identification according to Annex II of the Plant Protection Products Regulation and the working document, but should be taken into account in the overall approval decision of an active substance and should also be included in the risk assessment and authorisation decision of plant protection products at national level.

Directives for Medicinal Products

A PBT/vPvB assessment is not explicitly required under the Directives on Medicinal Products for Human Use or for veterinary use. However, the (draft) guidelines for environmental risk assessments¹³ include respective information.

The draft guidelines on PBT/vPvB assessment for medicinal products for veterinary use (VMP) refer to REACH Annex XIII and the respective ECHA guidance. The guidance on environmental risk assessment for medicinal products for human use (HMP) refers to the PBT/vPvB assessment described in the EU Technical Guidance document for Risk assessment (EU TGD) but is replaced by the REACH guidance on information requirements and chemical safety assessment, according to a Questions & Answers document by the EU Commission¹⁴. According to stakeholders and Rauert *et al* (2014)¹⁵ the criteria of REACH Annex XIII and the related ECHA guidance on PBT/vPvB assessment are also used in the assessment of HMP in practice.

¹¹ With the one exception that data on the EC10 may not be used to assess if the threshold value for toxicity is exceeded. However, a DG SANCO working document clarifies that EC10 data may be used as an additional source (EU Commission, DG SANCO (2012): ‘DG Sanco Working Document on “Evidence Needed to Identify POP, PBT and vPvB Properties for Pesticides’, Brussels, 25.09.2012).

¹² EU Commission, DG SANCO (2012): ‘DG Sanco Working Document on “Evidence Needed to Identify POP, PBT and vPvB Properties for Pesticides’, Brussels, 25.09.2012.

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¹⁴ European Medicines Agency, Committee for Medicinal Products for Human Use (CHMP) (2015): ‘Draft Questions and answers on ‘Guideline on the environmental risk assessment of medicinal products for human use’, EMA/CHMP/SWP/44609/2010 Rev. 1*.

¹⁵ Rauert C., et al (2014): Proposal for a harmonised PBT identification across different regulatory frameworks’, in *Environmental Sciences Europe*, 26:9.

POP Regulation

The EU POP Regulation¹⁶ implements two international agreements on persistent organic pollutants: the Stockholm Convention on Persistent Organic Pollutants and the Protocol on Long Range Transboundary Air Pollution on Persistent Organic Pollutants. In the EU POP Regulation, measures are defined to reduce production and use of internationally recognised POPs including management of stockpiles, wastes and unintended releases. The POP Regulation does not include individual POP criteria but refers to the substances listed in the international conventions.

Water Framework Directive

The Water Framework Directive requires identification of priority substances (PS) and priority hazardous substances (PHS) for the aquatic environment. According to Article 2(29) of the Water Framework Directive ‘hazardous substance’ “[...] means substances or groups of substances that are toxic, persistent and liable to bio-accumulate, and other substances or groups of substances which give rise to an equivalent level of concern”. Consequently, priority hazardous substances (PHS) could be PBTs/vPvBs or substances “of equivalent concern”. There are no clear-cut PBT/vPvB criteria in the Water Framework Directive. However, REACH Annex XIII is a core reference point in the PHS identification. Under the Water Framework Directive, degradation products are considered when establishing the list of priority and priority hazardous substances; however, no rules are defined on how this should be done.

Marine Strategy Framework Directive

The Marine Strategy Framework Directive refers to the Water Framework Directive and does not include any separate provisions for PBT/vPvB assessment.

2.1.2 Examples of international conventions

Stockholm Convention

The POP criteria for persistence and bioaccumulation correspond to the definitive criteria and threshold values for vP/vB identification in REACH Annex XIII.

According to the POPs convention, the bioaccumulation potential can be measured as bioconcentration factor (BCF) or bioaccumulation factor (BAF) of > 5000 or, in the absence of such data, a LogKow of > 5. The toxicity criterion is defined as the potential for, or indicators of, adverse effects on human health and/or the environment in general. Finally, an additional criterion “long range transport” is to be assessed to identify POPs. Consequently, POPs are a sub-group of EU PBTs/vPvBs according to REACH Annex XIII.

Protocol on Long Range Transboundary Air Pollution on Persistent Organic Pollutants

The Protocol does not include any self-standing POP criteria but includes a substances list which the contracting parties agree upon. Most of the listed substances are the same as included in the Annexes of the Stockholm Convention.

¹⁶ REGULATION (EC) No 850/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on persistent organic pollutants.

OSPAR

The Oslo Paris Convention (OSPAR) aims at protecting the North-East Atlantic from anthropogenic pressures and is established by the countries bordering it¹⁷. In 2004, OSPAR developed a “List of Substances of Possible Concern”¹⁸ based on hazard, modelling and measured data combined via a procedure called DYNAMEC¹⁹. By deselecting substances of lower hazard or risk, the List of Chemicals for Priority Action²⁰ was derived, which includes 29 (groups of) substances for priority action according to OSPAR’s criteria. These are stricter than REACH Annex XIII with regard to the P and B criterion. Furthermore, metals are included in the list, which cannot be PBT/vPvB according to REACH.

OSPAR PBT criteria:

- P: half-life in water ≥ 50 days (REACH 60 days);
- B: BCF ≥ 500 (REACH 2000 / 5000); and
- T: long term NOEC ≤ 0.1 mg/l (REACH: same, plus CMR).

Due to its focus on maritime protection, OSPAR developed several recommendations to prevent or limit emissions of hazardous substances to the marine environment from offshore activities. These include a reporting format, which should be used by the authorities of the Contracting Parties to collect information on the types and hazards of chemicals used in offshore industries²¹ as well as a pre-screening procedure²² to support future regulatory measures aimed at substituting and/or controlling the use of hazardous substances in offshore chemicals. The pre-screening criteria include criteria relating to persistence, bioaccumulation and toxicity; however, the values triggering concern are stricter than the PBT/vPvB criteria.

Due to the developments in the European Community, namely under the Water Framework Directive and REACH, OSPAR's work on the selection and prioritisation of substances has been put on hold, and OSPAR is now following the identification of substances of very high concern under REACH.

The OSPAR recommendations are differently implemented by the Contracting Parties. Under the UK Offshore Chemical Regulations 2002, for example, all chemicals require a consent to discharge. The chemicals, to be used in the UK and Netherlands, must be registered with CEFAS and selected through a risk based approach.

¹⁷ Contracting parties are: the EU, Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Luxembourg, The Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

¹⁸ OSPAR, ‘List of substances of possible concern’ available at <http://www.ospar.org/work-areas/hasec/chemicals/possible-concern/list>

¹⁹ OSPAR (2004): ‘Dynamic Selection and Prioritisation Mechanism for Hazardous Substances (DYNAMEC)’, publication number 146.

²⁰ OSPAR, ‘List of chemicals for priority action’, <http://www.ospar.org/work-areas/hasec/chemicals/priority-action>

²¹ OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF) and OSPAR Recommendation 2014/17 amending OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF).

²² OSPAR Recommendation 2010/4 on a Harmonised Pre-screening Scheme for Offshore Chemicals.

HELCOM

The HELSINKI COMMISSION on the protection of the Baltic Sea does not include any specific criteria for PBT/vPvB but only describes qualitatively what should be understood as a persistent, bioaccumulative and toxic substance. In practice, HELCOM has recently drawn upon work conducted in the EU, e.g. regarding the SVHC identification under REACH or work under the Water Framework Directive.

Barcelona Convention

The Barcelona Convention does not include a definition of PBT/vPvB but lists substances and substance groups, which are selected due to persistence, bioaccumulation potential and toxicity.

2.1.3 PBT/vPvB criteria in the United States, Australia and Canada

The PBT/vPvB criteria of the United States, Australia and Canada all include half-lives in air of more than two days. While the US differentiates between moderate and high concern substances, Canada and Australia only have one set of criteria. The cut-offs for persistence in water range between 60d (Australia) and 182d (Canada) and the BCF between 1000 (US) and 5000 (Canada). The cut-off criteria for toxicity resemble those of the EU definition in the US (No observed effect concentration (NOEC)) and in Australia (GHS classification, toxicity to terrestrial organisms and endocrine disrupting effects) but are based upon a different hazard concept in Canada, which takes exposure into consideration.

Table 2-1 summarises the numeric criteria in the different frameworks.

Table 2-1: Comparison of PBT/vPvB criteria in different frameworks and contexts					
Legislation	P	vP	B	vB	Toxicity
REACH	Half-life in <ul style="list-style-type: none"> marine water > 60 d fresh or estuarine water > 40 d marine sediment > 180 d fresh or estuarine water sediment > 120 d soil > 120 d Appropriate conditions in testing to be ensured	Half-life in <ul style="list-style-type: none"> marine, fresh or estuarine water > 60 d marine, fresh or estuarine water sediment > 180 d soil > 180 d 	BCF > 2000 Based on measured data on bio-concentration in aquatic species; both freshwater and marine water species possible	BCF > 5000	Long-term NOEC or EC10 marine or freshwater organisms < 0.01 mg/l, Classification as CM (1A or 1B), R (1A, 1B or 2) pursuant to CLP Other evidence of chronic toxicity: STOT RE 1 or RE 2 pursuant to CLP
Biocidal Products Regulation					Long-term NOEC ²³ marine or freshwater organisms < 0.01 mg/l, Classification as CM (1A or 1B), R (1A, 1B or 2) Other evidence of chronic toxicity: STOT RE 1 or RE 2 pursuant to CLP
VMP and HMP					
Plant Protection Products Regulation					
Water Framework Directive	No clear cut criteria but based on existing lists, RAs and other data				
Stockholm convention²⁴		Half-life in <ul style="list-style-type: none"> water > 60 d sediment > 180 d soil > 180 d Evidence of sufficient persistence		BCF > 5000 or LogKow > 5 or other reasons for concern; monitoring data indicating bioaccumulation	Potential to adversely affect or toxicity or ecotoxicity data indicating potential for damage to human health and/or the environment

²³ While the criteria in the PPR do not mention the EC10, this type of data can be used for identifying PBT according to a working document by DG SANCO on the data needs to identify PBT (EU Commission, DG SANCO (2012): 'DG Sanco Working Document on "Evidence Needed to Identify POP, PBT and vPvB Properties for Pesticides', Brussels, 25.09.2012).

²⁴ In addition, the Stockholm Convention includes the criterion "long range transport"; it is not included here as it is not relevant for PBT/vPvB identification under the EU legal framework.

Table 2-1: Comparison of PBT/vPvB criteria in different frameworks and contexts					
Legislation	P	vP	B	vB	Toxicity
UNECE POP Protocol ²⁵		Half-life in <ul style="list-style-type: none"> • water > 60 d • sediment > 180 d • soil > 180 d Evidence of sufficient persistence		BCF or BAF > 5000 or LogKow > 5	Potential to adversely affect human health or the environment
OSPAR	Half-life in water ≥ 50 d		BCF ≥ 500 or LogKow > 4		Acute aquatic toxicity L(E)C50 ≤ 1 mg/L or long term NOEC ≤ 0.1 mg/L or mammalian toxicity: CMR or chronic toxicity
HELCOM (19/5) ²⁶	A substance is defined as “persistent” if its conversion or the conversion of its degradation products is slow enough to permit long-term occurrence and widespread distribution in the marine environment		”Bioaccumulation” is defined as the enrichment of a substance in an organism and includes “bioconcentration” from environmental concentrations and additional uptake via the food chain; bioaccumulation includes all routes, i.e. via the air, water, soil and food		”Toxicity” is defined as the capacity of a substance to cause toxic effects to organisms or their progeny such as: reduction in survival, growth and reproduction; carcinogenicity, mutagenicity or teratogenicity; adverse effects as result of endocrine disruption
US EPA PBT profiler ²⁷	Half-life in water, soil and sediment > 60 d	Half-life in <ul style="list-style-type: none"> • water or soil or sediment > 180 d • air > 2 days 	BCF > 1000	BCF > 5000	Low concern: NOEC > 10 mg/l Moderate concern: NOEC 0.1-10 mg/L High concern: NOEC < 0.1 mg/L
Canada		Half-life in <ul style="list-style-type: none"> • Air ≥ 2 d 		<ul style="list-style-type: none"> • BAF ≥ 5000 or • BCF ≥ 5000 or 	CEPA toxic ²⁸

²⁵ Under the Convention on Long-Range Transboundary Air Pollution, http://www.unece.org/env/lrtap/pops_h1.html

²⁶ In its current work, HELCOM refers to REACH Annex XIII when addressing PBT/vPvB properties.

²⁷ The criteria “moderate” and “high” concern are assigned to PBT (moderate) and vPvB (high); however, for the high concern a toxicity threshold is also defined; hence a category vPvB does not exist in the US. The PBT profiler mirrors the legal risk management level triggered; i.e. for moderate concern control action should be started and for high concern PBTs, bans may be pending.

²⁸ “Canadian Environmental Protection Agency – toxic” – this is not a clear definition as it does not relate to inherent properties but is determined via risk assessment.

Table 2-1: Comparison of PBT/vPvB criteria in different frameworks and contexts					
Legislation	P	vP	B	vB	Toxicity
		<ul style="list-style-type: none"> • Water \geq 182 d • Soil \geq 182 d • Sediment \geq 365 d 		<ul style="list-style-type: none"> • LogKow \geq 5.0 	
Australia		Half-life in <ul style="list-style-type: none"> • Air > 2 d • Water > 2 months • Soil or sediments > six months 	BCF > 2000 or in its absence LogKow > 4.2		GHS chronic aquatic toxicity cat. 1 based on chronic or acute data; toxicity to other (terrestrial) organisms or evidence such as endocrine disruption effects

2.2 Data for PBT assessment

PBT/vPvB identification under REACH may be a two-step process consisting of an initial screening and, if necessary, a comparison of substance properties against the criteria. Different data may be used for screening and the definitive assessment.

Table 2-2 gives an overview of the standard information requirements under REACH, Plant Protection Products Regulation and the Biocidal Products Regulation that are needed to compare with the PBT threshold values. It should be noted for the standard REACH information requirements that a) if the registrants have any indication of PBTness, e.g. from the screening assessment, further information on the related property is to be generated in order to allow a conclusion, regardless of the registration tonnage and b) authorities may request any (additional) information when doing a substance evaluation, independent of the registered tonnage.

Table 2-2: Availability of data for PBT/vPvB assessment in different legal frameworks			
Legis-lation	P-criterion: simulation study required?	B-criterion: Bioconcentration test required?	T-criterion: classification possible, data required?
REACH	Further degradation testing for the “relevant compartment”, i.e. that exposed depending on CSA outcome CSA ²⁹ WoE is to be used in all assessment situations (including screening)	BCF as standard requirement in Annex IX ³⁰	CMR : available information and test proposals from Annex IX STOT : indications from Annex VIII (repeated dose toxicity) Aquatic toxicity : long term testing required from Annex IX
Plant Protection Products Regulation	Soil, water, water sediment system if not readily degradable	BCF required if LogKow > 3	Yes
Biocidal Products Regulation	Water, soil and water-sediment, if not readily biodegradable	BCF required if LogKow > 3	Yes

Table 2-2 shows that the standard data requirements for PBT/vPvB assessment are different under the three regulations. For the P-criterion, the Plant Protection Products Regulation and the Biocidal Products Regulation require data from simulation testing for any substance seeking approval, whereas under REACH this is only required if there are indications of PBTness. The same applies for information on the T-criterion, where the Plant Protection Products Regulation and the Biocidal Products Regulation require submission of information on toxicity and long-term aquatic toxicity and under REACH this information is only required as part of the information set for substances above 100 t/a. Consequently, the information basis to conclude on a PBT/vPvB under REACH depends on the decision making of the registrant (or the information request posed by an assessing authority),

²⁹ REACH Annex VIII: ‘Further degradation testing shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment’.

³⁰ The information need not be generated, if there are indications of a low bioaccumulation potential, e.g. indicated by a LogKow ≤ 3, is unlikely to cross biological membranes or if exposure is unlikely.

whereas that under the Plant Protection Products Regulation and the Biocidal Products Regulation should be similar (but might be extended differently based on further requests by authorities).

Indications that a substance fulfils P or B trigger further information collection under all legislation. The screening criteria / triggers for further information collection partly differ for the B criterion across legislation: LogKow > 3 for the Biocidal Products Regulation and the Plant Protection Products Regulation (and the REACH standard information requirement); LogKow of 4 under the Directives on Medicinal Products for Veterinary Use and LogKow under the Directives on Medicinal Products for Human Use and REACH (screening criterion).

The type of information generated if further information collection is triggered depends on the use and exposure of the substance (P criterion) and the information already available (B and T criterion) and is therefore case specific.

Under REACH, any available data including e.g. (Q)SARs, information from non-standardised testing and monitoring data may be used in a weight of evidence approach. This also applies to the Biocidal Products Regulation, which refers to the REACH criteria and guidance documents. Weight of evidence argumentation may be used to conclude a substance is a PBT / vPvB or to prove that the criteria are NOT fulfilled. There is, however, confusion on the possibilities to conclude based on WoE³¹.

The Plant Protection Products Regulation defines data requirements for active substances in Regulation EU 283/2013 and makes reference to existing guidance on testing methods in an additional communication. Similarly, data requirements for plant protection products are defined in Regulation EU 284/2013 and available test methods and guidance documents are provided in a communication³².

The Biocidal Products Regulation defines information requirements for substance approval in its Annex II. Due to the timelines of the Biocidal Products Regulation (and its review programme), it may not always be possible to obtain all necessary data within a substance approval procedure to finally conclude on the PBTness of a substance. If data are requested but cannot be taken into account in the assessment, the Biocidal Products Committee (BPC) may define a substance as “potential PBT/vPvB”, confirm the data request to the applicant and initiate reassessment of the substance upon receipt of this information. If data are not submitted in time, the BPC may also conclude on non-approval due to failure to meet the information requests³³.

As defined in the Directives on Medicinal Products for Human Use and Directives on Medicinal Products for Veterinary Use and related guidance the environmental assessment starts with an exposure estimation. If the exposure level remains below the “action limit”, the environmental risk assessment can be terminated, except if the LogKow exceeds the value of 4.5 (in the case of medicinal products for human use) or the value of 4 (in the case of veterinary medicinal products). In this case, a PBT assessment is to be performed based on REACH Annex XIII.

³¹ C.f. for example Cana R. (2016): ‘PBTs and vPvBs: different procedures under REACH’, in: Chemical Watch, March 2016, available at: <https://chemicalwatch.com/45725/pbts-and-vpvbs-different-procedures-under-reach>

³² The regulations and communications are available at:
http://ec.europa.eu/food/plant/pesticides/approval_active_substances/eu_rules/index_en.htm

³³ European Commission, DG ENV (2015): ‘Data requirements for the evaluation of the exclusion and substitution criteria under the BPR’, CA-March15-Doc.5.3 – Final.

The identification of PHS under the Water Framework Directive is based on “all available information”, which includes several information sources, such as existing (regulatory) lists and risk assessments, data on hazardous properties, as well as modelled or measured data on environmental concentrations. The information is evaluated based on expert judgement.

2.3 PBT identification procedures

The REACH provisions are subject to a self-standing fitness check. They are briefly summarised to enable comparison with other chemicals legislation.

2.3.1 REACH

Registrants' Chemical Safety Assessments/Compliance Checks

Registrants must make a PBT assessment according to Annex XIII for substances registered above 10 t/a as part of the chemical safety assessment (CSA). According to REACH, at least five percent of all registration dossiers shall be evaluated by ECHA. According to ECHA³⁴, dossier selection for compliance check is either random or concern based (targeted). In the targeted compliance checks, ECHA evaluates only a specific part of the registration dossier, e.g. specific endpoints based on a specified concern. Toxicity related endpoints relevant for the PBT-assessment as well as biodegradation and bioaccumulation are among those specific endpoints. Furthermore, targeted compliance checks take place prior to substance evaluation if, for example, a Member State Authority raises a concern due to a substance's PBT-properties.

Authorities' SVHC Identification

Upon their own initiative, authorities may propose a substance to be identified as PBT/vPvB. ECHA may do so on request of the EU Commission. The Member State competent authority or ECHA develops an Annex XV-dossier, which is subject to public consultation and, after consideration of the comments, decided upon. Comments are discussed in the Member State Committee, which is to unanimously decide if a substance is a PBT or vPvB. If no agreement is reached, the Commission prepares a proposal for the final decision by the Member States in the committee responsible for REACH matters. Intentions to identify a substance as SVHC are published in the registry of intentions, prior to the start of the process. Identification of a substance as SVHC due to PBT/vPvB-properties results in its inclusion in the candidate list for authorisation.

Substance Evaluation

Substance Evaluation (SEV) is a procedure under REACH, which has the aim of clarifying a specific concern about a substance that may, for example, be a concern due to suspected PBT-properties. SEV provides the opportunity for asking for further data from the registrants in order to clarify the concern, based on which identification as a Substance of Very High Concern could be a potential follow-up. Only the Member State competent authority / ECHA and the registrants, who may be requested to provide additional information, are involved in this process. The plan for substance evaluations (Community Rolling Action Plan (CoRAP)) is updated annually and specifies which substances will be evaluated by which Member State, including the timelines.

³⁴ See ECHA: <https://echa.europa.eu/regulations/reach/evaluation/compliance-checks>

The PBT expert group

The PBT expert group is informally consulted³⁵ under REACH, the Biocidal Products Regulation and the Directives on Medicinal Products for Veterinary Use. Its main role is to give scientific advice on PBT assessments, including determination of data requirements and testing strategies, interpretation of data and conclusions on the fulfilment of the Annex XIII criteria, as well as the assessment of borderline cases. Under the Biocidal Products Regulation, substances meeting the substitution criteria (2 out of 3 PBT criteria) are also referred to the expert group. In addition, the PBT expert group identifies relevant scientific findings and methods and discusses if and how they could be used for PBT/vPvB assessment. If agreed in the group, it gives informal advice on how to include scientific developments in guidance. Finally, the PBT expert group communicates the needs of regulatory hazard assessment to the scientific community so they could consider this in their work. The PBT Expert Group and its work are of informal preparatory nature and not part of ECHA's formal regulatory processes.

ECHA's report on the operation of REACH and CLP 2016³⁶ presents the results from discussions in the PBT expert group: a total of 145 substances were under assessment. For seven substances information was sufficient to conclude that a substance is PBT/vPvB and for 31 substances PBT/vPvB criterion could be shown as not fulfilled. For 64 substances it was concluded that further information is necessary and respective procedures enabling data request were started (e.g. substance evaluation, restriction procedure) and for 33 substances the assessment needs refining.

2.3.2 Approval procedures under pesticides legislation

Under the Plant Protection Products Regulation, the PBT assessment is part of the approval procedures of active substances, safeners or synergists³⁷. The active substance approval consists of several steps³⁸:

1. The applicant for active substance approval compiles a dossier, including substance property data and a PBT assessment, and submits it to a Member State (Rapporteur Member State, RMS).
2. The RMS checks if the dossier is admissible (complete, relevant, etc.), evaluates its content and develops a draft assessment report (DAR), which it forwards to the Commission and EFSA. EFSA sends the DAR to all Member state competent authorities and publishes it on its web after removing confidential information.
3. EFSA organises a public consultation of the DAR and collects all comments. EFSA and the RMS consider these comments, together with comments from Member State competent authorities. EFSA decides to involve the applicant requesting additional information, and/or organise a consultation of experts. EFSA compiles and publishes the DAR and the documentation of comments and answers.

³⁵ The PBT Expert group may also be consulted if a substance is proposed for identification as a POP.

³⁶ ECHA (2016): Operation of REACH and CLP, Helsinki.

³⁷ Substances that are not active substances, safeners or synergists and that are used in plant protection products are assessed by Member State authorities in the product authorisation procedure. This includes a PBT assessment but is not discussed further here.

³⁸ The process is slightly different for pesticide active substances for which dossiers have been submitted before June 2011.

4. EFSA considers all information available and adopts a conclusion on the peer review on whether the substance can be expected to meet the criteria for approval in the Plant Protection Products Regulation.
5. The Commission considers all information and EFSA's conclusion and submits an Implementing Regulation on the possible approval, restricted approval or non-approval of the active substance to the Standing Committee on Plants, Animals, Food and Feed.
6. The EU Commission adopts the Implementing Regulation as supported by the Standing Committee and publishes it in the EU Official Journal.

The process from deciding on the admissibility of a dossier to the approval / non-approval takes between 2.5 and 3.5 years. Variations are due to differences in the complexity of the dossier³⁹.

Applicants for authorisation of a plant protection product prepare a product dossier and submit it to the responsible Member State competent authority. The Member State competent authority assesses the dossier and draws conclusions on product authorisation, potentially in cooperation with other Member State competent authorities belonging to the same zone⁴⁰. The conclusions on the approval are to be implemented by all countries in the Zone. This process lasts between 1 and 1.5 years⁴¹.

2.3.3 Approval procedures under biocides legislation

Under the Biocidal Products Regulation, the PBT assessment is part of the active substance approval procedures⁴². The active substance approval consists of several steps:

1. The applicant compiles a dossier for substance approval, including substance property data and a PBT assessment. The dossier is submitted to a Member State competent authority (Rapporteur Member State, RMS).
2. The RMS checks if the dossier is admissible (complete, relevant, etc.), evaluates its content and prepares a draft assessment report, which is submitted to ECHA's BPC.
3. After consultation of the PBT expert group, the BPC drafts an approval recommendation, which it sends to the Commission.
4. The Commission takes the final decision on the approval, which enters into force upon publication in the EU Official Journal.

³⁹ See Approval of active substances, accessed at:

http://ec.europa.eu/food/plant/pesticides/approval_active_substances/index_en.htm

⁴⁰ Due to the different geographical and climate related conditions, which may affect the effectiveness and risks from the use of plant protection products, the EU is divided into zones for plant protection products authorisation.

⁴¹ See Procedure to apply for authorisation of a plant protection product, accessed at:

http://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/application_procedure/index_en.htm

⁴² Substances that are not active substances and are used in biocidal products are assessed by Member State authorities or at EU level in the product authorisation procedure. This includes a PBT assessment.

Regarding the timelines, a distinction has to be made between existing active substances and new active substances. For new active substance, the whole process takes on average two to three years. In contrast, existing active substances are part of an evaluation programme, which is organised by priority lists, and the whole review programme is planned to be finalised by 2024.

Product authorisation could be at national level or EU wide (Union Authorisation, which is only possible for some of the product types). The application dossier is evaluated either by the Member State receiving the dossier or by ECHA (Union Authorisation). A decision is taken within one year. Evaluating Member States may ask the PBT expert group to support identification of PBTs/vPvBs (non-active substances present in the final product).

2.3.4 Authorisation of medicinal products

According to the centralised procedure, manufacturers of VMP or HMP must submit an application for authorisation to the European Medicines Agency (EMA). The selected Rapporteur Member State (RMS) develops an assessment report. The report is discussed in the Committee for Medicinal Products for Human Use or the Committee for Medicinal Products for Animal Use. The Committees may comment on the application and the applicants may reply to these and/or provide additional information. The applications and the Committee opinions form the basis for a Commission decision on the product authorisation.

2.3.5 Water Framework Directive

The initial identification of priority hazardous substances⁴³, which include PBT/vPvB but also other substances of concern had two steps: Shortlisting of priority substances using the COMMPS procedure⁴⁴, and expert review of the shortlist to identify priority hazardous substances. In the latest review of the Water Framework Directive's Annex X, the list of Priority Substances (PS) was reviewed combining information from existing risk assessments for plant protection products and biocides, experience from the COMMPS procedure, criteria for PBT/vPvB and POPs as well as other evidence and expert judgement⁴⁵.

The criteria of REACH PBT/vPvB as well as the POPs were used to decide if a substance is a Priority Hazardous Substance (PHS) or not. Information from existing PBT assessments is used to identify PBTs under the Water Framework Directive⁴⁶. For the identification of priority (hazardous) substances all available information is taken into account; data generation is not foreseen.

⁴³ Water Framework Directive Art 2(29): "substances or groups of substances that are toxic, persistent and liable to bio-accumulate, and other substances or groups of substances which give rise to an equivalent level of concern".

⁴⁴ EU Commission (1999): Revised Proposal for a List of Priority Substances in the Context of the Water Framework Directive (COMMPS Procedure), Final report, Declaration ref.: 98/788/3040/DEB/E1; available at: http://ec.europa.eu/environment/water/water-dangersub/pdf/commps_report.pdf

⁴⁵ EU Commission (2012): Commission staff working paper – technical background accompanying the document Report from the Commission to the European Parliament and the Council on the outcome of the review of Annex X to Directive 2000/60/EC of the European Parliament and of the Council on priority substances in the field of water policy, SEC(2011) 1544 final.

⁴⁶ Examples are assessments under the Stockholm Convention or OSPAR.

The identification of priority hazardous substances and the development of environmental quality standards (EQS) are performed by the Working Group on Chemicals, an expert group, which is part of the Common Implementation Strategy for the Water Framework Directive. The expert group includes representatives from the EU Commission, the Member States and stakeholders. If no agreement can be reached on the PBTness of a substance or the value of the EQS, an opinion of the scientific committee SCHER is requested and normally followed. Documents for PBT identification are published on CIRCABC. The inclusion of substances in Annex X is preceded by a Commission impact assessment, identifying socio-economic impacts and the availability of suitable alternatives.

2.3.6 POPs identification under the Stockholm Convention

Any contracting party may propose a substance for inclusion in the Annexes of the Stockholm Convention. The contracting party compiles a so-called Annex D Dossier and provides all relevant and available information to assess if the substance fulfils the POP criteria. Information is collected from existing risk assessments, scientific literature and from submissions of other contracting parties and stakeholders.

The draft Annex D Dossier is discussed in the POP Review Committee. It is adopted (or not adopted) after revision and potential inclusion of additional information from the literature or by stakeholders. The Conference of the Parties takes the final decision on the inclusion of substances in the Annexes of the Convention based on the relevant dossiers. These do not only comprise the Annex D dossier confirming a substance as a POP but also a risk assessment (Annex E Dossier) and an assessment of risk management options (Annex F Dossiers). Stakeholders are involved in the development and commenting process of all dossiers.

2.4 RMM triggers and types of RMM

2.4.1 REACH

RMMs based on generic considerations

The identification of PBT/vPvB by registrants automatically obliges the registrants to:

- Conduct an emission estimation;
- Identify and implement measures to minimise emissions at the registrants' site;
- Indicate in the safety data sheet (SDS) that the substance is a PBT/vPvB; and
- Identify and communicate measures to minimise emissions during the use of the substance via the SDS.

Downstream users receiving an SDS are to implement the conditions of use, including all measures to minimise emissions at their site. In addition, they must forward relevant information to the further downstream users, if they are required to provide an SDS.

Identification of substances as PBT/vPvB by authorities and inclusion in the candidate list automatically triggers communication requirements for the articles they are contained in (c.f. Section 2.5). In addition, the identification as PBT/vPvB must be considered in the identification of RMMs in the chemical safety assessment. This is not an automatic trigger of specific RMMs but PBT/vPvB trigger certain conditions for the Chemical Safety Assessment and the resulting RMM advice. No automatic bans or restrictions of PBT/vPvB are included in the REACH text.

RMMs after further assessment

A restriction proposal, also for a PBT/vPvB, must include a risk assessment; unacceptable risks should be demonstrated (on a semi-quantitative or qualitative basis) as well as a need to regulate at Community level. The restriction proposal is also to include an assessment of potential impacts on human health, the environment and society as well as an assessment of alternatives.

Inclusion in the authorisation list requires a prioritisation proposal by ECHA that is agreed with the Member States and decided by the Commission. Prioritisation draws upon hazard information as well as information on uses, production and use volumes, possible exposures and risks. Inclusion of a PBT/vPvB substance in the authorisation list triggers the need for industry to apply for authorisation of further use of the substance. Applicants have to submit a socio-economic analysis (SEA), because no proof of adequate control is possible. An authorisation is only granted if the socio-economic benefits outweigh the risk to human health or the environment and if no suitable alternative substances or technologies are available.

If new information related to PBT-properties of a substance becomes available, e.g. as a result of a Compliance Check or a SEV, this needs to be taken into account by all market actors in their assessment of whether a substance is a PBT/vPvB.

2.4.2 Plant protection products

RMMs based on generic considerations

Active substances, safeners and synergists for use in plant protection products fulfilling the PBT/vPvB criteria of the Plant Protection Products Regulation shall not be approved⁴⁷. No derogations are possible from this requirement. As substances have been approved before this requirement was introduced, substances fulfilling the exclusion criteria may still be in use if the approval decision has not yet been renewed (renewals are after 10 years from the first approval decision).

A plant protection product may only be authorised if all active substances, safeners or synergists contained therein are approved and its co-formulants are not included in Annex III⁴⁸.

2.4.3 Biocidal products

RMM based on generic risk considerations

Active substances for use in biocidal products fulfilling the PBT/vPvB criteria of REACH Annex XIII shall not be approved. This obligation did not exist in the Biocides Directive and therefore, PBT/vPvB may have been approved and still be in use if the approval has not yet been reviewed. Derogations from non-approval of active substances are permitted. Three justifications for derogations from non-approval are possible:

- The exposure during normal and foreseeable use is shown to be negligible;

⁴⁷ Annex II, Section 3.7.2.

⁴⁸ Co-formulants may be included in Annex III of the regulation if they are found to, among others, cause unacceptable effects on plant health and the environment. This indicates that having PBT/vPvB properties is a reason to ban the use of a co-formulant in plant protection products.

- The use is essential for pest control (i.e. there are no or too few alternatives to prevent resistance); and
- Non-approval would result in disproportionate societal disadvantages⁴⁹.

Justification of derogations would require exposure information (first case), information on resistance of pests, alternatives and potential threats from the pest (second case) or socio-economic data on the costs and benefits of using / phasing out an active substance (third case). In all three cases, the availability of alternatives and the possibilities of implementing risk mitigation measures need to be considered.

Applicants for product authorisation (national or union level) are to assess the relevant components of their products (including metabolites and degradation products) with regard to their environmental risks.

If the biocidal product contains an active substance that fulfils the PBT/vPvB criteria, the authorising authority shall not grant an authorisation, unless it can demonstrate that no risks would occur under field conditions and unless the conditions for derogation of article 5(2) are met in that Member State. A product authorisation will include measures to mitigate risks.

2.4.4 Water Framework Directive

RMM based on generic risk considerations

Substances included in Annex X of the Water Framework Directive (many of which are PBT/vPvB) do not directly trigger any risk management measures. However, they are to be addressed under the programmes of measures that Member State authorities develop as part of the river basin management plans for achieving good status in EU waters, and have to be included in the river monitoring programmes implemented by the Member States and/or the river basin managers.

RMM involving additional implementation steps

Triggers for action under the Water Framework Directive are the EQS and their exceedance as indicated by monitoring data. The EQS are derived using a defined methodology, which is described in guidance documents. It was last updated in the context of the review of EQSs in 2011⁵⁰. If EQSs are exceeded, the Member States are to identify and implement risk management measures that would lead to decreasing environmental concentrations for the substances concerned.

⁴⁹ “(a) the risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment; (b) it is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or (c) not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.” (the Biocidal Products Regulation Art. 5.2).

⁵⁰ EU Commission, DG Environment (2011): Common implementation strategy for the Water Framework Directive (2000/60/EC) – Guidance document 27, Technical Guidance for Deriving Environmental Quality Standards.

According to Art. 7(a) of the Water Framework Directive⁵¹ the Commission is to assess if existing RMMs under the Plant Protection Products Regulation, the Biocidal Products Regulation, REACH and the Industrial Emissions Directive⁵² are sufficient to achieve the EQS and the emission reduction and/or phase out goals for the priority (hazardous) substances in the Water Framework Directive's Annex X. If this assessment shows that the measures are not sufficient, the Commission or the Member States shall either initiate a review of substance approvals / product authorisations under the Biocidal Products Regulation or the Plant Protection Products Regulation or impose restrictions under REACH. Member States could also consider revising installation permits according to the Industrial Emissions Directive.

In addition, the Water Framework Directive defines the instrument of River Basin Management Plans (RBMPs), which are a specific planning instrument that should be used to address any challenges of a water body, including chemical pollution. The RBMPs involve stakeholders in all management processes, including identification and implementation of risk management measures.

The programmes of measures drawn up by the Member States were analysed by the EU Commission⁵³. It is concluded that most Member States have failed to determine the load of PS and PHS that should be reduced in their water bodies to achieve good environmental status. Therefore, a solid basis to identify the most cost-effective risk management measures is missing. Of the measures that could be implemented, the reduction of emissions from the use of pesticides, advisory services for agriculture, and measures for phasing-out of emissions and upgrades / improvements of industrial wastewater treatment plans are listed as most relevant.

2.4.5 Medicinal products

The identification of PBT/vPvB under the Directives on Medicinal Products for Human Use may not prevent the authorisation of an HMP. The only measures that could be triggered by the outcome of an environmental assessment or PBT assessment and related evaluation by the EMA are communication obligations regarding the disposal.

For PBT/vPvB for use in VMP a cost-benefit assessment is carried out to support the authorisation decision. Depending on the outcome of the cost-benefit assessment product authorisation may be denied.

⁵¹ Included as part of the amendments introduced by DIRECTIVE 2013/39/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy.

⁵² Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control).

⁵³ EU Commission (2015): Commission Staff Working Document - Report on the progress in implementation of the Water Framework Directive Programmes of Measures, Accompanying the document Communication from the Commission to the European Parliament and the Council the Water Framework Directive and the Floods Directive: Actions towards the 'good status' of EU water and to reduce flood risks, SWD(2015) 50 final.

2.4.6 RMMs for PBT/vPvB in other legislation

Article 6.6 of the EU Ecolabel regulation explicitly excludes substances which fulfil the criteria of REACH Article 57⁵⁴. Hence, applicants for an eco-label of any product category should demonstrate that no PBT/vPvB is included and the authorities should check this information. No operationalisation of this requirement is included in the legal text or the guidance documents and it is, hence, unclear what an applicant for an eco-label should check, which information sources he should consult and what type of assessment he should make to demonstrate absence of PBT. It is not possible to claim an exemption for candidate list substances under the EU ecolabel (Article 6.7 of the EU ecolabel directive).

The Eco-Design Directive, the Industrial Emissions Directive and the Construction Products Regulation do not (yet) refer to the candidate list but consideration is being given to including references in guidance documents. It may occur that related considerations are included in the methodology for defining design requirements under for the Eco-Design Directive, the BAT discussions under the Industrial Emissions Directive and the communication requirements under the Construction Products Regulation.

2.5 Communication on PBT/vPvB

According to REACH, placers on the market of substances and mixtures that require provision of an SDS and that include PBT/vPvB are to indicate this in Section 2 of the SDS under “other hazards” (REACH Annex II, Section 2.3). In addition, the result of any PBT/vPvB assessment should be communicated in Section 12 of the SDS.

Identification of substances as PBT/vPvB by authorities and inclusion in the REACH candidate list automatically triggers communication requirements for article producers and importers to the article recipients and consumers (on request), if the substance is present in concentrations above 0.1% (w/w) in the article (Article 33). In addition, according to REACH Art. 7(2), inclusion in the candidate list triggers the obligation for article producers and importers to notify ECHA of the content of the SVHC in an article under certain conditions. Finally, inclusion on the candidate list should lead to an update of registration dossiers, if PBT/vPvB is not identified by the registrant (“new information”) in his dossier.

Under the approval / authorisation procedures for pesticides, biocides or medicinal products, the committees or the Member States evaluate the applicants’ assessments of the PBTness of the substances. The PBT conclusions are published in the opinions, or decisions on substance approval or product authorisation as well as related background documents. A list of substances approved under the Biocidal Products Regulation, including information on their PBTness and whether or not they are candidates for substitution according to its Art. 10(1) is available from CIRCABC⁵⁵.

⁵⁴ “The EU Ecolabel may not be awarded to goods containing substances [...] referred to in Article 57 of Regulation (EC) No 1907/2006 [...]. It could be interpreted from this wording of the legal text that the applicants for an eco-label should also make a PBT assessment. However, with a view to their (usually) limited experience in chemicals (applicants are article producers or formulators, depending on the product group) this does not appear to be realistic. REGULATION (EC) No 66/2010 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 November 2009 on the EU Ecolabel, Article 6.

⁵⁵ See <https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d>; according to that list, no substances are approved which fulfil the PBT criteria. Substances that have not been approved are not included in the list.

Articles may be treated with biocides. Biocides used to treat articles can only be PBTs/vPvBs if they have been approved based on derogations from the exclusion criteria (the Biocidal Products Regulation Art. 5(2)) or based on a dossier submitted under the Biocidal Products Directive. The treated articles have to be labelled specifying, among others, the name of the biocide active substance⁵⁶. However, it is not required to communicate explicitly that the substances is a PBT/vPvB.

The Directives on Medicinal Products for Veterinary Use and the Directives on Medicinal Products for Human Use do not specify labelling requirements but suggest including information on (safe) use and disposal in the information provided with the products. The PBTness of substances does not have to be explicitly communicated.

⁵⁶ European Commission, Health and Food Safety Directorate General, Safety of the Food Chain, Pesticides and Biocides (2015): Note for discussion with Competent Authorities for Biocidal Products – Labelling of treated articles, CA-May15-Doc.6.1 – Final.

3. Evaluation

3.1 Overview

In this chapter, information from literature and internet research, from the stakeholder consultation and from the Fitness Check workshop in April is brought together. It should provide an overview of the evaluation of the current provisions regarding the PBT/vPvB criteria as such, the evidence for PBT assessment, the procedures of PBT identification as well as the RMM triggers and types of measures, including communication. The text aims to answer the evaluation questions of the fitness check in a coherent way and does not explicitly refer to the individual questions.

3.2 PBT/vPvB criteria

3.2.1 Coherence of the criteria

The criteria to define PBT/vPvB included in REACH Annex XIII have evolved to being the core reference point of EU legislation. They consist of numerical criteria and the option to use “other evidence in a WoE approach”. The Biocidal Products Regulation, the Directives on Human and Veterinary Medicinal Products⁵⁷, and the Water Framework Directive⁵⁸ either in the legal text or in the guidance documents refer to the PBT definition in REACH Annex XIII. Only the Plant Protection Products Regulation includes self-standing criteria for PBT/vPvB, which stem from REACH Annex XIII before it was revised. The option to use “other evidence in a weight of evidence approach” is included in its PBT/vPvB criteria on a case-by-case basis, as detailed in the Working Document SANTE 2012¹².

The Commission Services and stakeholders discussed the PBT criteria and their implementation at a workshop in December 2014⁵⁹. The workshop revealed that besides minor differences in numeric PBT criteria, differences exist in the evidence used for the determination of the P-, B- and T-properties. The workshop compared the different procedures for the identification of PBTs and examined which guidance documents are applied under the various pieces of legislation. A close cooperation between agencies and all players, also for guidance development, was identified as a solution to possibly reach coherent assessments.

⁵⁷ No explicit reference is included in the legal texts. However, the implementation guidance for the VMP refers to REACH. The guidance for HMP refers to the EU Technical Guidance Document for Risk Assessment, but REACH Annex XIII and the related PBT assessment guidance document are used in practice.

⁵⁸ The Water Framework Directive does not define PBTs but identifies Priority Hazardous Substances (PHS). In doing so, it refers to REACH PBTs and hence indirectly includes the REACH PBT criteria.

⁵⁹ Workshop - Assessment of Persistent, Bioaccumulative and Toxic (PBT) substances in different EU legislations Brussels, 17 December 2014; available at: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_type=250&lang=en&item_id=7978

The most frequently named differences in stakeholder interviews are:

- Temperature for persistence testing, which is 20°C under the Plant Protection Products Regulation (in accordance with the OECD simulation test 308) and 12°C under the Biocidal Products Regulation⁶⁰;
- Use of information other than the BCF to assess the bioaccumulation potential; and
- The possibility of using data from terrestrial organisms and birds under REACH.

However, many stakeholders at the Commission workshop were of the opinion that differences in PBT conclusions across legislation would mainly originate from the approach of using “other evidence based on WoE”, in particular when many different and/or contradicting test results are available. Differences in the non-numeric PBT criteria as identified from the workshop documentation, literature and stakeholder inputs are:

- Consideration of constituent substances (REACH in general > 0.1%; Biocides > 10%), transfer and degradation products in the PBT assessment;
- Availability and type of data used and the interpretation for PBT assessment (e.g. reliability; application of WoE approach) as well as aggregation of results from multiple studies;
- Different committees being responsible for the PBT assessment;
- Existence of different guidance documents⁶¹ and procedures for guidance development;
- Non-extractable residues (NER) are considered as removed / non-bioavailable under the Plant Protection Products Regulation. The discussion on how to deal with NER under other legislation is ongoing;
- Use of field studies for determining persistence;
- Consideration of the forms of the tested substance; and
- Differences in thresholds triggering the detailed PBT assessment (in particular LogKow for medicinal products).

Several stakeholders mentioned that the PBT/vPvB criteria should include further criteria to consider terrestrial bioaccumulation and substances not bioaccumulating via lipid partitioning. Furthermore, the T-criterion should be extended to include e.g. neurotoxic and endocrine disrupting effects, according to some stakeholders. Finally, a public authority highlighted that persistent, toxic and mobile substances are of concern with view to potential groundwater contamination.

An additional aspect, mentioned by industrial actors and partly by authorities, concerns the question of whether or not and how a particular compartment should be identified as most relevant⁶².

⁶⁰ The applicability and relevance of results from the OECD simulation test 308 is currently being discussed by several scientists. The results from the test are found to be not sufficiently certain and robust, due to the difficulties in distinguishing between actual elimination of substances and transfer between compartments. Furthermore the test results were found to depend on the geometry of the test. It is recommended to invest further research in developing standardised tests (at lower costs) to derive persistency values; c.f. among others: Honti, M. and Fenner, K. (2015): Deriving Persistence Indicators from Regulatory Water-Sediment Studies – Opportunities and Limitations in OECD 308 Data, in: Environ. Sci. Technol., 49 (10), pp 5879–5886 and Honti et al. (2016): Bridging across OECD 308 and 309 Data in Search of a Robust Biotransformation Indicator, in: Environ. Sci. Technol., 50 (13), pp 6865–6872.

⁶¹ Whereas there are different trigger values for the PBT assessment under the medicinal products directive, the actual PBT assessment is carried out according to REACH. Data requirements are, however, different according to the guidance on the environmental risk assessment under these frameworks.

⁶² Under REACH, the relevant compartment(s) should be identified for the assessment of degradation and for the selection of a suitable degradation simulation test, if needed (see e.g. Guidance on information requirements. Chapter R.11: PBT assessment or Rauert et al. (2014).

Respective testing can be limited to this compartment, for reasons including saving resources and obtaining more relevant information on persistence.

One NGO stakeholder proposed to decrease differences in PBT assessments by establishing a committee of independent experts, who should oversee the guidance development under different legislation and thereby contribute to harmonisation of approaches.

In conclusion, the legal basis of the PBT criteria and partly also the guidance documents used are regarded as harmonised under REACH, the Biocidal Products Regulation, the medicinal products directives and the Water Framework Directive. The main numeric differences concern the Log K_{ow} values triggering data generation and further assessment for medicinal products for human and veterinary use. In addition, for medicinal products different committees exist which could reach different PBT conclusions. The legal definition of the PBT criteria in the Plant Protection Products Regulation and the related guidance documents are partially different as well the assessment procedures.

3.2.2 PBT conclusions

Based on the above assessment of coherence of the PBT definitions, different PBT conclusions could have different reasons such as: differences in the legal text, the assessment triggers, guidance documents or the assessment procedures as such. Only a few examples of inconsistent conclusions could be identified, which are presented below.

Coordination of procedures - time of decision making

A difference (also) due to the timing of decision making on the PBTness of a substance is observed for quinoxifen, which was first assessed under Directive 91/414/EEC, which was repealed by the Plant Protection Products Regulation in 2001, and then under the Water Framework Directive. The expert group under Directive 91/414 concluded that the substance is not a PBT, based on data and guidance available at that time. Several years later, the expert group of the Water Framework Directive concluded that quinoxifen is a PBT following REACH guidance. Until the review of the pesticides approval, quinoxifen is hence considered a PBT under the Water Framework Directive and not a PBT under the Plant Protection Products Regulation. It is not clear whether EFSA will come to the same conclusion as the Water Framework Directive expert group, since they might evaluate the existing information differently. Furthermore, additional new information is likely to be available to EFSA.

Hypothetical examples: consideration of degradation products

Endosulfan and DecaBDE are examples of substances, which are considered as POP due to their degradation products. As degradation products are not considered they would not be identified as PBT under the Plant Protection Products Regulation. Both cases are hypothetical because endosulfan is banned and therefore will not be assessed under Plant Protection Products Regulation and DecaBDE is unlikely to be used in pesticide applications⁶³.

⁶³ However, if a relevant metabolite is a PBT, the parent compound is not likely to be approved unless a risk assessment showed that no unacceptable risks are expected.

Assessment of Flufenoxuron under the Biocidal Products Directive and the Plant Protection Products Regulation

The assessment of flufenoxuron is included in the respective legal decisions:

The Biocidal Products Directive⁶⁴: Flufenoxuron fulfils the criteria of vPvB and PBT and is therefore not approved in biocidal products, except for the PT8 (wood preservatives), where a risk assessment showed that no unacceptable risks are expected. Although having vPvB properties, the substance was nevertheless approved for a limited period of time (3 years instead of 10 years).

The Plant Protection Products Regulation⁶⁵: Flufenoxuron is not approved for use in pesticides due to a lack of possibility of reliably estimating consumer exposure and a high risk identified for the aquatic environment. The substance was not identified as PBT/vPvB.

Assessment of tebuconazole under the Biocidal Products Regulation and the Plant Protection Products Regulation

A case where the assessment under the Biocidal Products Regulation and the Plant Protection Products Regulation are very different is the one of tebuconazole, which only concerns two of the PBT criteria. To check if it is a candidate for substitution (i.e. if two of the PBT criteria apply), tebuconazole was assessed under the Plant Protection Products Regulation and the Biocidal Products Regulation and the P and T properties were evaluated differently: EFSA concluded⁶⁶ that tebuconazole is moderate to medium persistent and that it does not fulfil the T-criterion. In the Commission Regulation on tebuconazole for use as biocide active substance⁶⁷ it is considered as very persistent and very toxic, hence fulfilling the substitution criteria.

PBT identification in the international context

The identification of PBT / vPvB in other regions, such as the US and Canada is based on different criteria and therefore, substances may be a PBT in the EU and not elsewhere and vice versa. An example is siloxanes (D4/D5), which are considered PBT/vPvB in the EU but not in Canada.

Conclusions

While there are noted differences in the criteria of PBT/vPvB, related guidance and assessment approaches (c.f. Section 3.2.1), only a few examples could be identified that show that different conclusions for the same substance are reached across legislation. No information could be obtained on differences in the national assessment procedures (e.g. product authorisation) and the differences between Member State assessments. Consequently, while aligning legislation and harmonising assessment approaches and guidance may be an issue of efficiency and overall

⁶⁴ Commission Directive 2012/20/EU of 6 July 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include flufenoxuron as an active substance for product-type 8 in Annex I thereto.

⁶⁵ Commission Implementing Regulation (EU) No 942/2011 of 22 September 2011 concerning the non-approval of the active substance flufenoxuron, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Decision 2008/934/EC.

⁶⁶ EFSA (2014): 'Conclusion on the peer review of the pesticide risk assessment of the active substance tebuconazole', in *EFSA Journal*; 12(1):3485.

⁶⁷ Commission Implementing Regulation (EU) No 1038/2013 of 24 October 2013 approving tebuconazole as an existing active substance for use in biocidal products for product- types 7 and 10.

coherence at EU level, it does not appear to be an issue of high priority regarding unjustifiable inconsistencies or discrimination of substances under different legal areas.

3.2.3 Challenges in PBT assessment

According to industry stakeholders and some authorities, the application of the WoE approach is the most unclear issue of the entire assessment process. Some stakeholders, including NGOs and industry representatives stated in the interviews and at the Fitness Check workshop that they believe that using WoE decreases the predictability of the PBT assessment and could lead to inconsistent PBT conclusions because of the expert judgement involved⁶⁸.

Several stakeholders propose developing a consistent EU-wide WoE methodology (clear and transparent), including scoring methods to allow identification of the (most) reliable and relevant data, which are of sufficient quality for use in the assessment. The WoE methodology should allow considering all scientific studies available, with GLP data being prioritised. Non-GLP data, including monitoring data should be useable if conducted according to scientific standards.

All stakeholder groups are of the opinion that the PBT identification is subject to political interests. Due to the risk management consequences of PBT identification, in particular for active substances used as biocides and pesticides, scientific debate on substances' properties could be affected by the political interests of the stakeholders involved. Examples of how the scientific assessment could be affected by political/economic interests include through discussions on the reliability and validity of data, whether or not the conditions of testing are appropriate (e.g. temperature of degradation testing) and the specific interpretation of study results. Whereas some of these difficulties might be solved if clearer guidance was developed (including a more specific and objective approach to WoE) many stakeholders believe that other difficulties are likely to remain due to the variability of tests, substances and procedures and depending on the experts in the expert groups and committees. This is partly due to the complexity of the assessment (in particular for UVCB), which can hardly be covered by guidance documents⁶⁹.

Industry stakeholders also commented that exposure and risk considerations should be taken into account in PBT identification, as is partly the case in the PBT assessment in other regions (e.g. Canada, US). Other stakeholders, in particular NGOs and some competent authorities, strongly advocate that the PBT assessment should be primarily based on hazardous properties as well as information on occurrence in the environment (modelled or monitored exposure information). The latter should, however, not be used to derive a potential risk, but for example to support conclusions on persistence and bioaccumulation or to target simulation testing to a relevant compartment.

In conclusion, guidance on the application of the WoE approach in relation to PBT/vPvB identification might support more harmonised and potentially more efficient PBT identification procedures. Most stakeholders appear to accept such guidance. While efficiency would address any assessment by a more targeted data evaluation, harmonisation effects should occur for procedures under different legislation (the Biocidal Products Regulation, the Plant Protection Products Regulation, medicinal products, etc.). Whether or not the application of such guidance would

⁶⁸ C.f. above, this statement could not be verified by any example or statistical evidence on rejection or use of data in a particular manner.

⁶⁹ These political interests that could influence the selection and assessment of validity of data or the decision on how data should be interpreted are obviously not apparent from the documentation that is available from published sources. Hence, it could not be verified if and to which extent this is actually the case and only the stakeholder opinions can be quoted.

actually change the outcome of an assessment (i.e. the evidence would be evaluated differently) cannot be judged.

3.2.4 Effectiveness of the criteria

At the Commission's stakeholder Workshop on PBT assessment, several presentations analysed if the PBT/vPvB criteria are effective and sufficient to identify substances of high environmental concern, inter alia:

- Stefania Gottardo (JRC) concluded that the current PBT criteria may fail to identify substances that are bioaccumulative and/or toxic in non-aquatic compartments. P and T criteria for non-aquatic compartments would have to be developed.
- In his presentation on the development of the POP criteria, Michael Matthies (Institute of Environmental Systems Research, University of Osnabrück, Germany) pointed out that the original cut-offs were based on property information of reference substances, i.e. PCBs and chlorinated pesticides. The final cut-offs are based on half-lives protective for the Nordic environment that were recalculated at 20°C (resulting in lower cut-off-values), which is usually the temperature under which OECD degradation simulation tests are carried out in laboratories. As regards the B-criterion, inter alia political views played a role in choosing the cut-offs. According to Mr. Matthies, the current criteria (and the temperature under which degradation simulation tests are carried out) should not be modified, because this would change the intention of the original POP criteria and in principle mean a double accounting of the influence of temperature on degradation.
- Johanna Peltola (ECHA) illustrated that many PBT/vPvB could not be identified via a 1:1 comparison with the PBT criteria but were identified based on "other evidence". This indicates the need for case-by-case assessments and for more extensive data than required under REACH and other legislation.

Based on their analysis, Rauert *et al* (2014) developed several suggestions to improve the PBT criteria and the rules for data evaluation, which are partly controversial.

Proposals for extending the PBT criteria collected in the stakeholder consultations related to:

- Widening the possibilities to identify persistence (e.g. "overall persistence" considering physical-chemical property data and environmental fate under "real life conditions");
- Adaptation of B-criteria to better reflect terrestrial bioaccumulation and bioaccumulation which is not based on lipid partitioning; and
- Extending toxicity criteria to endocrine disruption, neurotoxicity and immunotoxicity.

The ECHA guidance document on PBT-assessment under REACH is currently under discussion. Approximately 20 scientific issues are being evaluated, indicating the scale of scientific challenges in PBT assessment as well as the efforts by ECHA and stakeholders to include new scientific findings in the assessment methods and evidence used. It was mentioned by one stakeholder that predictability of the PBT assessment outcomes would be crucial for industry to plan and innovate. Therefore, it would be helpful if only well approved new scientific methods were used and clear criteria were defined for those substances which have been identified as PBT/vPvB in recent years (e.g. non-lipophilic substances which are considered bioaccumulative because of their ability to bind to blood proteins).

The literature review and stakeholder consultation showed that the PBT screening criteria in REACH Annex XIII, as well as in the medicinal products directives, is not always suitable to identify all PBTs. In particular the LogKow was noted as being a poor indicator, because several substances, such as those accumulating via other mechanisms than lipid partitioning (for example, perfluorinated substances), would not be identified via the LogKow. In addition, the (ease of) application of PBT criteria differs depending on the type of assessed substances: i.e. the more complex the substance or the more difficult it is to test (e.g. because of its physical chemical properties), the more expert judgement will be needed.

Different opinions exist regarding the relevance of the PBT criteria for addressing chemicals of concern for the environment. Whereas industry representatives would welcome exposure and risk considerations in the PBT identification (e.g. substance behaviour under environmental conditions or accounting for effects of implemented RMMs), NGOs require extension of property based criteria (i.e. hazard-based criteria) mainly related to ecotoxicity. Authorities' comments focus on clarifying and broadening the cut-off values, mainly relating to P and B criteria.

Industry provided further comments on the PBT criteria and related guidance for assessment in the consultation for this case study:

- PBT criteria and assessments do not take into account the newest scientific findings, such as environmental monitoring and fate data or “real world data” on exposure levels⁷⁰; and
- The P- assessment should be focussed on the compartments, where a substances is likely to end up, based on its physical-chemical properties. This might include describing interactions between compartments, should consider all possible degradation routes and apply the concept of “overall persistence”.

Additional comments on the effectiveness and appropriateness of criteria obtained from different stakeholders via the consultation are provided in Table 3-1.

Table 3-1: Additional comments on the effectiveness of criteria	
Issue	Assessment of relevance
There are very few REACH registrations indicating substances with PBT properties. This may highlight a need to provide more/better guidance and/or to more strongly enforce the implementation of PBT assessments under REACH	ECHA's database of registered substances indeed lists very few substances identified as PBT/vPvB ⁷¹ Registration data are core information for SVHC identification, hence it is important that such data are correct. However, it cannot be judged whether or not the small number of PBT/vPvB according to registration dossiers results from incorrect assessments
Screening exercises on PBT frequently reveal more than 600 potential candidates but further assessment reduces the number to very few substances; this may indicate that the	It is intended that screening criteria are overprotective, i.e. result in false positives This is not an important issue with regard to the fitness of current legislation as the PBT/vPvB screening criteria are only a trigger for further assessment. However, the screening cut offs

⁷⁰ The two industry representatives providing this statement did not specify how far scientific findings related to monitoring data and exposure levels, etc. are not taken into account. Therefore, it is not possible to verify if this is actually the case or not. However, stakeholders from other groups, e.g. authorities and NGOs made clear that they believe new scientific findings and data are used in the assessments; with the exemption that new scientific methods are only applied if they are sufficiently well developed and reliable.

⁷¹ 54 substances are listed in a search for “Outcome of PBT assessment = PBT/vPvB”. The list includes inorganic substances.

Table 3-1: Additional comments on the effectiveness of criteria

Issue	Assessment of relevance
screening criteria are not suitable	for Log Kow are not consistent and some are more protective than others. Furthermore, the current screening criteria would miss certain substances (e.g. lipophilic ones like PFC)
Consistency of PBT assessment could be increased, if the P and B properties were included as hazard classes in the CLP Regulation	It is unclear if inclusion in the CLP Regulation would solve challenges in the assessment of properties as the named differences in the criteria as such are of minor relevance. This issue is an individual aspect in relation to the CLP, which is currently not up for discussion
The scientific debate on how degradation testing could be optimised is ongoing. This includes modifying the OECD test methods for ready degradability so that “enhanced information” could be obtained from them. This should be implemented to make PBT assessment more efficient. It furthermore relates to the relevance and reliability of OECD simulation testing ⁶⁰	Work on the methodology is indeed ongoing. The effect on efficiency of the assessments cannot be judged. This concerns the implementation of the assessment rather than the framework as such and shows that scientific developments are taken into account
Stating the aims of assessing the individual PBT criteria could support their consistent application, e.g. for B assessment an explanation of the aim to prevent food chain accumulation is not included in the guidance	The effect of including such information in the guidance cannot be judged. While a valid comment as such, this is not of high importance to the overall fitness of the framework
The PBT criteria were developed as a set of interlinked criteria. The approach under the Biocidal Products Regulation and the Plant Protection Products Regulation to impose legal requirements on substances fulfilling only 2 out of the 3 criteria is not adequate (candidate for substitution)	PBT criteria are to be viewed in conjunction. The question of how and why candidates for substitution are identified under the Biocidal Products Regulation and the Plant Protection Products Regulation does not directly relate to the fitness of the legal framework for identification of PBT/vPvB. Nevertheless, the concept of candidates for substitution might be re-evaluated

Conclusions

The PBT/vPvB criteria were developed to protect man and the environment from a particular type of substance, namely those that persist and accumulate because it was anticipated that their concentrations might reach levels where toxic effects could occur⁷². The current criteria do still fulfil this aim. However, the screening criteria triggering an in depth assessment have been shown as missing PBT/vPvB, in particular if the numeric criteria cannot be applied due to physico-chemical substance properties (i.e. WoE including other data would trigger a PBT/vPvB conclusions). The most prominent current examples are some PFCs (failing B and T).

⁷² Assuming that not all toxic effects are already known and taking a generally precautionary approach, substances without a known toxicity should also be covered if they appear to accumulate significantly in the environment.

Whether or not the T-criterion should include further toxic properties, such as endocrine disruption or neurotoxicity is a relevant discussion within the overall intention of the definition of PBT/vPvB. It cannot currently be judged if this would change the level of protection⁷³.

3.3 Evidence used for PBT assessment

The PBT assessment according to REACH Annex XIII should consider all available information. The Plant Protection Products Regulation and the Biocidal Products Regulation require compilation and generation of data sets for any substance approval. Under the medicinal products directive, data needs to be generated, if an initial exposure assessment or the value of the LogKow exceeds the trigger values. Under the Water Framework Directive, no new data must be generated and to a large extent, data that have already been evaluated and aggregated (risk assessments) are considered.

In general, the data requirements are more extensive for active substances in plant protection products and biocidal products than under REACH. All legislation includes a required core data set (e.g. Reg. 283/2013 and Reg 284/2013 under the Plant Protection Products Regulation, Annex VII and VIII under REACH) and suggests providing additional data if necessary, e.g. under certain exposure conditions. Because in most cases the PBT assessment is a non-standard assessment and the data requirements may be fulfilled using existing information as well as alternative data (e.g. computer models, (Q)SARs), it cannot be stated at a general level if the data requirements in the respective legislation are sufficient to allow PBT assessment.

3.3.1 Understandability of data requirements

Most stakeholders consider the legal framework sufficiently clear regarding the wording of data requirements and related explanation in guidance documents. This includes the quality requirements on all types of data.

The REACH guidance document on PBT assessment is extensive and continuously developed further (in agreement with stakeholders) to take account of technical and scientific progress. None of the stakeholders complained of it being difficult to understand or unclear. For plant protection products, the two Regulations on data requirements are accompanied by two Communications which detail the validated testing methods available³². Stakeholders commented that the SANCO working document on evidence needed for PBT assessment for plant protection products was clear, although further guidance on higher tier testing and use of the WoE was welcomed.

Under the Water Framework Directive, the level of evidence and criteria to identify PHS (among these PBT/vPvB relevant for the aquatic environment) are clearly defined. However, there are differences of opinion on the use of studies in the chemicals expert group under the Water Framework Directive.

⁷³ It cannot be assessed based on available data if and how many additional substances would be identified as PBT, if endocrine disruption, neurotoxicity and/or other properties of high concern were considered under the T-criterion. Furthermore, it cannot be determined which risk management consequences this would have (e.g. if additional measures would be triggered).

3.3.2 Overall data availability

As has been indicated in ECHA's evaluation reports and several publications in the context of the REACH review 2012 as well as in the latest ECHA report on the operation of REACH and CLP⁷⁴, the data quality and the quality of hazard and safety assessments in the REACH registration dossiers are not yet sufficient. A similar overall evaluation of available data for PBT assessments does not exist for other pieces of legislation.

Some authorities and NGOs commented that the data requirements under some legislation are not sufficiently aligned with the needs for PBT assessment, e.g. under the Biocidal Products Regulation and REACH. This would partly be due to the screening criteria not being appropriate PBT indicators (false negatives and false positives). In addition, difficulties in testing of substances and the need for non-standard information, such as monitoring data or exposure information to interpret study results would be other reasons why the information requirements are not sufficient for PBT identification in many cases.

Most stakeholders evaluate the data availability under the Plant Protection Products Regulation as sufficient for PBT assessment, as an extensive data set is required for substance approval. However, some NGOs expressed concerns that industry conducted studies (for PBT assessments) may be biased, due to the severe consequences related to PBT identification, in particular under the Plant Protection Products Regulation. Industry commented that the data requirements are appropriate, i.e. neither lowering⁷⁵ nor increasing the requirements on the type, amount and quality of data that are regarded necessary. Pesticides are "data rich" and, compared to REACH, no alternative data such as (Q)SARs or lower tier tests are normally used. Furthermore, field data with multiple test systems form a thorough basis for estimating environmental fate.

Information from the PBT expert group on their experience with the data availability for PBT assessment indicates the following challenges:

- Substances are technically difficult to test and therefore information is (and might remain) missing;
- The interpretation of test results might need additional information, which is not available and/or collected with initial testing; if there are timelines for decision making, additional information may not be generated in time;
- Read across and (Q)SARs are not well documented and therefore difficult to check; this slows down the assessment or triggers the need for new / additional information; and
- Available data are not always taken into account (not found, evaluated as not reliable, relevant or valid, not conforming to GLP, etc.).

Apart from the data that are legally required from registrants / applicants for approval or authorisation, all available data should be taken into account in all of the legal frameworks covered in this case study. NGOs critically commented they believe industry does not always use all available

⁷⁴ ECHA (2016): Report on the Operation of REACH and CLP 2016, Helsinki.

⁷⁵ However, industry commented that targeting of information collection e.g. for P-assessment would be useful, which might result in a lowering of requirements in specific cases.

data⁷⁶. However, there is a higher level of confidence that authorities would use data from academia or independent laboratories (not working according to GLP) in their assessment⁷⁷.

Additional comments provided by industry are:

- Costs of generating more data need to be balanced with the revenue for the substance volume produced; and
- Where impurities, and/or degradation products exist, exposure considerations should guide intelligent testing requirements for the most relevant constituents.

Conclusions

The standard information requirements in legislation form the basis for PBT/vPvB assessment. Experience e.g. in the PBT expert group shows that this information is normally not sufficient to conclude on the PBTness of substances. Consequently, either this information can be deduced from existing data in a WoE approach or must be generated via new tests or from other sources. The in-depth assessment and the need for further information depend amongst other things, on the physical-chemical properties of a substance and are case-by-case. Consequently, any broadening of the standard information requirements aimed at providing a better starting point for PBT assessments would be achieved at the cost of testing substances that are (obviously) not PBT/vPvB.

As the screening of information is crucial for initiating an assessment, consideration could be given to the PBT screening criteria and the availability of suitable information, for example, if an additional criterion should be introduced which would catch e.g. lipophilic substances or substances accumulating in terrestrial organisms.

3.3.3 Data quality

Legislation defines quality requirements for the data used in PBT assessments. These are in principle:

- Data should be generated according to GLP and using accepted international standards, such as OECD guidelines;
- If data are used which were not generated according to GLP and either deviate from accepted guidelines or are based on testing protocols which are not internationally accepted, this should be justified and can be accepted, if the overall principles of GLP and science are implemented;
- Data should be reliable, relevant and valid for the assessment; and
- If data from non-testing methods are used, the applicability domain of the method as well as other limitations should be considered and described, and transparent and scientifically sound justification for the use of data must be provided.

All stakeholders agree that there is no objective approach to the quality assessment of data, including relevance, reliability and validity. The currently applied systems (e.g. Klimisch criteria) are

⁷⁶ Some NGOs expressed their concerns that industry evaluates studies from other organisations as not relevant, reliable or valid and thereby does not consider information that would endanger their product.

⁷⁷ In this regard some NGOs expressed concerns as to the capacities of authorities to screen and integrate all available information.

ambiguous and therefore, it is inevitable that the data quality is subject to interpretation and discussion.

According to stakeholders in the PBT expert group, the reliability of studies can be and is disputed but frequently unanimity is achieved in the end. The assessment of data reliability is context specific and must be taken into account where identified deficiencies of a study would have an impact on the purpose for which it is envisaged to be used in a weight of evidence approach.

Under the Water Framework Directive, the CRED system is introduced to support the assessment of information quality. At the Fitness Check workshop in April and according to feedback from the stakeholder consultation, the approach and criteria are regarded as useful and more objective and replicable than the Klimisch criteria.

Stakeholders mostly agree that GLP ensures good working practices of laboratories as well as the transparent and systematic documentation of studies. However, GLP is not a sufficient requirement to ensure high quality data.

Additional comments received in the stakeholder consultation regarding the quality of data for use in PBT assessments include:

- The review timetables of the Plant Protection Products Regulation and the Biocidal Products Regulation may delay taking account of new scientific findings and data in approval decisions; hence data of higher quality could be available but not used for the assessment;
- A discussion on use of screening data and read-across approaches for making definitive conclusions on PBTness is needed, regarding both the positive and the negative PBT identification; and
- It would be useful to assess if the GLP requirement prevents the use of scientific studies, which are conducted by academia and which do not use GLP.

Conclusions

Regarding the quality of data related specifically to PBT identification, there are no particular aspects to highlight. Stakeholders identify and mention similar issues as for any data and assessment under chemicals legislation. As PBT assessments are carried out with the participation of several actors, partly from different stakeholder groups, justifications for PBTness or conclusions on non-PBTness can be regarded as being of high quality. Issues related to the system of measuring data quality are not PBT specific.

3.4 Procedures for PBT identification

3.4.1 Committees and expert groups

ECHA's PBT expert group, which includes Member State experts and stakeholders from industry and NGOs, (pre-)assesses substances under REACH, the Biocidal Products Regulation and the VMP as well as proposals for listing substances under the Stockholm Convention (POPs). In addition, the following committees are involved in decision making: Member State Committee (REACH), Biocidal Products Committee (BPC) and the Committee for Medicinal Products for Animal Use. Under the Plant Protection Products Regulation, the RMS and EFSA organise the PBT identification process, which involves all Member States and may include an expert consultation. PBT identification for HMP takes place in the Committee for Medicinal Products for Human Use based on the draft

assessment report by the RMS. Under the Water Framework Directive, an expert group for chemicals exists, which identifies priority hazardous substances including PBT.

Stakeholders expect that differing conclusions on the PBTness of substances could be due to the varying interests of the involved experts and/or different interpretations of available data. These differences could occur within the expert groups and committees but are mainly expected across different legislation and related procedures and committees. Variations in the level of expertise are seen as another reason for differences in the PBT assessment, but are regarded as being of lower relevance. According to members of the PBT expert group, one area where different interpretations frequently manifest are not fully developed scientific methods and approaches. Whereas authorities appear to argue more precautionary, industries tend more to defend their products.

Overall, the work of ECHA's PBT Expert group is well received by all stakeholders, as the group ensures harmonisation of approaches to PBT identification under REACH, the Biocidal Products Regulation and VMP. According to stakeholders, the discussions are constructive and the work is considered both useful and successful. The work of the expert group under the Water Framework Directive is also considered constructive, useful and transparent.

All consulted stakeholders expressed the wish to harmonise PBT assessment and conclusions, with some, in particular from the authorities' side suggesting a centralised procedure. The parallel assessment procedures are regarded as inefficient and time consuming, in addition posing the risk of inconsistent PBT conclusions.

Conclusions

While there is a general assumption that the PBT assessment requires a high amount of resources, no statement on the efficiency of the procedures can be made due to a lack of information on the time investments made by different stakeholders and a lack of opportunities to compare these with other procedures that would reach the same conclusions. A high degree of satisfaction and acceptance of the PBT expert group's work can be observed.

3.4.2 Speed of PBT identification

The time for PBT assessment differs under the different pieces of legislation. SVHC identification under REACH has defined timelines and should be finalised within approximately 1.5 years⁷⁸. The assessment under the Plant Protection Products Regulation is part of the overall substance approval and might therefore take much longer (i.e. up to approximately 3 years).

None of the stakeholders considered the process as "quick" or "too quick". Opinions on the speed of the process were divided with some stakeholders evaluating the speed as appropriate with a view to the science and "democracy" involved and others considering it "too slow".

Industry sees optimisation potential by improved coordination in decision making within legislation as well as across legislation, so as to provide e.g. the results from SVHC identification to any processes under other legislation or for dossier evaluation under REACH.

⁷⁸ The Annex XV Dossier is to be prepared within a year, followed by public consultations and a decision process, which may be of different durations depending on the degree of unanimity on the PBT conclusion.

Conclusion

It appears that the time foreseen to come to a PBT conclusion is adequate. No information has been found that could be used to compare the assessment speed with other processes.

3.4.3 Allocation of responsibilities

In all chemicals legislation, industry provides the data and an initial PBT assessment⁷⁹ either in the registration dossier (REACH) or as part of application dossiers for substance approval or authorisation. In a second step, EU or national authorities either evaluate industries' assessments individually or in expert groups. They discuss the assessments amongst themselves or with the involvement of stakeholders. In case of differences in opinion or lack of information to conclude on a substance, further information is requested from the registrant/applicant and or clarification is sought. The EU Commission takes the final decision on the PBTness of a substance in most cases⁸⁰. Authorities do not evaluate the PBT assessments by REACH registrants, except where they are subject to dossier evaluation or a substance evaluation.

Under the Water Framework Directive the burden of proof is different than under other legislation, as the PBT identification is led by the authorities and only existing information and/or assessments are used; i.e. no new data are generated for PHS identification. The different allocation of burden of proof is partly due to the Water Framework Directive being environmental legislation and not targeted to the manufacturers of products; i.e. "chemical environmental pressures" are identified and their relevance assessed by the authorities and stakeholders with the only aim being to look at the status of the environment.

In the interviews and written input provided to the case study, only some of the stakeholders commented on the allocation of responsibilities and burdens. Overall, each group of actors tends to evaluate the burden placed on itself as too high, with NGOs tentatively asking for more actual resources to be used by industry and authorities alike. One Member State representative stated that SMEs are unlikely to properly implement the PBT assessment. An industry stakeholder found too little justification is provided for PBT conclusions by the authorities.

Conclusions

The allocation of responsibilities is consistent across legislation and reflects the principle of burden of proof. While all stakeholders have limited resources, it is natural that they strive towards lower workloads.

3.4.4 Transparency and stakeholder involvement

All in all, most stakeholders claim good progress is being made regarding transparency of procedures and participation opportunities for stakeholders in the assessment.

⁷⁹ No PBT assessment is required for substances registered below 10 t/a, as no chemicals safety report is required.

⁸⁰ Inclusion on the candidate list based on PBTness may be decided by the Member State Committee, if there are no diverging opinions.

Most of the consulted stakeholders consider the PBT identification under REACH / Biocides /VMP as the most transparent⁸¹ procedure and giving the stakeholders sufficient opportunity to get involved. This is, among others, due to the existence of the “Public Activities Coordination Tool” and the registry of intentions (ROI). A similar conclusion was reached regarding the transparency of procedures and related stakeholder participation at the Fitness Check workshop in April. The process of identifying POPs under the Stockholm Convention was also considered by one stakeholder as transparent and open for stakeholder involvement.

Industry commented that the involvement in the guidance development process is appreciated and that the opportunity of “defending a substance” implemented in the Biocides Product Committee could be regarded as good practice.

According to some stakeholders (industry, authorities), the outcome of PBT assessments are not predictable due to the application of WoE as well as the possibilities that new data are requested during the process. Furthermore, changes in which substances are considered as PBT/vPvB fulfilling the non-numeric criteria (i.e. based on monitoring data, non-lipophilic) would decrease the predictability of the assessments.

Comments on the level of transparency of PBT assessment processes from NGOs include that neither raw data from the studies nor sufficient justification is published with the approval / non-approval or authorisation decisions for pesticide active substances. Another point of criticism, which was also raised at the Fitness Check workshop in April, relates to the composition of expert groups and committees. Here, the dependence of experts on industry is regarded as critical as well as the question of whether or not the Committee members sufficiently cover all areas of required expertise⁸².

3.4.5 Costs and benefits related to PBT identification

Industry commented that the regulators would benefit from the current provisions on PBT/vPvB identification, as they could apply “one approach to all substances” and avoid resource consuming scientific work due to a lack of a thorough WoE. Industry questioned if PBT assessment and management results in the expected (increase in) level of protection for consumers, workers and the environment. In addition, there would be unnecessary burdens in data generation⁸³, where it is

⁸¹ Note that the substance evaluation procedure was regarded by one stakeholder at the Fitness Check workshop in April as not being transparent since information published during the assessment process, if any, is difficult to trace.

⁸² Procedures are in place at EU level to avoid conflicts of interest. Whether or not these do exist and/or if competences are missing in the expert groups cannot be judged by the consultants.

⁸³ The burdens of such data generation (in the context of substance evaluations) are difficult to quantify as it is a case-by-case decision as to which information is requested. It could regard standard tests, which are well established (e.g. for biphenyl information on ready biodegradability, sediment simulation testing and EOGRTS) or specific tests, which are not conducted in labs on a routine basis and might hence be more expensive (e.g. for decahydronaphthalene: Mysid Acute Toxicity Test and Mysid Chronic Toxicity Test) or regard refined information on available exposure information (e.g. 3,3-dimethylphenyl-4,4 diyl diisocyanate: Exposure scenarios, explanation of parameters used in the exposure assessment and more detailed information on the lifecycle). In addition to the diverging types of information requests triggering different types of costs and efforts, the costs might be shared between registrants; the number of registrants in a SIEF per PBT/vPvB may significantly differ, resulting in different costs for individual companies. Consequently, it is not possible to estimate generalised costs for additional data generation.

unclear if the information helps decision making (e.g. on constituents, degradation studies under different legislation at different temperatures, related to different compartments).

Authorities and NGOs acknowledged that the identification and management of PBTs/vPvBs results in costs to authorities and industry. However, costs to industry were regarded as justified according to the “polluter pays principle”. Costs to authorities are regarded as unavoidable if they are to take their responsibility to protect health and environment. Overall, the benefits of identification and management of PBTs should outweigh the costs and therefore justify the efforts by industry and authorities. Several stakeholders pointed out that the costs for data generation should be balanced and it would be useful to implement intelligent testing strategies.

The literature review and the stakeholder feedback did not include any information on the actual resource / financial investments necessary to identify one PBT/vPvB under any of the legal acts.

Benefits of PBT/vPvB identification depend on the subsequent risk management measures. If any comments were received on the extent of benefits, they were very general (“improves the level of protection”) or pointed out that the quantification of environmental (and health) benefits is difficult to determine. Therefore, normally no thorough cost-benefit assessments could be performed (and inform decision making).

Conclusion

Due to the various aspects influencing industry’s costs for data generation and assessment of PBTs, it is not possible to draw a general conclusion on the significance and potential effects of these costs to companies.

3.4.6 Other aspects

The responses to the targeted consultation of manufacturers of plant protection products show that there have been disagreements on the classification of active substances between EFSA and the rapporteur Member States as well as between EFSA and the RAC. This is an indication that similar differences could also exist also on the identification of PBT/vPvB.

The responses also indicate that there are different opinions on the classification of plant protection products between the applicants and the Member State authorising a product as well as between Member States in different zones, the latter resulting in differently classified products in different regions. Also this indicates that there could be differences in opinions on the PBTness of substances in a plant protection product.

The procedures for product authorisation conducted by the Member States were not subject to detailed consultation. However, it was indicated by Member State authorities and industry that the assessment procedures and interpretation of data (for substances and products) differ across the Member States. The consultees did not provide any examples for PBTs. Industry stressed that respective harmonisation and consistency were crucial.

Another comment by industry was that the available guidance is too extensive and streamlining would be necessary to support industry stakeholders in PBT assessment.

One Member State authority and NGOs commented that competitive disadvantages from bans are expected to be low, because of internationally converging RMM approaches (and identification procedures).

3.5 Triggers of risk management and types of measures

The RMM triggers are not the same across the legislative framework: whereas automatic bans are included under the Plant Protection Products Regulation and the Biocidal Products Regulation (with options for derogations in case of the Biocidal Products Regulation), REACH “only” automatically triggers communication requirements upon PBT candidate listing. In addition, emission minimisation for PBTs is triggered automatically, regardless of how and by whom a PBT is identified under REACH. For VMP, marketing restrictions could be implemented based on a cost-benefit assessment whereas authorisation as HMP may not be denied based on environmental considerations/PBTness. Under the Water Framework Directive no RMMs are automatically triggered for PBTs/vPvBs listed in Annex X.

Overall, many stakeholders commented that the different frameworks including provisions for PBT/vPvB identification and management have slightly different objectives and protection goals as well as concerning different application areas. These differences would justify inconsistencies in the risk management approaches, including in relation to the RMM triggers.

Limited comments were obtained during the stakeholder consultation in the context of this case study on the appropriateness of RMM triggers and the types of measures foreseen in the legal framework. The overall tendency observed is that industry pleads more strongly for more risk based assessments and taking exposure as well as existing risk mitigations measures into account, whereas some authorities and NGOs strongly advocate a hazard based (and precautionary) approach to risk management.

Overall, the requirements automatically triggered by a REACH registrant’s PBT identification (minimisation of emissions by registrant and downstream users) are considered appropriate. The step-wise process of SVHC identification via candidate listing or substance authorisation followed by further assessment and implementation steps for risk management measures (restriction, authorisation) is also considered as appropriate by most stakeholders⁸⁴. No comments were obtained on REACH Article 33.

The opinions on the automatic marketing ban of PBTs/vPvBs under the Plant Protection Products Regulation and the Biocidal Products Regulation were divided. Some authorities and NGOs generally found market restrictions automatically triggered under the Plant Protection Products Regulation and the Biocidal Products Regulation appropriate with one NGO stating that the option for derogations under the Biocidal Products Regulation should be deleted. Some Member States and NGOs stated that derogations from market bans should also be introduced under the Plant Protection Products Regulation in order to enable inclusion of socio-economic information and information on possible alternatives in the approval of active substances and facilitate the PBT identification process. Industry stakeholders are generally of the opinion that any RMM decision should be based on risk assessment rather than hazard information only. This should include consideration of RMMs in the exposure assessment. This is partly supported by one Member State competent authority, which specified that RMM decisions should take into account the degree of containment of an application, the dispersiveness of the application as well as the availability of alternatives. In addition, industry would welcome opportunities to implement risk management

⁸⁴ It was mentioned by some stakeholders that this is an inconsistency of the legislative framework. This inconsistency was regarded as justifiable because of the potentially lower emissions of industrial chemicals as compared to e.g. plant protection products.

measures other than marketing restrictions, such as effective product stewardship programmes or risk mitigation measures during product application.

The lack of automatic market restrictions (with possibilities to derogate) for VMP and the lack of possibilities to adopt any RMM for HMP based on environmental considerations were regarded as major inconsistencies of the legal framework by some authorities and NGOs.

Hardly any comments were obtained in relation to the Water Framework Directive. One authority stakeholder commented that inclusion of PHS in Annex X of the Water Framework Directive should automatically trigger a review of substance approvals under the Biocidal Products Regulation and the Plant Protection Products Regulation, regardless of the respective review periods. It was furthermore stated that the lack of controls for VMP and HMP would endanger reaching the goals of the Water Framework Directive's objectives for PHS, as would the longer timeframes for phase out under other legislation. As the identification of PHS and inclusion in the Water Framework Directive's Annex X is based on an impact assessment, including an assessment of alternatives, socio-economic considerations are already taken into account and could be used in the procedures under other legislation.

Other comments received on the implementation of RMMs are provided in the following:

- Industry states that the opportunities for stakeholders to get involved in the decision making on RMMs differ depending on the respective legislation and which Member State prepares the decision proposal;
- NGOs stated that product approval dossiers should take into account mixture effects to a higher degree, e.g. if persistence is increased;
- NGOs found RMMs required as part of (national) product authorisations less efficient than market bans;
- NGOs also claimed market restrictions as the most efficient type of RMM due to clarity of perspectives for substances and marked incentives to innovate and develop alternatives as well as straight forward enforcement possibilities; and
- It was questioned whether waste legislation sufficiently takes PBTs into account. Waste treatment, in particular recycling, was mentioned as a potential loophole for the phase out of PBTs.

The effect of the cut-off criteria in the Biocidal Products Regulation / the Plant Protection Products Regulation is unclear. According to NGOs, up to now no pesticide was denied approval because of its PBTness and only a few biocides were approved under the Biocidal Products Regulation despite there being PBT (derogations). However, the number of substances so far assessed under these two pieces of legislation is not very high, as for both most of the substances were still approved under the old legislation (Dir 91/414/EEC and 98/8/EC, respectively).

Conclusions

The identification of a substance as PBT/vPvB triggers different risk management triggers across legislation. Reasons for the differences are mainly due to the different exposure potentials of substances (active substances/industrial chemicals), or differences in expected benefits (medicinal products). While these justifications explain well the differences in general, the lack of a derogation possibility for active substances in pesticides or, vice versa, the existence of a derogation option for biocides, is questioned by stakeholders and points to an inconsistency. Furthermore, the lack of any possibility to regulate active substances in human medicinal products is also inconsistent, as all other legislation includes such options, after assessment of risks and/or a socio-economic analysis.

3.6 Costs and benefits of RMMs for PBTs/vPvBs

Little information is available on the costs and benefits related to the risk management measures of PBT/vPvB. According to SEAC⁸⁵, no quantitative information on the impacts of restrictions and authorisation of PBT/vPvB is available. To conduct their cost benefit analysis, the SEAC therefore used a cost-effectiveness approach using the cost per kg of reduced emissions as one input parameter. The following information is relevant for this case study:

- Three substances are included in the assessment which are PBT/vPvB: DecaBDE, PFOA and Siloxanes (D4/D5);
- The costs caused by the restrictions range from 2.3 (DecaBDE) to 51.3 (Siloxanes)⁸⁶ million Euro per year; and
- The benefits cannot be monetised but the amount of emissions reduced is specified in all three cases.

The main cost elements identified are substitution costs. For D4/D5 reformulation costs, product performance loss and testing costs are also considered. Overall, the SEAC concludes that the costs for PBT assessment and restrictions of the three substance (groups) are justified/balanced. This view is mostly supported by the consulted authorities.

The SEAC report includes information from a study⁸⁷ identifying costs and benefits related to the implementation of restrictions and authorisations of PBT/vPvB under REACH. Information was collected on the costs to reduce stocks and flows of D4/D5, DecaBDE, HBCDD, HCB, HCH, PCBs, PFOA and PFOS and related to the reduced emissions. Among others, the following observations are provided in the report:

- Cost estimates range from one to several millions of Euros per kg avoided emissions;
- Costs may vary between and within the different types of measures (substitution, emission reduction and remediation);
- The implementation costs tend to be higher in cases where PBTs have a wide dispersive use or are used in low concentrations;
- Costs per kg avoided use are lower than costs per kg avoided emissions, indicating that uses with good risk management (low emission per use) are more costly to replace; and
- The comparison of costs is hampered by the inclusion of different cost types for different substances and uses.

In the targeted consultation of pesticide producers, it was pointed out that due to the harmonised classification procedures and the existence of cut-off criteria for active substances approval, the number of active substances to control a particular pest has reduced. This would result in fewer possibilities to manage pests and an increase in resistance to the existing products, as well as higher

⁸⁵ See ECHA (2014): Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC, accessed at:

https://echa.europa.eu/documents/10162/13580/approach_for_evaluation_pbt_vpvb_substances_seac_en.pdf and ECHA (2016): Cost and benefit assessments in the REACH restriction dossiers, Helsinki.

⁸⁶ Only a small part of the uses were assessed; hence the actual costs are higher.

⁸⁷ Frans Oosterhuis, Roy Brouwer (2015): Benchmark development for the proportionality assessment of PBT and vPvB substances, Report R-15/11.

costs for the users of plant protection products. Similar answers could be expected in relation to the cut-off criteria for PBT/vPvB.

Conclusions

Information on the benefits of regulating PBT/vPvB is not readily available in monetised form. In its report on the operation of REACH and CLP, ECHA only specifies the amount of emissions avoided from reduced use of PBT/vPvB. The costs from the PBT assessment e.g. resource input and data generation are case-by-case and may be shared by several members of a SIEF or only one registrant. Therefore, assessment costs cannot really be quantified in general. Finally, the costs from substituting PBTs/vPvBs may also diverge significantly, depending on the use of the substance. Consequently, an “overall conclusion” on the cost-benefit ratio of PBT assessment and regulation cannot be derived based on the available information but would require a larger study.

3.7 Communication on PBT/vPvB

3.7.1 Classification and labelling of PBT/vPvB

PBTs either fulfil the “T” criterion because of a high chronic aquatic toxicity or because of human health effects, or both. Those substances being “T” due to the aquatic toxicity would in most cases have to have an environmental label⁸⁸. An exception is DecaBDE, which is identified as PBT because of the toxicity of its degradation products. Consequently, DecaBDE is not labelled with an environmental pictogram.

vPvBs, which are not at the same time PBT, are likely to be classified for the environment in the hazard class aquatic chronic toxicity category 4⁸⁹. This hazard category does not require a hazard pictogram for the environment but should be labelled with an environmental hazard statement.

In addition, some PBT/vPvB might not be classified for the environment as they do not meet the trigger values and/or are identified based on other concerns (e.g. monitoring data contradicting predictions based on bioaccumulation potential and persistence from laboratory testing). Examples are some of the perfluorinated substances on the candidate list.

Table 3-2 shows a list of candidate PBTs/vPvBs and their environmental classification as well as whether or not they should be labelled with an environmental pictogram. The environmental classification in the table either quotes the harmonised classification, where available, or lists the most stringent H-statements provided in the classification and labelling inventory from self-classifications. PBT/vPvB substances that do not need to be labelled are shaded in grey.

Name	CAS-	vPvB	PBT	Env. H	Env Pict.	Comment
2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	36437-37-3	Yes		H 413	No	
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	25973-55-1	Yes	Yes	H 413	No	
2,4-di-tert-butyl-6-(5-chlorobenzotriazol-	3864-99-	Yes		H 413	No	

⁸⁸ No “dead fish and tree” pictogram is to be provided for substances and mixtures classified in the hazard classes chronic aquatic toxicity category 3 and 4.

⁸⁹ No classification might occur for substances with a water solubility below 1 mg/l.

Table 3-2: REACH PBT/vPvB and hazard classification / labelling with pictograms						
Name	CAS-	vPvB	PBT	Env. H	Env Pict.	Comment
2-yl)phenol (UV-327)	1					
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	3846-71-7	Yes	Yes	H 413	No	
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane	-	Yes		H410	Yes	
5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	81-15-2	Yes		H410	Yes	
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	Yes	Yes	H410	Yes	
Ammonium pentadecafluorooctanoate (APFO)	3825-26-1		Yes		No	
Anthracene	120-12-7		Yes	H410	Yes	
Anthracene oil	90640-80-5	Yes	Yes	H412	No	content of Anthracene
Anthracene oil, anthracene paste	90640-81-6	Yes	Yes		No	content of Anthracene
Bis(pentabromophenyl) ether (decabromodiphenyl ether) (DecaBDE)	1163-19-5	Yes	Yes	H 413	No	T due to degradation products
Bis(tributyltin) oxide (TBTO)	56-35-9		Yes	H410	Yes	
Henicosfluoroundecanoic acid	2058-94-8	Yes			No	
Heptacosfluorotetradecanoic acid	376-06-7	Yes			No	
Hexabromocyclododecane	25637-99-4		Yes	H410	Yes	
Pentacosfluorotridecanoic acid	72629-94-8	Yes			No	
Pentadecafluorooctanoic acid (PFOA)	335-67-1		Yes		No	
Perfluorononan-1-oic-acid	375-95-1		Yes		No	
Pitch, coal tar, high-temp.	65996-93-2	Yes	Yes	H410	Yes	
Tricosfluorododecanoic acid	307-55-1	Yes		(H410)	No	

The table shows that many vPvB do not have a hazard pictogram for the environment: of 15 vPvB, four need to be labelled with the environmental hazard pictogram (that depicts a dead fish and a tree). Of the 13 PBT substances, eight do not need to be labelled with the environmental hazard pictogram; seven substances fulfil the “T” criterion due to human health hazards and one because of its degradation products.

3.7.2 Harmonisation of criteria

Several stakeholders confirmed it as important that the conclusions on the PBTness of substances are consistent at global level to facilitate negotiations on environmental protection, emission controls and trade. Although most of the stakeholders generally support approaches to harmonise PBT criteria and assessments at global level, almost all of them were sceptical with a view to the potential burdens and success of the needed process. Maintaining the EU standards as a minimum was mentioned as a condition for any such process.

One industry association does not support harmonisation of PBT criteria at any level, because of the different data availability in different contexts. A laboratory commented that not only the criteria but also the testing methods would have to be harmonised.

Introduction of a new classification category “vPvB” and “PBT” with an own label was also viewed sceptically by many of the stakeholders. The main reasons were doubts that self-classification of PBT would work due to the frequent lack of data and the high level of expertise needed. Furthermore, some stakeholders fear inconsistencies with the GHS. It was mentioned that agreement on the POP criteria was a lengthy process and it was suggested to use these criteria in GHS/CLP, if any should be introduced. However, NGOs in particular would welcome inclusion of a new hazard class for PBT/vPvB in the GHS/CLP Regulation.

With a view to the knowledge that PBT/vPvB properties are the starting point for any (risk management) actions, one stakeholder proposed creating a “global list of PBT/vPvB”, including all substances identified as PBT/vPvB and indicating the criteria/legal framework under which each substance is assessed as being one. Others suggested focusing on communicating PBTness, e.g. with a specific label element/hazard pictograms.

Annex 1 PBT/vPvB screening criteria

Table A1-1: Screening criteria (Source: ECHA IR/CSA guidance, Chapter R11; P: Table 11-4; B: p. 54 and T: Table 11-6)		
Data source	Screening criteria	Conclusion
Persistence		
Biowin 2 (non-linear model prediction) and Biowin 3 (ultimate biodegradation time) or Biowin 6 (MITI non-linear model prediction) and Biowin 3 (ultimate biodegradation time)	Does not biodegrade rapidly (probability < 0.5)* and ultimate biodegradation timeframe prediction: ≥ months (value < 2.25 (to 2.75)**) or Does not biodegrade rapidly (probability < 0.5)* and ultimate biodegradation timeframe prediction: ≥ months (value < 2.25 (to 2.75)**)	Potentially P or vP Potentially P or vP
Ready biodegradability test	≥70% biodegradation measured as DOC removal (OECD TGs 301A and 301E) or ≥60% biodegradation measured as ThCo2 (OECD TG 301B) or ThOD (OECD TGs 301C, 301D and 301F)*** <70% biodegradation measured as DOC removal (OECD TGs 301A and 301E) or <60% biodegradation measured as ThCo2 (OECD TG 301 B) or ThOD (OECD TGs 301C, 301D and 301F)	Not P and not vP Potentially P or vP
Modified ready biodegradability tests or enhanced screening tests	biodegradable not biodegradable	Not P and not vP Potentially P or vP
Specified tests on inherent biodegradability:		
- Zahn-Wellens (OECD TG 302B)	≥70 % mineralisation (DOC removal) within 7 d; log phase no longer than 3d; removal before degradation occurs below 15%; no pre-adapted inoculum Any other result	Not P and not vP Potentially P or vP
- MITI II test (OECD TG 302C)	≥70% mineralisation (O2 uptake) within 14 days; log phase no longer than 3d; no pre-adapted inoculum Any other result	Not P and not vP Potentially P or vP
Bioaccumulation		
Log Kow	Log Kow > 4.5 Not applicable to metals and metal compounds	Not B and not vB
Toxicity		
Short-term acute aquatic toxicity (Algae, Daphnia, Fish – acute tests)	EC50 or LC50 < 0.01 mg/L	T, criterion considered to be definitely fulfilled

Table A1-1: Screening criteria (Source: ECHA IR/CSA guidance, Chapter R11; P: Table 11-4; B: p. 54 and T: Table 11-6)		
Data source	Screening criteria	Conclusion
Short-term acute aquatic toxicity (Algae, Daphnia, Fish – acute tests of valid / applicable (Q)SARs)	EC50 or LC50 < 0.1 mg/L	Potentially T
Notes: * The probability is low that it biodegrades rapidly ** For substances fulfilling this but BIOWIN indicates a value between 2.25 and 2.75. More degradation relevant information is generally warranted *** These pass levels have to be reached within the 28-day period of the test. The conclusions on the P or vP properties can be based on these pass levels only (not necessarily achieved within the 10-day window) for mono constituent substances. For multi-constituents substances and UVCBs these data have to be used with care as detailed in Section R.11.4.2.2 of the guidance		

Annex 2 Comparison of PBT/vPvB identification procedures

Table A2-1: Comparison of PBT/vPvB identification procedures					
Legis-lation	Responsibility for PBT/vPvB identification	Accessibility of assessment	Identification process	Assessment criteria	Constituents, metabolite
REACH	Obligation Registrants; only substances registered in volumes > 10t/a	Summary information in ECHA's registration database	PBT-assessment according to ECHA guidance R11 and using any available data	Annex XIII; REACH Annex XIII REACH Annex XIII	To be considered in substances registered in volumes above 100 t/a
	ECHA evaluates registrants' dossiers; PBT/vPvB dossiers are prioritised	Dossier evaluation decisions are published	Only evaluation, request for further data possible		
	Voluntary: Member State authorities & ECHA (on request of the Commission), no conditions	SVHC dossier is published	RMOA, ROI, dossier preparation and consultation; decision taking depends on number and types of comments; final decision in Member State Committee		
Plant Protection Products Regulation	Industry applies for substance approval; only active substances, safeners and synergists	Approval decision (i.e. NOT a PBT/vPvB) published; no details of the dossier(s))	Manufacturer submits application to RMS, RMS checks admissibility and prepares DAR; EFSA organises a peer review including experts from all Member States and input from the general public. EFSA finally adopts conclusions on overall hazard and risk assessment. Standing Committee Plants, Animals, Food and Feed votes on approval, non-approval or restricted approval. Approval is time-limited; maximum of 10 years and normally foresees several risk mitigation measures	Criteria in Annex II of the regulation	No specific requirements to consider
Biocidal Products Regulation	Industry applies for the approval of active substances under the Biocidal Products Regulation	Approval decision and justification. Assessment reports are published on ECHA's website	The manufacturer/importer submits dossier to RMS. RMS compiles DAR and submits to ECHA's Biocidal Products Committee. The Committee, with the help of the PBT expert group reviews the DAR, finalises it, and provides an opinion on the approval, including conclusions the PBT/vPvB status. The European Commission takes the final decision. The approval is time limited	REACH Annex XIII	To be considered, different thresholds and conditions

Table A2-1: Comparison of PBT/vPvB identification procedures					
Legis-lation	Responsibility for PBT/vPvB identification	Accessibility of assessment	Identification process	Assessment criteria	Constituents, metabolite
VMP	Applicants for authorisation of active substances	European public assessment report available on EMEA website	Authorisation application discussed by EMA/Standing Committee for Veterinary Medicinal Products; Committee develops opinion, which is discussed with applicant, final opinion is forwarded to Commission for final decision taking	PBT assessment according to REACH	To be considered, if > 10%
HMP	Applicant for authorisation	European public assessment report available on EMEA website	Centralised: Authorisation application to EMA Committee for Medicinal Products for Human Use; opinion forming in dialogue with applicant, final opinion forwarded to the Commission for decision making. Decentralised: Authorisation applications are sent to the Member States for national approvals via mutual recognition; reference Member State makes evaluation and shares with other Member States. In case of disagreement, a coordination group should solve the issue		To be considered, if > 10%
Water Framework Directive	EU Commission	Background information available on CIRCABC	Expert group develops proposal based on available information and opinions and input from e.g. Parliament, Member States, EEA, Scientific Committee; list of substances to be reviewed regularly and extended, where necessary	Art. 16	Not applicable

Case Study 7: Awareness of SMEs of their hazard and risk communication obligations

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1 Introduction

1.1 Key issues

The CLP Regulation applies to millions of products being placed on the EU market and most of the manufacturers of these products will be SMEs; indeed, the numbers used in the calculations of costs in the main report suggest that of the 32,000 companies of interest, nearly 31,000 are SMEs with a third of these classed as micro-enterprises. The importance of SMEs to the effectiveness of the CLP Regulation is recognised in Recital 60, which highlights the importance of ensuring SMEs have the information required to fulfil their obligations. Thus, establishing the degree to which SMEs are aware of their obligations under the CLP Regulation is essential to an evaluation of the performance of the Regulation, and its linkages to other chemicals legislation more generally.

The CLP Regulation also introduced changes in labelling requirements, which included not only changes in the colour requirements of pictograms, but also in the size of the pictograms and in the safety phrases that must be included (e.g. precautionary (P) statements). Moreover, there is not just Globally Harmonised System (GHS)-based information, but also additional labelling as previously required under the Dangerous Substances Directive and the Dangerous Preparations Directive with respect to European Hazard (EUH) statements. Other issues relate to labelling of different layers and use of INCI codes (see case study 5). In addition, many industry stakeholders have commented that some Member States may have set their own requirements for the number of mandatory languages that must be provided on labels.

National helpdesks have also noted frequent helpdesk queries over the potential for using fold-out labels to respond to such problems, as well as the desire to include multiple languages on labels, from SMEs who supply mixtures across several Member States¹. Although Article 31 of the CLP Regulation states that labels must be easy to read, potential limits on the number of languages that can be included on a label will increase the costs faced by SMEs not only in label design, but also in the number of stock keeping units that must be produced and stored to meet demand (as stocks will become more country specific). This may be a particular issue for SMEs who supply mixtures in low quantities but across a wide range of Member States.

Supplemental labelling obligations arise under Article 25 of the CLP Regulation, in particular for specific EUH statements derived from the Dangerous Substances Directive and corresponding directly to statements required under the Dangerous Substances Directive. This need for dual labelling may be confusing for SMEs (and it is not clear whether there is anything similar in other jurisdictions).

In addition, packages will require labelling for both supply and transport, e.g. drums of hazardous substances or mixtures, or multi-pack boxes of smaller containers. Article 33 of the CLP Regulation sets out the requirements in such cases. There appears to be confusion, however, in some sectors as to what is required in terms of labelling, as there are differences in requirements for substances or mixtures that are supplied in a single package or in multi-packaging. This includes confusion over when transport or CLP labelling requirements should take precedence, whether certain CLP

¹ BAuA (2014): CLP - 2015 – Activities of the German Helpdesk, EU Commission Workshop on the safe use of chemicals by SMEs; 16 September 2014, accessed at: <http://ec.europa.eu/DocsRoom/documents/6891/attachments/1/translations/en/renditions/native>

pictograms can be omitted or not if they are already covered by the corresponding transport pictograms, and whether in the case of multiple layers of packaging the same label is required on all packaging (i.e. on a can and on a box containing multiple cans).

1.2 Case study aim

The aims of this case study are as follows:

- 1) To collect information on the awareness of SMEs and their obligation to update their hazard classifications and labelling in line with revisions made to the CLP Regulation through the Adaptations to Technical progress (ATP), which occur every two years;
- 2) To establish whether SMEs have systems in place to identify whether or not they need to respond to the changes brought about by an ATP; this will include examining the capacity of SMEs to respond to on-going changes due to both CLH activities and UN-level revisions; and
- 3) It will also confirm whether there are any issues with respect to SMEs understanding the relationship between the CLP Regulation and other legislation, and in particular international transport regulations, which may potentially discourage SMEs trading internationally.

1.3 Methodology

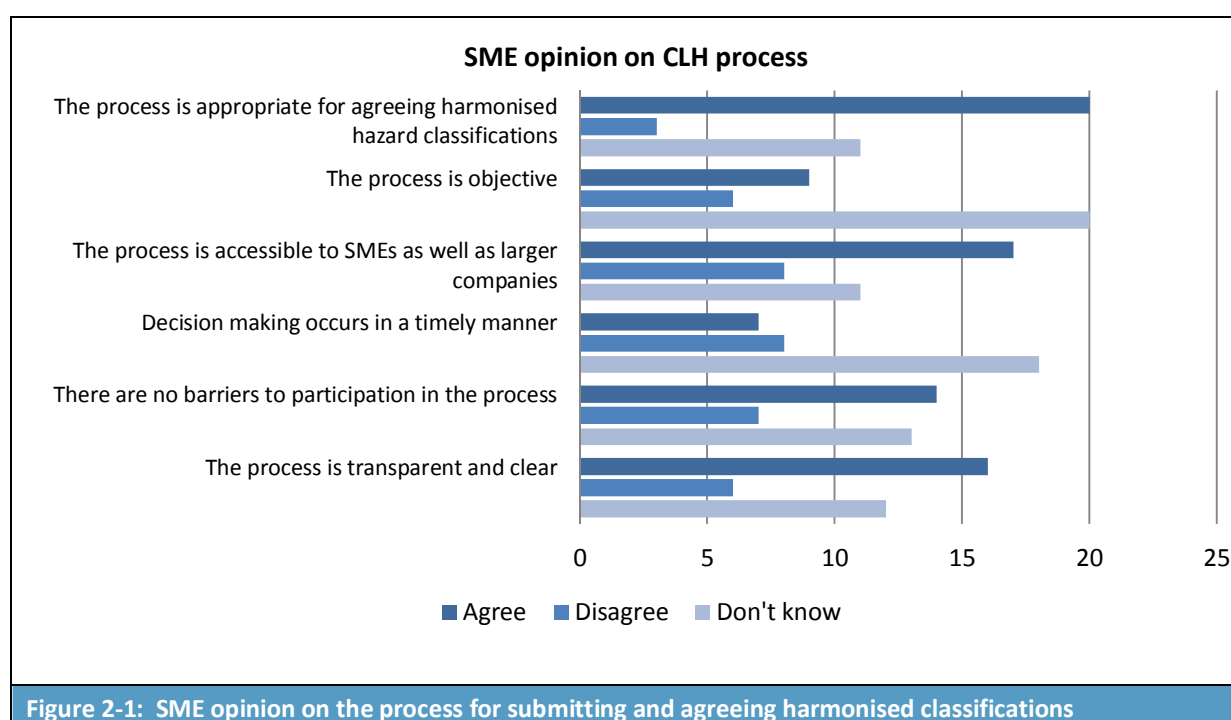
An SME panel was developed targeting manufacturers, importers, formulators, distributors and other downstream users involved in the chemicals industry. In total there were 246 responses from companies with fewer than 250 employees (though in many cases, the numbers responding to each question deviated from this). The results of this SME panel have been supplemented by targeted interviews with the following industry associations: UEAPME, Cefic, FECC, FEA, German BDI, Belgium help desk and CEPE. Discussions have also been held with the European Chemicals Agency (ECHA) given their past research on SME awareness and enforcement authorities.

In addition, a survey was sent to providers of classification and labelling services for SMEs to establish their perspective on their clients' understanding of the legislation and ability to respond. These stakeholder consultations were also supported by the results of the other targeted questionnaires sent to industry, NGOs, Member State competent authorities and the open public consultation.

2 SME Awareness of their Obligations Relating to CLP

2.1 Awareness of obligations to update hazard classifications and labelling in line with revisions made to the CLP Regulation through the Adaptations to Technical progress (ATP)

Most stakeholders (industry, agencies, Member States, etc.) believe that the processes which underlie CLP are transparent and accessible to all, including SMEs. Yet, there is concern amongst Member State competent authorities that, despite the process being transparent and accessible, SMEs may not have the resources or knowledge to keep track of these different processes (such as which CLH proposals are being considered), and are therefore unable to participate in these processes. There is also concern that for some SMEs, resources may not be available to attend RAC or CARACAL meetings. However, when asked about the RAC process for submitting and agreeing harmonised classifications, the responding SMEs indicated positive attitudes towards the process as a whole, with 20 out of 34 agreeing that “the process is appropriate for agreeing harmonised hazard classifications” (see Figure 2-1). Sixteen out of 34 respondents agreed that the process was transparent and clear, with 14 indicating that they did not feel that there were any barriers to being able to contribute to the process. Seventeen out of 36 respondents agreed with the statement “the process is accessible to SMEs as well as to larger companies”. However, it is important to note that eight respondents disagreed with the statement, thus suggesting that there are some barriers for SMEs in terms of engaging in this process which could affect the ability of SMEs to understand the requirements that result from these CLHs.



There was more disparity in the responses to the question of whether the 18 month transition period allowed for responding to changes in labelling as a result of ATPs was long enough: 26 out of 38 respondents indicated that the time period was sufficient, but 12 respondents disagreed. One stakeholder commented that 18 months was not a long enough phase-out period to sell stock with old labels. A second stakeholder shared this view, adding that more time was needed to sell stock

with the old label rather than being obliged to re-label. One Member State competent authority commented that SMEs in particular may face difficulties arising from the complexity of the transition times of different ATPs overlapping.

Another Member State competent authority responding to the targeted questionnaire suggested that SMEs that come under the scope of downstream legislation may have difficulty in staying updated with regards to the CLH process and ATP timings. ATPs to CLP can have significant consequences for downstream legislation and so it is important that all stakeholders are aware of such changes and how they impact their legislative obligations under both CLP and other legislation. This concern is amplified by the response to one of the questions in the SME panel. Participants of the SME panel were asked whether they were aware of any other legal requirements under other legislation that had been triggered by a CLP classification. Of the 179 responses to this question, 31% replied “don’t know” which is a significant proportion potentially indicating that they are unaware of the possible consequences of CLP classifications for their obligations under other legislation. Further breakdown of these responses shows that those describing their companies as micro-enterprises indicated the highest rate responding “don’t know” to this question (43% compared to only 19% for medium-sized enterprises). This supports the theory that the smaller companies are at a disadvantage in terms of understanding the legislation and how it impacts their company in relation to other legislative obligations.

Though there seem to be positive attitudes towards the transparency and accessibility of the CLH process, results from the SME panel indicate that SMEs do not participate in other CLP processes. One of the questions asked whether participants had taken part in a public consultation by ECHA. Of the 189 respondents to this question, 93% indicated that they had not. Further elaboration of these responses is not available, so it is not explicitly clear why so few had participated in an ECHA public consultation. One possibility is that they are not made aware that a consultation process is taking place. This would suggest a lack of communication with SMEs from public bodies and agencies and a missed opportunity for SMEs to participate and contribute to the development of chemicals legislation.

2.2 SME ability to identify the need to respond to ATP changes and their capacity to respond to the on-going changes due to both CLH activities and UN-level revisions

In terms of implementing the changes induced by ATPs to CLP, the results of the survey for service providers suggest that most SMEs only had to make a small number of minor amendments. One indicated that there were no impacts. However, two service providers commented that the ATPs have had significant impacts on their clients. When asked how their clients received these changes, eight indicated that their clients were unaware of the ATPs, with five of these suggesting that their clients were not sure how they would be affected by these ATPs, even after being made aware of them.

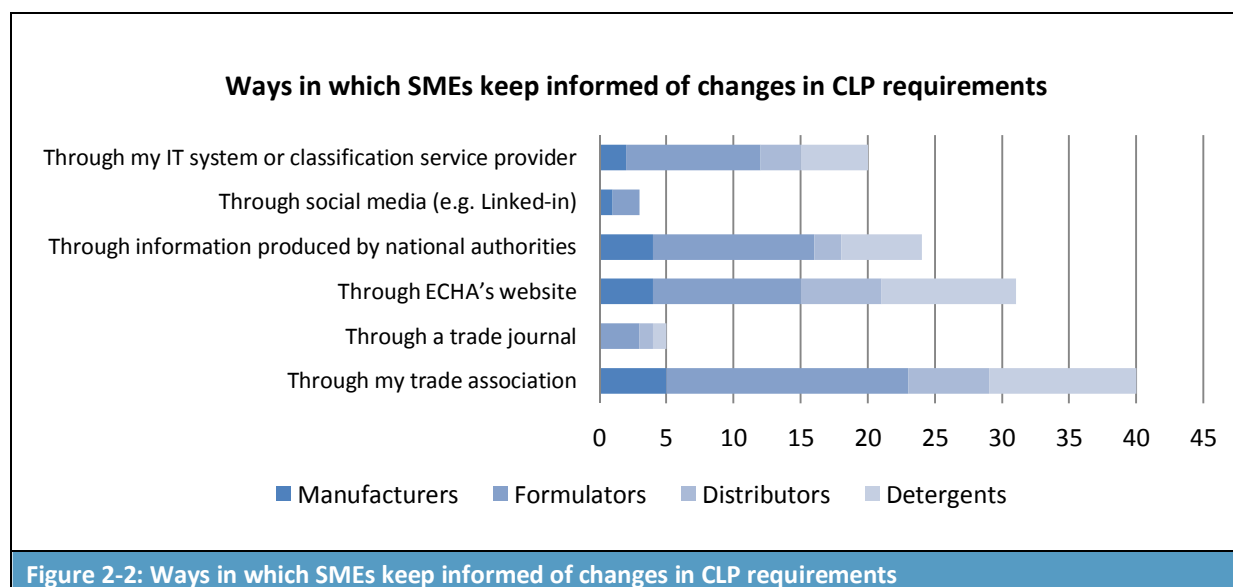
When asked how they keep up to date with changes in regulatory requirements, 28% of respondents to the SME panel indicated that they monitor the conclusions of ATPs themselves. The second most popular method is to rely on suppliers to inform them of any changes which might impact on them (25% of respondents), followed by relying on external service providers (22% of respondents). Only 17% of respondents rely on their national association to tell them of the changes introduced by ATPs. Across the different company types (manufacturers, formulators, etc.), the responses to this question show some key differences. These can be seen in Table 2-1, which shows the breakdown of responses by company type.

Table 2-1: SME panel responses indicating the ways in which SMEs stay updated on changes in regulatory requirements

Method used	Number and percentage of each company type									
	Manufacturers		Formulators		Importers		Distributors		Downstream Users	
My company monitors the conclusions of ATPs	38	30%	15	48%	3	16%	3	15%	9	18%
We rely on an external service provider to tell us of changes introduced by ATPs	25	20%	7	23%	5	26%	7	35%	10	20%
We rely on our suppliers to inform us of any changes that impact on us	28	22%	4	13%	6	32%	6	30%	17	34%
We rely on our national association to tell us of changes introduced by ATPs	22	18%	3	10%	4	21%	2	10%	10	20%
None of the above / other (please describe below)	1	1%	2	6%	1	5%	0	0%	2	4%
Don't know	10	8%	0	0%	0	0%	2	10%	0	0%
No answer	1	1%	0	0%	0	0%	0	0%	2	4%
Total number of respondents to question	125		31		19		20		50	
<i>Note: the question asked of SMEs was "How do you keep up-to-date with changes in regulatory requirements under EU chemicals legislation, for example, with respect to changes in labelling or packaging requirements, or in risk management requirements?"</i>										

Responses from across the different industry targeted questionnaires were also collected from those companies identifying themselves as SMEs (see Figure 2-2 overleaf). A direct comparison between the responses to the industry targeted questionnaire and those from the SME panel is not possible because the available response options differed.

All of the service providers consulted said that they spend resources informing SMEs of their regulatory obligations, though one added that they also did this for non-SMEs. Clarification of regulatory obligations is required mainly for the U.S., although it is not clear from the way this question is phrased whether this means U.S. companies require the most help in meeting their obligations or whether companies need the most help with U.S. legislation.

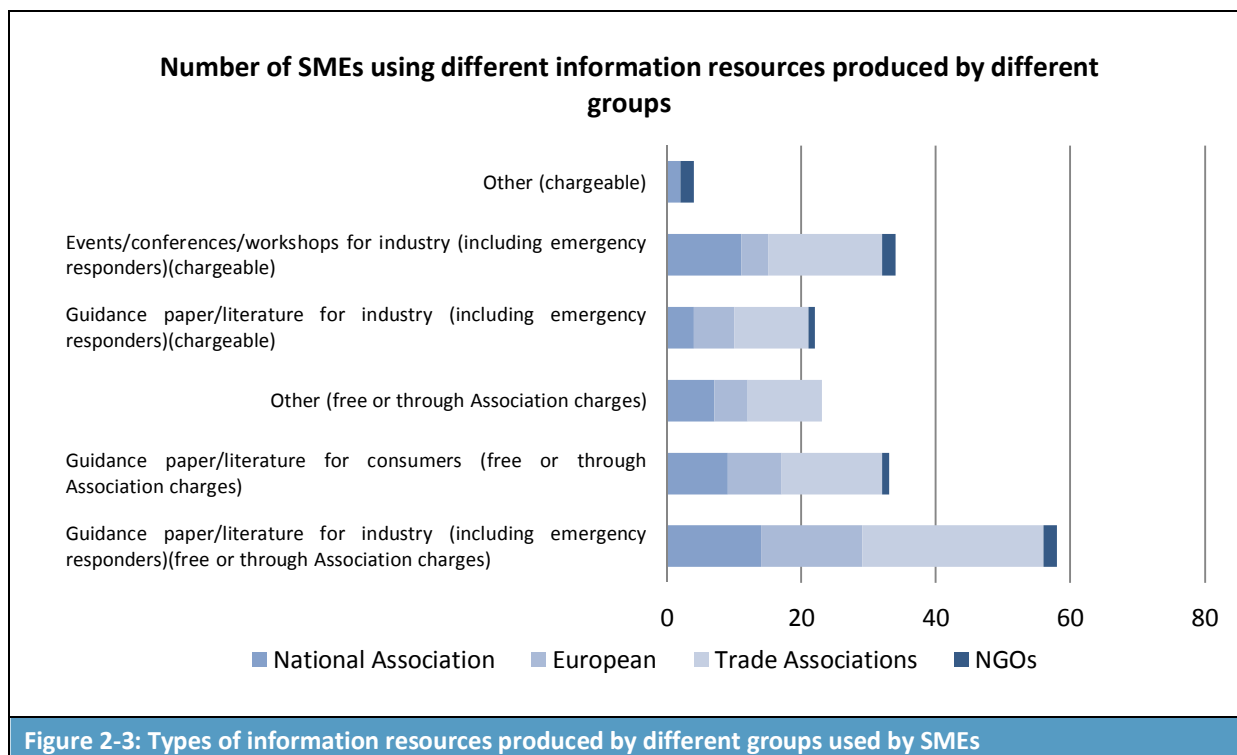


The frequency with which service providers updated their clients about newly published harmonised classifications varied significantly: four companies indicated they would alert their clients when newly harmonised classifications had been agreed and one company provided updates three times a year as well as any ad-hoc updates. Another company provided quarterly updates. In terms of other changes in CLP, six out of ten service providers responded that they updated their clients; however, one responded that they “generally” do “but not always”. Three companies indicated that they did not provide updates on such changes. When asked how clients track the differences in the GHS building blocks implemented by different countries or regions, five service providers said that it was not the client who tracked this but they themselves who provided this service. One respondent, however, said that their client mainly compared the labelling elements in section 2 of the SDS, looking out for such things as missing H-phrases, etc. The remaining four service providers indicated that they were not aware of how clients tracked these differences.

A question was asked of the service providers as to how their clients kept up-to-date with changes in the classification and labelling requirements of CLP resulting from ATPs. The responses, given in Table 2-2 below, support the findings presented in Figure 2-2 above.

Table 2-2: Ways in which clients stay updated regarding changes to classification and labelling requirements resulting from ATPs	
Response	Number indicating this response
Tracking bulletins/updates issued by ECHA	2
Articles in trade publications	1
Updates from industry groups	3
Updates from other commercial organisations (e.g. consultants, SDS software providers)	2
Not tracked	2
Other:	4
- Probably mix of the above plus LinkedIn forum	
- Unknown	
- We track	
- HSE	

Figure 2-3 below summarises the number of SMEs who make use of the different information resources available to them.



These resources include literature, guidance, workshops and conferences, amongst others. A significant number make use of free material provided by national associations, European associations, trade associations and NGOs, particularly guidance papers or literature prepared by trade associations. Furthermore, a significant number make use of events, conferences and workshops intended for industry, particularly those organised by trade associations.

A 2014 AISE survey² of 15 SMEs suggests that all companies are aware of their obligations under CLP and that they feel well prepared and supported as they have access to ECHA documents, trade associations (through training, workshops, information notes), consultants, external events and communication with peers.

The final question of the SME panel questionnaire asks respondents for any remaining comments relating to the way chemicals legislation (excluding REACH) is implemented. One respondent commented that it would be helpful for SMEs if trade associations organised more training events concentrating on the contents and requirements of the CLP Regulation. It was further suggested that workshops should be organised regularly by local sectorial organisations and Chambers of Commerce in order to keep SMEs informed of the changes or updates in the chemicals (and related) legislation. A workshop presentation by BAuA³ states that the target group of its two day workshop

² Lemoine S. (2014): CLP Challenges for SMEs – Workshop on the safe use of chemicals by SMEs, AISE. Available at: <http://ec.europa.eu/DocsRoom/documents/6885/attachments/1/translations/en/renditions/native>

³ Fleisher A. (2015): CLP 2015 – Activities of the German Helpdesk, BAuA. Available at: <http://ec.europa.eu/DocsRoom/documents/6891/attachments/1/translations/en/renditions/native>

was SMEs and that the event was completely sold out (290 participants over the two days) with 90 potential participants on the waiting list. There were also requests for a second similar workshop to be organised. This supports SME panel feedback that more events and workshops should be organised as there is significant demand for these from SMEs.

One respondent suggested that national helpdesks provide such support. The responses from Member States to this question about the availability of information for SMEs vary (as indicated in Table 2-3).

Table 2-3: Member States views on whether SMEs have enough guidance, information and support to comply with EU chemicals legislative requirements				
Is the guidance available to employers adequate to ensuring that they understand and are able to comply with the requirements of EU chemicals legislation? Do employers, and in particular SMEs, receive enough support to enable them to comply with the legislation?	Number of responses			
	Yes, adequate	SMEs need more	No, not adequate	Don't know
Guidance documents available from the European Commission, ECHA or Member States	4	5	1	1
Level of support from Member States	1	9	1	1
Level of support from industry associations	1	2		8

Five out of eleven respondents believe SMEs need more guidance documents from the European Commission, ECHA or Member States. Nine of twelve Member State competent authorities believe SMEs need more support from Member States. However, comments to this question do not support these statistics: one respondent has commented that there is enough, perhaps too much, information available to companies to meet their regulatory obligations. Yet this respondent believes that there are other resources which SMEs do not have which would help them with compliance; these include training opportunities and the availability of experts and competent consultants. Another Member State respondent suggests that the number of guidance documents available is “overwhelming” and that what is needed by SMEs is individual support in their language; the respondent indicates that this is already available from ECHA’s National Helpdesks.

One stakeholder, representing European SMEs, who was interviewed, believes it would be useful to have a single point of contact with which SMEs can confirm their obligations under legislation, particularly under specialised legislation. The same stakeholder goes on to say that it can take several weeks for an SME to implement the legislation and ensure it meets its obligations. In addition to a single point of contact, the stakeholder suggests it would be useful if local or regional meetings were held where companies could discuss any issues they face regarding the legislation.

A respondent to the Member State competent authority targeted questionnaire suggested that there is enough information available to industry to allow them to meet their legislative obligations even if they are changing. However, they did concede that SMEs do face difficulties as they may not have access to the same training opportunities or experts and consultants that larger companies do. Another Member State respondent agreed with this comment and added that SMEs need more individual support, particularly in their language.

However, there are resources available to SMEs to help them understand and comply with their obligations which were not mentioned by consultees. For example, the Enterprise Europe Network (EEN) is a support network for SMEs which offers services and expertise across 17 sectors with

regards to understanding sector-specific regulation in other countries as well as helping to connect SMEs with potential partners and clients, amongst other services. The network was launched by the European Commission in 2008 and is co-funded under COSME (Competitiveness of Small and Medium-sized Enterprises), an EU funding programme which helps to encourage the competitiveness of European SMEs.

3 SME Awareness of the Relationship between CLP and Other Legislation

3.1 SME issues with other legislation

A survey was sent out to a subset of service providers whose clients include SMEs. When asked which of the European chemicals legislation their SME clients found most complex, The Biocidal Products Regulation⁴ was reported most frequently (six times; followed by REACH which was reported five times). Two out of 10 service providers indicated that clients found international transport legislation to be the most complex.

3.1.1 International Transport Legislation

Six out of 10 service providers indicated that they receive queries from their clients for clarification regarding the rules for outer packaging, inner packaging and over-packs under CLP and international transport legislation.

One of the questions in the SME panel asked whether companies understood the rules regarding labelling of outer packaging, inner packaging and over-packs under CLP and transport legislation. All 24 respondents answering this question said that the rules were clear to them.

Further details regarding the issues identified with regards to stakeholder understanding of the requirements of transport legislation and the linkages with the CLP Regulation are provided in case study 5 and the main Task 2 report.

3.1.2 Biocidal Products Regulation

The Biocidal Products Regulation has been designed to enable SMEs to be competitive against larger companies; recital 58 is a clear example of this intent as it states that *“a level playing field should be established as quickly as possible on the market for existing active substances, taking into account the objectives of reducing unnecessary tests and costs to the minimum, in particular for SMEs...”* There is also a provision within this legislation (Article 81(2)) which states that Member State competent authorities have an obligation to provide support and advice to all stakeholders, particularly SMEs, regarding their obligations under the Biocidal Products Regulation. Despite such provisions, the Biocidal Products Regulation is seen by some SMEs as being complicated and difficult to understand. Broad analysis of the key themes drawn from the SME panel responses suggest that SMEs believe the Biocidal Products Regulation can be simplified or improved and that currently, the processes underlying the regulation are time and resource-intensive where they do not need to be. For example, when asked about specific cases of incoherence between different pieces of chemicals or chemicals-related legislation, one respondent to the SME panel commented that the overlaps between CLP and the Biocidal Products Regulation (and the Plant Protection Products Regulation⁵) relating to the use of the same substance for different purpose are so complicated that only experts

⁴ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

⁵ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

can fully understand them. Another stakeholder commented that the requirements for registering biocides are different in different Member States. Other comments indicate that significant time and resources are required to comply with the Biocidal Products Regulation; one stakeholder suggested that the requirements of the Biocidal Products Regulation are not clear and therefore it is unnecessarily resource-intensive to comply with this legislation.

3.1.3 Toy Safety Directive

There is concern amongst stakeholders, particularly Member State competent authorities, that the legislative obligations of the Toy Safety Directive are not clear to toy manufacturers, particularly SMEs who may not have the capacity or resources to understand the implications for their products⁶. One competent authority commented that the obligations regarding CMR substances in Annex II, Part III are not clear and so are often ignored as they are not understood. It is generally agreed that more needs to be done to ensure that the legislative requirements are made clearer to all stakeholders, particularly smaller companies. One way of doing this would be to set specific limits for dangerous substances so that the requirements for them are clearer.

Another problem which SMEs manufacturing toys face is that there is often confusion arising from the implications of other vertical and horizontal legislation. For example, the Toys Safety Directive sets a limit for CMR substances in toys which corresponds to the relevant concentration limit established in the CLP Regulation. Simultaneously, specific CMR limits for toys are also set in the REACH Regulation. It is recommended that, in order to make obligations clearer, all requirements relating to toys in other legislation should be included in the Toy Safety Directive. The issues relating to SMEs meeting their requirements under the Toy Safety Directive are considered in greater detail in case study 9.

⁶ One stakeholder who was interviewed for this case study suggested (without specifying which legislation) that the legal text is not written in a way that allows it to be easily understood by those who have to follow it and put it into practice.

4 Conclusion

4.1 Summary of findings

The main conclusions which can be drawn from this case study relating to the awareness of SMEs of their obligations under CLP and other chemicals legislation in terms of hazard and risk communication are as follows:

- The CLH process is deemed to be transparent, clear and accessible to SMEs;
- Despite this, SME participation in the processes underlying CLP is low: 93% of 189 respondents to the SME panel have never participated in a public consultation organised by ECHA;
- SMEs show low awareness of the changes which occur due to ATPs to CLP or the way in which they are affected by these changes;
- The information provided to SMEs is adequate but more practical assistance in complying with regulation would be useful; and
- SMEs and other stakeholders in this sector are not all familiar with the services of the Enterprise Europe Network (EEN), a potentially useful resource for compliance.

4.2 Final remarks

The findings of this case study and the consultations do not suggest that SMEs face significant adversity in understanding and complying with their obligations under CLP and the wider chemicals legislative framework. However, comments have been made by both SMEs and Member State competent authorities about ways in which SMEs could be better supported in meeting their obligations. The biggest issue which was made apparent during the SME panel consultation was that there are significant overlaps and inconsistencies across different pieces of legislation (the Biocidal Products Regulation, the Plant Protection Products Regulation, international transport legislation) which cause problems such as a misunderstanding of the requirements across legislation and across Member States, as well as the unnecessary use of resources (time and personnel) in meeting these requirements. However, this is not a problem which affects SMEs exclusively; these inconsistencies and overlaps have been mentioned by stakeholders of all sizes from different sectors.

**Case Study 8: Awareness of Chemical Safety
Assessment and labelling requirements for toys**

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1 Introduction

1.1 Overview

1.1.1 Background

The Toy Safety Directive (Directive 2009/48/EC) lays out the legal requirements that all toys sold within the European Economic Area (EEA) must comply with. Manufacturers, importers and suppliers are required to ensure that their products comply, including mechanical and physical safety, flammability and the migration of certain elements (Conformance, 2015).

The Directive is intended to provide a common standard for the safety of toys throughout the whole of the EEA. All toys that are sold within the EEA are required to meet the requirements of the Directive, and may be sold without any further local legal controls so long as they are legitimately CE marked (Conformance, 2015).

To enhance EU citizens' (and in particular children's) safety, the Toy Safety Directive lays down "essential" safety requirements and regulates the conditions for trade and production of toys within and across Member States. The Directive had to be transposed into national legislation by 20 January 2011 and applied in the national territories from 20 July 2011, with the exception of the chemical requirements, which started to be applied from 20 July 2013 (Technopolis et al., 2015).

Toys are defined in **paragraph 1** of **Article 2** of the Directive as *"products designed or intended, whether or not exclusively, for use in play by children under 14 years of age"*. Article 2 also indicates that products listed in Annex I of the Directive are in particular not considered as toys within the meaning of the Directive (European Parliament and the Council, 2014).

The products excluded in particular from the scope of the Directive (in accordance with **Annex I**) are (European Parliament and the Council, 2014):

- Decorative objects for festivities and celebrations;
- Products for collectors, provided that the product or its packaging bears a visible and legible indication that it is intended for collectors of 14 years of age and above (e.g. detailed and faithful scale models, historical replicas of toys, reproduction of firearms);
- Sports equipment, including roller skates, inline skates and skateboards intended for children with a body mass of more than 20 kg;
- Bicycles with a maximum saddle height of more than 435 mm;
- Scooters and other means of transport designed for sport or which are intended to be used for travel on public roads or public pathways;
- Electricity driven vehicles which are intended to be used for travel on public roads or public pathways;
- Aquatic equipment intended to be used in deep water, and swimming learning devices for children, such as swim seats and swimming aids;
- Puzzles with more than 500 pieces;
- Guns and pistols using compressed gas, with the exception of water guns and water pistols, and bows for archery over 120 cm long;
- Fireworks, including percussion caps which are not specifically designed for toys;
- Products and games using sharp-pointed missiles, such as sets of darts with metallic points;

- Functional educational products, such as electric ovens, irons or other functional products operated at a nominal voltage exceeding 24 volts which are sold exclusively for teaching purposes under adult supervision;
- Products intended for use for educational purposes in schools and other pedagogical contexts under the surveillance of an adult instructor, such as science equipment;
- Electronic equipment, such as personal computers and game consoles, used to access interactive software and their associated peripherals, unless the electronic equipment or the associated peripherals are specifically designed for and targeted at children and have a play value on their own, such as specially designed personal computers, key boards, joy sticks or steering wheels;
- Interactive software, intended for leisure and entertainment, such as computer games, and their storage media, such as CDs;
- Babies' soothers;
- Child-appealing luminaires;
- Electrical transformers for toys; and
- Fashion accessories for children which are not for use in play.

In addition **paragraph 2 of Article 2** indicates that the Directive does not apply to the following toys:

- Playground equipment intended for public use;
- Automatic playing machines, whether coin operated or not, intended for public use;
- Toy vehicles equipped with combustion engines;
- Toy steam engines; and
- Slings and catapults.

The Directive applies to all toys within its scope and manufacturers, authorised representatives, importers and distributors all have defined obligations and may be held responsible for supplying toys which do not comply with the Directive's requirements. An entity in the supply chain, most often the manufacturer, takes responsibility for affixing a CE mark to the toy (Conformance, 2015). Manufacturers (or an authorised representative if mandated by the manufacturer) are responsible for affixing the CE mark to their products. Importers and distributors of toy products are required to ensure or verify, respectively, that they bear the CE mark.

1.1.2 Requirements for manufacturers, importers and distributors

Manufacturers, importers and distributors have decreasing responsibilities to ensure that a toy is safe when it is placed on the EU market. Only toys that bear the CE mark and are therefore declared compliant with EU safety requirements can be placed on the EU market (European Commission, 2015a).

Manufacturer requirements

Before toys can be placed on the EU market, a manufacturer (whether located in the EU or outside the EU) has to take the following steps (European Commission, 2015a):

- Carry out a safety assessment, which involves an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards, as well as an assessment of the potential exposure to those hazards. The safety assessment must be kept by the manufacturer in the technical documentation for 10 years after the toy has been placed on the market (TIE, 2009a);

The chemical safety assessment process comprises three main stages (identification, characterisation and assessment) (European Commission, 2016e):

- **Identification** relates to the examination of information within documentation to identify materials and substances contained in the toy together with the amounts (if known). Each identified material or substance then goes through the characterisation stage;
- **Characterisation** is the process by which a material or substance is reviewed against known prohibitions/restrictions, to determine whether it falls within scope, and reviewed against scientific knowledge on potentially hazardous substances. The outcome of the characterisation is to place the material or substance into one of two groups:
 1. Materials or substances subject to legal restrictions or restrictions in safety standards; or
 2. Materials or substances not subject to restrictions.

Once a material or substance is characterised it is put through the appropriate assessment process.

- **Assessment** is concerned with establishing the likelihood of a given material containing an undesirable substance in amounts that are high enough to present an unacceptable risk taking into consideration the hazard and the exposure of the user (European Commission, 2016e). In the case of '*materials or substances not subject to restrictions*', these can be divided into two categories (TIE, 2011):
 1. Materials or substances that are classified as hazardous (according to the CLP Regulation) (but not covered by any specific restriction); or
 2. Materials or substances that are not classified as hazardous (according to the CLP Regulation) (and not covered by any specific restriction).

Category 1 must be evaluated in terms of how the user (child) is exposed to the substance during foreseeable use in play. Category 2 could be substances that are not classified since they are considered "safe", but could also include substances that are subject to discussion, e.g. for future classification as hazardous (TIE, 2011).

The result of the safety assessment should be a conclusion, indicating whether the toy can be considered safe in terms of chemical properties (TIE, 2011).

- Undertake one of two conformity assessment procedures to demonstrate that the toy complies with essential safety requirements:
 - **Self-verification:** the manufacturer applies only harmonised standards to cover all relevant safety requirements for the toy and makes sure that the manufacturing process ensures compliance ('internal production control procedure'). Self-verification is used in cases where harmonised standards cover all relevant safety aspects of a toy. In such instances, the manufacturer is required to apply the existing harmonised standards and ensure that the toy is in conformity with these. The manufacturer must

also put in place an internal production procedure in accordance with Module A of Annex II to Decision No 768/2008/EC (on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC). Module A does not require the involvement of a notified body (TIE, 2009a).

- **Third party certification:** the manufacturer submits an application for EC-type examination to a notified body. The notified body examines the toy and issues an EC-type examination certificate if the toy meets the applicable safety requirements of the Toy Safety Directive. Manufacturers are required to ensure that their manufacturing processes only generate toys that are compliant with the approved type. **EC-type examination is required in cases where:** 1) harmonised standards do not exist, 2) harmonised standards have not or have only partly been applied by a manufacturer, 3) one or more harmonised standards have been published with a restriction, or 4) the manufacturer considered that the nature, design, construction or purpose of the toy requires third party verification (TIE, 2009a).
- Draw up technical documentation with all relevant details that ensure their toy complies with the essential safety requirements;
- Draw up the EC Declaration of Conformity stating that the fulfilment of the essential safety requirements has been demonstrated. By drawing up this document, the manufacturer assumes responsibility for the compliance of the toy with the essential safety requirements. The manufacturer or the authorised representative within the EU must keep the Declaration of Conformity for 10 years after the toy is placed on the market (TIE, 2009b);
- Affix the CE mark to the toy, either directly on the toy, on a label or on the packaging;
- Affix their names and address, as well as an element allowing identification of the toy for traceability (e.g. a batch or serial number); and
- Ensure that the toy is accompanied by instructions and safety information and bears the required warnings.

Article 4 of the Toy Safety Directive outlines obligations for manufacturers and **paragraph 4** indicates that, when deemed appropriate with regards to the risks presented by a toy, manufacturers are required to carry out sample testing of marketed toys, investigate, and, if necessary, keep a register of complaints, of non-conforming toys and toy recalls and keep distributors informed of any such monitoring in order to protect the health and safety of consumers (European Parliament and the Council, 2014).

Paragraph 8 of **Article 4** notes that manufacturers who consider or have reason to believe that a toy that they have placed on the market is not in conformity with the relevant Community harmonised legislation should immediately take the corrective measures necessary to bring that toy into conformity or to withdraw or recall it if appropriate. Where the toy presents a risk, manufacturers are required to immediately inform the competent national authorities of the Member States in which they made the toy available to that effect, giving details in particular, of the non-compliance and of any corrective measures taken (European Parliament and the Council, 2014).

Chapter IV of the Toy Safety Directive relates to conformity assessment with **Article 18** outlining requirements for safety assessments. This indicates that, before placing a toy on the market, manufacturers are required to carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards (European Parliament and the Council, 2014).

Importer requirements

Importers may only place toys compliant with safety requirements on the EU market. An importer is therefore required to take the following steps (European Commission, 2015a):

- Ensure that the manufacturer has carried out the appropriate conformity assessment procedure to demonstrate that the toy complies with essential safety requirements;
- Ensure that the manufacturer has drawn up technical documentation that shows that the toy complies with the essential safety requirements;
- Keep a copy of the EC Declaration of Conformity that states the fulfilment of the essential safety requirements has been demonstrated (for a period of 10 years after the toy has been placed on the market (TIE, 2009b);
- Ensure that the CE marking is affixed either directly on the toy, on an affixed label or on the packaging;
- Affix their own name and address;
- Ensure that the manufacturer has affixed his name and address, as well as an element allowing identification of the toy for traceability (e.g. a batch or serial number); and
- Ensure that the toy is accompanied by instructions and safety information and bears the required warnings.

Article 6 of the Toy Safety Directive outlines obligations for importers and **paragraph 6** indicates that, when deemed appropriate with regards to the risks presented by a toy, importers are required to carry out sample testing of marketed toys, investigate, and, if necessary, keep a register of complaints, of non-conforming toys and toy recalls, and shall keep distributors informed of such monitoring (European Parliament and the Council, 2014).

Paragraph 7 notes that importers who consider or have reason to believe that a toy that they have placed on the market is not in conformity with the relevant Community harmonised legislation should immediately take the corrective measures necessary to bring that toy into conformity or to withdraw or recall it if appropriate. Where the toy presents a risk, importers are required to immediately inform the competent national authorities of the Member States in which they made the toy available to that effect, giving details in particular, of the non-compliance and of any corrective measures taken (European Parliament and the Council, 2014).

Distributor requirements

Distributors are required to act with due care when making toys available on the EU market. Hence, a distributor has to verify that (European Commission, 2015a):

- The CE marking is affixed directly to the toy, on a label or on the packaging;
- The manufacturer has affixed his name and address, as well as an element allowing identification of the toy for traceability (e.g. a batch or serial number);
- The importer has affixed their name and address; and
- The toy is accompanied by instructions and safety information and bears the required warnings.

Article 7 of the Toy Safety Directive outlines obligations for distributors and **paragraph 2** indicates that, where a distributor considers or has reason to believe that a toy is not in conformity with the requirements set out in Article 10 and Annex II, it will not make the toy available on the market until the toy has been brought into conformity. Furthermore, where the toy presents a risk, the distributor has to inform the manufacturer or the importer, as well as the market surveillance authorities, to that effect (European Parliament and the Council, 2014).

Paragraph 4 notes that distributors who consider or have reason to believe that a toy that they have made available on the market is not in conformity with the relevant Community harmonised legislation should make sure that corrective measures necessary to bring that toy into conformity or to withdraw or recall it if appropriate are taken. Where the toy presents a risk, distributors are required to immediately inform the competent national authorities of the Member States in which they made the toy available to that effect, giving details in particular, of the non-compliance and of any corrective measures taken (European Parliament and the Council, 2014).

Further details regarding the specific chemical and labelling requirements outlined in the Toy Safety Directive are provided in Annex 1.

1.2 The issue

The Toy Safety Directive lays down toy safety rules to ensure that all toys placed on the EU market are safe. Since 2011 these include requirements for a safety assessment, i.e. *"an analysis of the chemical (...) hazards that the toy may present, as well as an assessment of the potential exposure to such hazards."* Moreover, since 2013 manufacturers must ensure that toys are *"designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to chemical substances or mixtures"*. In addition to these risk based requirements, toys must comply with the European Union's general chemicals legislation and other specific chemical requirements laid down in other horizontal legislation (such as RoHS, WEEE, etc.). Furthermore, toys that are substances or mixtures must comply with the CLP Regulation ((EC) No 1272/2008). Specific requirements are set out in relation to carcinogens, mutagens and reprotoxins (CMRs) in toys, although there are also potential derogations from these if certain conditions are met.

Some toys may also take the form of cosmetics and in such cases must comply with the compositional and labelling requirements laid down in the Cosmetics Regulation ((EC) No 1223/2009). Toys are not permitted to include certain (55) allergenic fragrances, which in most cases are also prohibited in cosmetics, but in other cases are only subject to labelling in cosmetics under the Cosmetics Regulation. For a further set of (11) allergenic fragrances, labelling on the toy, on the label, on packaging or in accompanying instructions is required if concentration limits are exceeded. Warning statements, instructions for use, precautions may also be required in some other cases, and traceability elements, labelling of manufacturer/importer contact details and CE marking are mandatory. Guidance on applying the above requirements is available in Toy Safety Directive specific documents. Harmonised standards lay down technical details regarding many of the requirements, inter alia by providing additional warnings not listed in Annex V of the Toy Safety Directive.

With respect to the linkages with the Cosmetics Regulation, the Toy Safety Directive explanatory guidance document (p104 and 108) refers readers to guidelines and opinions that have been issued on various aspects of the Cosmetics Regulation that are relevant to toys, including Scientific Committee opinions and guidelines (European Commission, 2016d).

Given that 99% of EU toy manufacturing companies are SMEs, with these accounting for 61% of EU toy industry employment¹, this case study explores the degree to which SMEs are aware of labelling and traceability requirements as set out above and that they understand their obligations in relation to toys that are substances/mixtures.

¹ European Commission, DG Grow, Sectors, Toys, accessed at http://ec.europa.eu/growth/sectors/toys/index_en.htm

1.3 Case study aims/objectives

This case study on the “awareness of toy manufacturers of chemical safety assessment and labelling requirements for toys” feeds into Task 2 with regard to evaluating the horizontal links between EU legislation on hazard identification and communication and in particular identifying and assessing gaps, overlaps and inconsistencies in horizontal links. The case study links to Task 2b of the study, which relates to assessing the relevance, effectiveness, efficiency, coherence and EU added value of hazard and risk communication in the CLP Regulation and other relevant EU legislation. The overall purpose of the 2b case studies is to assess the overall awareness of SMEs of hazard and risk communication obligations in the CLP Regulation and other relevant EU legislation.

As outlined in Section 1.2, the Toy Safety Directive lays down toy safety rules which include requirements for chemical safety assessments, compliance with specific chemical requirements laid down in other legislation with a horizontal link to CLP (such as RoHS, WEEE, etc.) and the CLP Regulation. Specific requirements are set out in relation to CMRs and certain allergens, which can also lead to cosmetics-based labelling requirements. Specific limits are laid down for nitrosamines and nitrosatable substances, for a range of (metallic) elements and for a (growing) variety of chemicals including strongly sensitising preservatives (in Appendix C). The purpose of this case study is to examine SMEs’ awareness of this range of obligations. The case study will examine the awareness of SMEs in relation to their full set of labelling requirements. It will cover awareness of traceability requirements, labelling of manufacturer/importer contact details, CE marking, instructions for use, precautions and warnings.

The case study therefore aims to identify (to the extent possible) answers to the following questions:

- Are toy manufacturers, in particular SMEs, aware of the requirements under the Toy Safety Directive to undertake a chemical safety assessment? Are these requirements clear and understandable? Are the chemical requirements outlined in the Directive considered to be clear and understandable?
- Do toy manufacturers and in particular SMEs experience any issues with regard to meeting the chemical safety assessment requirements outlined in the Toy Safety Directive? Are there any aspects that are particularly burdensome or could be improved?
- Do toy manufacturers, in particular SMEs, understand their obligations with regard to toys that are substances/mixtures?
- Do toy manufacturers, in particular SMEs, understand when chemical requirements (including those related to labelling) under other pieces of legislation apply (e.g. under the CLP Regulation, Cosmetics Regulation, Directive 2002/95/EC restricting the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive), and Directive 2002/96/EC on waste electrical and electronic equipment (WEEE Directive))?
- Do toy manufacturers, in particular SMEs, consider the labelling requirements outlined in the Toy Safety Directive to be clear and understandable? Is it clear when labelling requirements under other legislation apply to toys (e.g. under the Cosmetics Regulation)? If not, which aspects are unclear?
- Is the current system of labelling toys considered to be effective at communicating the hazards and risks associated with chemical substances/mixtures contained in toys? If not,

what changes could be made to ensure that the hazards/risks of chemicals used in toys are communicated more effectively?

- Are there issues with toys not meeting the labelling requirements outlined in the Toy Safety Directive (e.g. missing information, lack of a CE mark, labelling not in the correct language, etc.)?

This case study also takes into account the evaluation questions for the study as a whole (i.e. the evaluation questions that form the basis of the fitness check on the chemicals legislative framework (excluding REACH) to be undertaken by the European Commission).

1.4 Case study methodology

The process for undertaking this case study consisted of a combination of desk-based research and stakeholder consultation. The desk-based research included a review of the legislative text of the Toy Safety Directive as well as any supporting guidance documents (European Commission, 2016d). In addition, the evaluation report produced by Technopolis et al. in 2015 was reviewed to obtain information on any issues raised with regard to the requirements to undertake a chemical safety assessment and labelling of toys. In addition, relevant position papers from consumer organisations (e.g. ANEC and BEUC) and industry associations (e.g. Toy Industries Europe (TIE)) were reviewed to identify concerns and/or positive views regarding the labelling of toys and the chemical safety assessment process.

Research into the chemical requirements (including those related to labelling) under other pieces of legislation that apply to toys was also undertaken (e.g. under the CLP Regulation, Cosmetics Regulation, Directive 2002/95/EC restricting the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive), and Directive 2002/96/EC on waste electrical and electronic equipment (WEEE Directive)) to determine how and when these relate to toys. Further desk-based research was also undertaken to collect any additional information that could be used to support the case study.

As well as undertaking desk-based research, an important element of the information collection exercise was consultation with relevant stakeholders. The purpose of this process was to discuss stakeholders' views of the chemical safety assessment process, including any issues with regard to understanding and meeting the associated requirements. The consultation exercise also allowed discussion with stakeholders' regarding awareness and understanding (in particular of SMEs) of the chemical requirements and labelling requirements outlined in the Toy Safety Directive as well as the relevant requirements under other legislation.

Table 1-2 provides a list of relevant stakeholders that were contacted for input to this case study.

Table 1-1: Relevant stakeholders to be contacted as part of the Case Study 8 (toys)	
Stakeholder	Type
European Commission (DG GROW)	Regulator
Expert Group on Toys Safety	Expert group
Toy Industries Europe (TIE)	Industry association
ANEC	Consumer association
BEUC	Consumer association
UEAPME	Industry association

To facilitate the consultation process an e-mail was sent to the above stakeholders providing an overview of the fitness check study as well as further details regarding the purpose of this case study specifically. This also included an invitation to participate in a telephone interview to discuss the aspects under consideration and the issues experienced. If this approach was acceptable to the stakeholders, follow-up telephone interviews were held. Alternatively, if stakeholders were unable or unwilling to partake in a telephone interview then they were invited to respond in writing to a series of questions, the answers to which contributed to the final evaluation. In the case of the Expert Group on Toys Safety, members were invited to respond to a short questionnaire which was made available via CIRCA BC.

2 Detailed Description of Issues

As outlined in Section 1.2, the Toy Safety Directive lays down toy safety rules which include requirements for a chemical safety assessment, compliance with specific chemical requirements in other legislation with a horizontal link to CLP (such as RoHS, WEEE, etc.) and the CLP Regulation. Specific requirements are set out in relation to CMRs and certain allergens, which can also lead to cosmetics-based labelling requirements. Specific limits are laid down for nitrosamines and nitrosatable substances, for a range of (metallic) elements and for a (growing) variety of chemicals including strongly sensitising preservatives (in Appendix C).

This case study will examine SMEs' awareness of this range of obligations as well as the requirements regarding labelling of toys (including awareness of traceability requirements, labelling of manufacturer/importer contact details, CE marking, instructions for use, precautions and warnings).

In the first instance it is necessary to determine the rules for a chemical safety assessment and labelling of toys under the Toy Safety Directive as well as the requirements triggered under other EU legislation. It will then be necessary to investigate the extent to which these requirements are understood by industry (in particular SMEs) and whether these are clear and appropriate from the perspective of manufacturers, importers and distributors. The views of consumer organisations will also be sought to investigate the appropriateness of labelling requirements for effectively communicating the hazards and risks associated with chemical substances/mixtures contained in toys.

Annex 1 provides an overview of the chemical requirements and labelling requirements that are relevant to toys under various pieces of legislation (including the Toy Safety Directive). The following section provides a summary of the key issues that have been identified through desk-based research and stakeholder consultation and attempts to answer the case study questions outlined in Section 1.3.

3 Key Issues

3.1 RAPEX data

Information obtained from the Rapid Alert system for non-food dangerous products (RAPEX) indicates that there have been a considerable number of notifications for toy products between 2009 and 2015. In the two most recent years, toys have been the products most notified by EU Member States as posing risks to consumers (as indicated in Table 3-1).

Table 3-1: Number of notifications by product category between 2009 and 2015							
Product category	Year						
	2009	2010	2011	2012	2013	2014	2015
Chemical products	44	29	38	54	69	62	53
Childcare articles and children's equipment	67	72	66	43	68	81	86
Clothing, textiles and fashion items	395	625	423	668	583	530	346
Communication and media equipment	10	6	5	15	23	12	23
Construction products	N/A	N/A	104	5	8	19	25
Cosmetics	96	66	104	86	106	74	52
Decorative articles	14	10	9	11	27	21	48
Electrical appliances and equipment	138	158	153	205	207	217	199
Food-imitating products	40	51	16	22	40	13	13
Furniture	17	12	9	15	22	13	14
Gadgets	6	4	2	2	1	1	3
Gas appliances and components	15	8	7	12	6	16	3
Hand tools	2	1	1	3	N/A	N/A	N/A
Hobby/sports equipment	49	42	24	19	55	38	28
Jewellery	7	7	12	22	28	63	117
Kitchen/cooking accessories	14	5	8	11	8	16	16
Laser pointers	8	15	11	30	37	16	18
Lighters	30	35	14	18	43	36	50
Lighting chains	39	23	12	49	53	24	56
Lighting equipment	52	48	53	50	77	79	54
Machinery	7	17	15	21	23	26	10
Motor vehicles	146	175	171	149	160	194	214
Other	19	33	34	68	47	47	44
Pressure equipment/vessels	N/A	N/A	1	1	N/A	1	2
Protective equipment	12	29	31	20	41	44	37
Pyrotechnical articles	N/A	N/A	N/A	11	46	38	1
Recreational crafts	5	3	13	3	3	5	1
Stationary	5	1		2	3	5	4
Toys	472	488	324	366	580	650	555
Source: Technopolis et al. (2015) and European Commission (2015c)							

In 2015 there were 2,072 alerts registered in the RAPEX system with 27% of these notifications relating to toy products in which corrective measures had to be taken. The products with the second highest number of notifications were clothing, textiles and fashion items, which accounted for 17% of the total number of notifications in 2015 (European Commission, 2015d).

RAPEX data also give an indication of the type of risk that relates to a product notification by a Member State. This can range from chemical risks and risk of injuries to risks of damaging sight and risks of choking. An analysis undertaken by Technopolis et al. (2015) using RAPEX data indicates that the majority (35%) of toy products were notified in the RAPEX system because of chemical risks between 2009 and 2014 (as indicated in Figure 3-1). This therefore indicates that the potential exposure of consumers (in particular children) to chemicals when using toys is an issue in the EU.

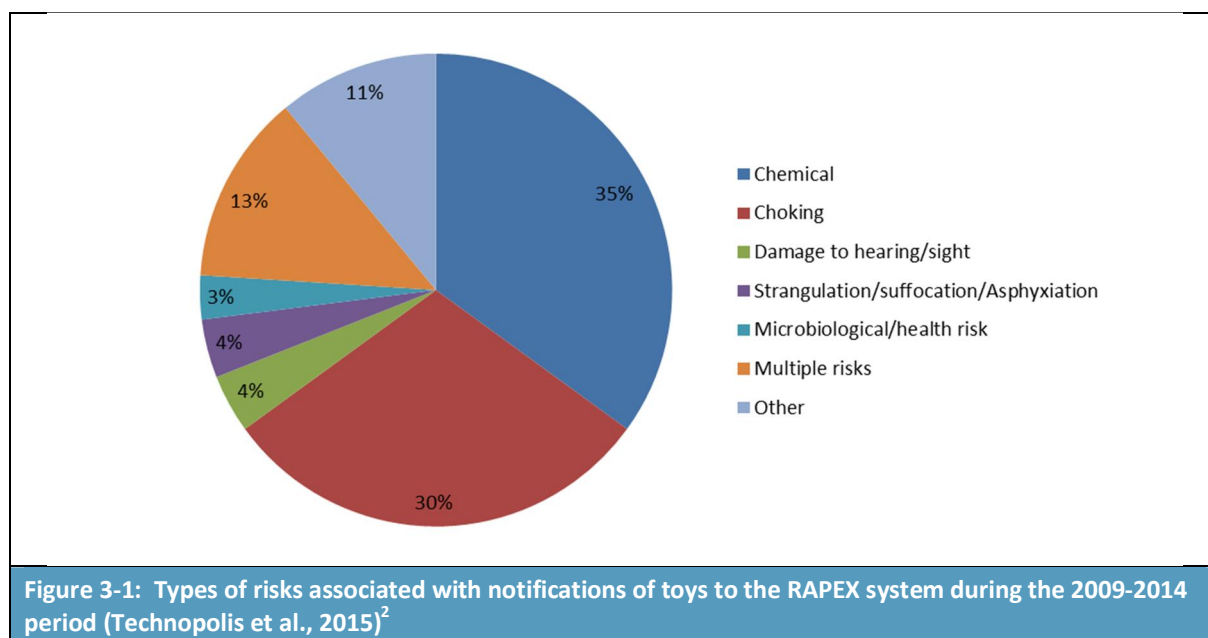


Table 3-2 provides the number of toys that have been recalled from the market between 2009 and 2015 by the country in which the product originated from (based on RAPEX data). This indicates that the vast majority of recalled products enter the EU from China. This therefore highlights the importance of effective communication with Chinese authorities and toy manufacturers to ensure that they understand the regulatory requirements concerning toys within the EU and help reduce the number of non-conforming products that represent a risk to consumers from entering the EU market.

Table 3-2: Number of recalled toys by country of origin between 2009 and 2015								
Country of origin	Year							Total
	2009	2010	2011	2012	2013	2014	2015	
Bosnia and Herzegovina	0	0	0	0	1	0	0	1
China	135	106	78	79	74	112	377	961
EU-28	6	20	16	4	11	6	23	86

² Note that the 'Other' category includes risks of injuries, cuts, burns, fire, electric shock, electromagnetic disturbance, environment and other.

Table 3-2: Number of recalled toys by country of origin between 2009 and 2015

Country of origin	Year							Total
	2009	2010	2011	2012	2013	2014	2015	
Hong Kong	3	0	0	2	1	9	0	15
India	0	0	0	0	0	0	1	1
Japan	0	0	0	0	1	0	0	1
Malaysia	0	0	1	0	0	0	0	1
Mexico	0	19	0	1	0	0	0	20
Philippines	0	2	0	0	0	1	0	3
Republic of Korea	0	0	1	0	0	0	0	1
Russia	0	1	0	0	0	0	0	1
Sri Lanka	1	0	0	0	0	0	0	1
Taiwan	2	2	5	0	1	1	3	14
Thailand	1	1	1	0	3	0	2	8
Ukraine	0	1	0	1	0	0	1	3
United Arab Emirates	0	0	0	0	1	0	0	1
United States	0	3	1	0	0	0	1	5
Vietnam	0	0	8	0	0	1	3	12
Unknown	6	10	1	7	6	2	19	51
Total	154	165	112	94	99	132	430	1186

Source: Technopolis et al. (2015) and European Commission (2016c)

The following sections provide answers (to the extent possible) to the key case study questions outlined in Section 1.3 based on the information obtained from desk-based research and stakeholder consultation. These case study questions have also been linked to relevant evaluation questions that form the basis of the fitness check on the chemicals legislative framework (excluding REACH) to be undertaken by the European Commission. Thus, the findings from this case study will contribute to answering the evaluation questions provided below.

3.2 Research/consultation findings

Are toy manufacturers, in particular SMEs, aware of the requirements under the Toy Safety Directive to undertake a chemical safety assessment? Are these requirements clear and understandable? Are the chemical requirements outlined in the Directive considered to be clear and understandable?

As part of the consultation exercise, stakeholders were asked whether toy manufacturers (and in particular SMEs) are aware of the requirements under the Toy Safety Directive to undertake a chemical safety assessment. It is the view of an industry association that the guidance from the Commission and from the toy industry is very clear with respect to toy manufacturers' obligations. The industry association and its national members have educated those involved in the toy industry within the EU and further afield for several years with regards to the requirements in the Toy Safety Directive (including the requirements to undertake a chemical safety assessment) before they entered into force. This has included organising educational programmes and toy safety information campaigns, which will continue to take place to ensure that economic operators within the sector remain informed.

Another industry association indicates that, in general, once SMEs have looked into legal-matter of the legislation they understand their obligations in the concrete case. However, it is noted that when entering a different product-line the challenge starts again, thus requiring a level of flexibility, which can be difficult for smaller companies. It is also noted that an issue with the Toy Safety Directive is that the legal text is not really written for practitioners, in particular in SMEs, where a technical person is usually responsible for such legal aspects. This therefore means that the legal text is not always understandable and it is suggested that it seems that formalities (e.g. exact wording on a label) are more important than transporting the right message.

As part of the consultation process stakeholders were asked whether the obligations relating to essential safety requirements as outlined in Paragraph 2 of Article 10 of the Toy Safety Directive are clear and understandable. Paragraph 2 of Article 10 states that toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children. Paragraph 2 notes that the ability of the users and, where appropriate, their supervisors shall be taken into account, in particular, in the case of toys which are intended for use by children under 36 months or by other specified age groups. In addition, Paragraph 2 of Article 10 indicates that labels affixed in accordance with Paragraph 2 of Article 11 and instructions for use which accompany toys shall draw the attention of users or their supervisors to the inherent hazards and risks of harm involved in using the toys, and to the ways of avoiding such hazards and risks.

Consultation with a consumer association, three Member State Competent Authorities, an industry sector association representative and a Public Health Authority indicates that, in their view, most stakeholders understand the obligations relating to essential safety requirements as outlined in Paragraph 2 of Article 10 of the Toy Safety Directive. However, it is noted by a Member State Competent Authority that there are differences in opinion regarding whether the obligations relating to essential safety requirements (Article 10, paragraph 2) outlined in the Toy Safety Directive are clear and understandable. Another Member State Competent Authority is of the view that the obligations relating to the essential safety requirements are not considered to be sufficiently clear. The authority indicates that these are general requirements, which leaves it up to the manufacturer to set the standard for safe toys. It is suggested that clear and specific requirements relating to chemicals would be specific concentration limits for problematic chemicals, which should be set in the Toy Safety Directive and not in accompanying standards.

Stakeholders were also asked whether the obligations outlined in Part III of Annex II of the Toy Safety Directive (regarding particular safety requirements in relation to chemical properties) are clear and understandable (further details of the specific requirements outlined in Annex II, Part III are provided in Annex 1 and Box A1-1). It is the view of a consumer association and four Member State Competent Authorities that obligations outlined in Annex II, Part III of the Toy Safety Directive (regarding particular chemical safety requirements) are not sufficiently clear. The provisions in Annex II, Part III include a general requirement “that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures...” and it is suggested that this can be interpreted in many ways. Where specific limits are not established it is difficult for all parties involved to determine the amount (or release) of a substance that is acceptable, which poses difficulties in assessment of conformity and enforcement. Whilst the consumer association recognises the necessity of generic provisions it is indicated that these should not be regarded as a substitute for stipulating precise chemical requirements. This is so that the application of the generic safety requirements becomes the exception rather than the main route to ensure the chemical safety of toys. Following from this, the consumer association indicates that the number of chemicals subject to restrictions should be broadened significantly and mechanisms need to be implemented to do this in an efficient manner.

A Member State Competent Authority notes that points 4 and 5 of Annex II, Part III are written in a complicated manner, which makes it difficult to determine what the requirements are. It is the view of the competent authority, that these two points (and the corresponding sections 3 and 4 in Appendix B) could have easily been merged together, thus addressing all classes of CMR in a single paragraph. Another Member State Competent Authority indicates that the obligations regarding CMR substances and the link to the CLP Regulation (with regards to 'classification limits') in the Toy Safety Directive are not clear. It is noted that in a Member State there are many small enterprises producing toys, however, they often ignore the obligations outlined in Annex II, Part III of the Directive because they do not understand them. A Member State Competent Authority also suggests that most stakeholders do not know how to deal with CMR substances and substances that are not listed in the REACH Regulation because the limits are not clear.

A Member State Competent Authority indicates that although the content of Annex II, Part III is considered appropriate the drafting of paragraphs 4 to 10 is not clear because the points relate to each other and to other Regulations. It is also the view of a Member State Competent Authority that the derogations outlined in Annex II, Part III paragraphs 4 and 5 of the Toy Safety Directive are complex as there is a need to compare/refer to several parts of different Directives/Regulations. There is a concern that manufacturers that do not fully understand these requirements could potentially make mistakes with regards to the use of chemical substances/mixtures in toy products. A Public Health Authority is also of the view that the obligations under the provisions laid down in Annex II, Part III of the Directive are not sufficiently clear and indicates that requirements have to be more clear, concise and precise. In addition, it is suggested that the use of wide/broad terminology (e.g. the use of "applicable", "have reason to believe") in the Directive does not specify unique criteria, which may cause differences in interpretation of provisions and further implementation. As also raised by other stakeholders, the authority notes that the Toy Safety Directive refers to many other pieces of legislation, which is considered to cause difficulties with understanding the requirements.

It is the view of a Market Surveillance Authority that to ensure the Toy Safety Directive is applied properly requirements should be clearly outlined in the Directive. Therefore, instead of the Directive making references to other applicable regulations it would be preferable to include a list of restricted chemical substances (and associated limits) within the Toy Safety Directive. It is currently very difficult for economic operators to understand the process/requirement of looking for limit values for certain substances under various pieces of legislation, particularly as limit values differ under different pieces of legislation (e.g. the Toy Safety Directive and the REACH Regulation set different limit values for phthalates, azo dyes and benzene). If the economic operator does not look at the limits under both the Toy Safety Directive and the REACH Regulation and are unaware of the rules that apply (i.e. the stricter limit is applicable), this can cause potential compliance problems.

The findings from the consultation exercise seem to support those of the evaluation of Directive 2009/48/EC on the Safety of Toys that was undertaken by Technopolis et al. in 2015 with the purpose of assessing the relevance of the Directive in addressing current needs, effectiveness and efficiency of its provisions, its coherence with the EU legislative framework and the added value at the European level. As part of this evaluation several Member States highlighted a need for clarification on different issues. In relation to chemical requirements, one Member State thinks that "they are worded in a very convoluted way and are barely comprehensible", whilst another Member State claims that chemical requirements need a more precise and transparent structure and simpler wording (Technopolis et al., 2015).

In summary, it can be concluded that extensive efforts have been (and will continue to be) made to ensure that economic operators are aware of their requirements under the Toy Safety Directive to undertake chemical safety assessments and ensure that toys and the chemicals they contain do not jeopardise the safety and health of consumers. In general, the obligations to perform a chemical safety assessment are considered to be clear and understandable for most stakeholders. However, the obligations outlined in Part III of Annex II of the Toy Safety Directive (regarding particular safety requirements in relation to chemical properties) are not generally deemed to be sufficiently clear. The complexity of these requirements means that some economic operators (particular SMEs) are choosing to ignore them because they are not easily understandable. This therefore suggests that simplifying the obligations outlined in Annex II, Part III of the Toy Safety Directive could assist in the effective communication and understanding of the requirements by relevant stakeholders.

Do toy manufacturers and in particular SMEs experience any issues with regard to meeting the chemical safety assessment requirements outlined in the Toy Safety Directive? Are there any aspects that are particularly burdensome or could be improved?

Issues with regards to meeting the chemical safety assessment requirements outlined in the Toy Safety Directive

As part of the consultation exercise, stakeholders were asked whether toy manufacturers and in particular SMEs experience any issues with regards to meeting the chemical safety assessment requirements outlined in the Toy Safety Directive and whether there are any aspects that are particularly burdensome or could be improved.

Consultation with an industry association indicates that the requirements of the Toy Safety Directive are specifically aimed at protecting human health and ensuring a high level of protection that is commensurate with exposure. From the perspective of the association, it is important to recognise the good fitness of purpose of the Directive in this respect as it enables the adoption of appropriate risk management measures that are relevant to the use of toys. The Directive also borrows from parallel legislation where necessary and this is considered one of its strengths. It is also noted that toys are the only consumer product that requires a chemical safety assessment for articles and industry supports this approach as being both necessary, given that children are a susceptible population, and appropriate. The environment is not specifically considered within the context of the Toy Safety Directive, but is considered to be adequately addressed in other legislation (e.g. toys are not exempt from being regulated as they are within the scope of other horizontal legislation such as the RoHS Directive, the REACH Regulation and the Persistent Organic Pollutants (POPs) Regulation ((EC) No 850/2004)).

In addition the industry association was asked whether toy manufacturers (and in particular SMEs) experience issues with regards to meeting the chemical safety assessment requirements outlined in the Toy Safety Directive. The main issue identified with carrying out the safety assessments is ensuring that the required information is available on which to base the assessment. This applies equally to operators that undertake the assessment themselves or those that engage a third party. However, this situation is considered to have improved significantly since the Toy Safety Directive came into force as manufacturers in third countries are now aware of the requirements and the quality of information is much improved. The requirements for chemical information in the technical documentation is already part of the Toy Safety Directive, as such there is no additional measure required. It is the view of the industry association that the chemical safety assessment procedure follows established risk assessment methods and there is no justification for making any further adaptations for toys. Information received from an industry sector association

representative indicates that, in their view, there are not considered to be any particularly burdensome aspects of the chemical safety assessment requirements outlined in the Directive that could be improved.

A Member State Competent Authority notes that the obligation to undertake a chemical safety assessment is an important step for ensuring the safety of consumers, but indicates that it can be burdensome especially for smaller manufacturers. The chemical safety assessment requires knowledge of all the chemicals used throughout the entire production of a toy product. It can be difficult for the toy manufacturer to obtain information on all chemicals in every raw material used during production, thus leaving it to the manufacturer of the toy to determine when and what to test to ensure an appropriate chemical safety assessment and the safety of the toy. It is also the view of a Market Surveillance Authority that some manufacturers (often those located in China) do not understand what a safety assessment or chemical safety assessment is. In terms of the chemical safety assessment the problem relates to a lack of knowledge regarding the materials and/or substances used as well as the restrictions imposed on certain substances and their scope.

An evaluation of the Toy Safety Directive undertaken by Technopolis et al. (2015) also notes that SMEs are particularly concerned with the costs related to the safety assessments (which include chemical as well as physical, mechanical, electrical, flammability, hygiene and radioactivity aspects) under the Toy Safety Directive and that this hinders the overall quality of the assessment procedures that are often incomplete and missing relevant information (according to eight Member States) (Technopolis et al., 2015). It is also reported that twenty Member States have experienced difficulties in obtaining information to be included in the technical documentation (such as safety assessment, test reports, names of supplier etc.) from economic operators, particularly when imported toys are concerned. In particular ten Member States indicate that safety assessments are often not included in the technical documentation, as they are seen to be too complex and merely a formal requirement. One Member State also suggests that economic operators often lack knowledge on what information they are required to provide. In many cases, it is not possible to link the documentation to the toy, resulting in the documentation being of limited (or of no) value (Technopolis et al., 2015).

Information obtained from a Member State Competent Authority as part of the consultation exercise undertaken for this study indicates that, in their experience, small enterprises do not understand the requirements outlined in Annex II, Part III of the Toy Safety Directive, with some choosing to ignore them. It is suggested that a possible way of improving the situation is to set specific limits for dangerous substances (not only for elements, allergenic fragrances and nitrosamines), so that the requirements for specific substances are clearer. A Member State Competent Authority also suggests that it would be useful to modify paragraph 8 of Annex II, Part III to ensure uniform limits are set across the EU. Paragraph 8 of Annex II, Part III of the Toy Safety Directive indicates that nitrosamines and nitrosatable substances are to be prohibited for use in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth if the migration of the substances is equal to or higher than 0.05 mg/kg for nitrosamines and 1 mg/kg for nitrosatable substances. However, there are lower limits given in the German Consumer Goods Ordinance, namely 0.01 mg/kg for N-nitrosamines and 0.1 mg/kg for N-nitrosatable substances for toys made of natural or synthetic rubber designed for children under 36 months and intended or likely to be placed in the mouth, which have been approved by the European Commission under

Decision 2012/160/EU³. It is therefore considered important to ensure consistent and coherent requirements, thus facilitating economic operators' understanding of these requirements and helping to reduce the possibility of misinterpretation.

Another Member State Competent Authority indicates that Appendix C of Annex II to the Toy Safety Directive sets specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth. However, for substances such as allergenic isothiazolinones that are used as preservatives dermal contact is important. Limiting these restrictions to toys used by children under 36 months or toys intended to be placed in the mouth does not reduce the health risk in the case of relevant dermal exposure of hazardous substances, which might increase the health risk for children over 36 months of age.

It is the view of a Public Health Authority that, given consumers of toys are children and therefore a vulnerable population; the requirements for chemicals to be used in toy production (e.g. types, limits) should be completely laid down in the Toy Safety Directive. It is also suggested that the reference to other pieces of legislation within the Directive should be avoided as this can hinder the understanding of the requirements. Thus, inclusion of all requirements relating to chemicals within the Toy Safety Directive instead of referencing other pieces of associated legislation would facilitate understanding of the obligations by economic operators and other relevant stakeholders.

Findings from the evaluation of the Toy Safety Directive undertaken by Technopolis et al. (2015) have identified safety assessment procedures as a process that could be improved to enhance the Directive's effectiveness. A large Italian manufacturer notes that the European legislator concentrates too much on chemical issues and that a more comprehensive safety assessment would represent a higher guarantee of toys' safety. It is suggested that a toy can comply with all safety requirements, but can still be dangerous for children as their behaviour is unpredictable. It is for this reason that the company, together with another large Italian manufacturer, involves different categories of experts (including psychologists) when performing the safety assessment in order to fully take account of the complexity of child play. These higher safety and compliance parameters can be attributed to manufacturers being incentivised to protect the reputation and accountability of their brand (Technopolis et al., 2015).

The evaluation of the Toy Safety Directive undertaken by Technopolis et al. (2015) noted that SMEs denounce the very high costs caused by the Toy Safety Directive, particularly in relation to the safety requirements. However, there is no evidence to suggest that these costs would reduce by means of national legislation instead of an EU Directive on the safety of toys. SMEs do not point to any benefit stemming from national rather than European rules in the case of toy safety. An Italian industry association of SMEs indicates that the existence of a sectorial EU Directive for toys directly triggers SMEs to take measures to ensure toy safety (Technopolis et al., 2015).

The most expensive provision concerns the new chemical limits. Related requirements are considered to be particularly burdensome for manufacturers, who had to modify production processes, to put in place extra software able to collect information all along the supply chain and to

³ European Commission (2012): Commission Decision of 1 March 2012 concerning the national provisions notified by the German Federal Government maintaining limit values for lead, barium, arsenic, antimony, mercury, and nitrosamines and nitrosatable substances in toys beyond entry into application of Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys. Official Journal of the European Union. Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:080:0019:0029:en:PDF>

engage external contractors, experts and dedicated human resources (e.g. risk assessment managers, chemists). The Directive requires the gathering of quality information throughout the whole supply chain to ensure that chemical limits are respected. This means to check, for instance, that all the materials provided by different suppliers (and then used for toy manufacturing) are compliant with the Directive, hence further increasing costs, particularly when complex (e.g. multi-material, multi-colour) toys are concerned (Technopolis et al., 2015).

Discussions with an industry association as part of this fitness check study indicate that the investment required for a new product (e.g. tests, certificates) to meet the requirements of the Toy Safety Directive can be considerable and is often the reason new products are not introduced. Thus, in general, innovation is considered to be hampered, particular where complex products are concerned. It is also noted that constant changes to the annexes of the Toy Safety Directive, resulting in the fulfilment of new requirements, can be problematic for companies and, in particular, SMEs. Such changes are often perceived as unnecessary (e.g. regulating paper-quality of labels) and costly, without providing any added value for safety. This can have implications for SMEs compared to larger organisations since SMEs may be less able to absorb these additional costs.

It is important to note that, when asked about the opportunity to reduce conformity assessment related costs, the majority of consultees argue that these costs cannot be reduced and that *“the benefits of having the chemical assessment outweigh its costs”* (Technopolis et al., 2015). This view is also supported by the stakeholders contacted as part of this case study. Information received from a consumer association indicates that, in their view, the benefits to society of having the chemical safety assessment requirement outlined in the Toy Safety Directive are considered to outweigh the costs of this procedure for industry. The association also suggests that it may be the case that the costs for industry are potentially small compared to the cost involved in non-compliance leading to enforcement activities and subsequent corrective action, which may also result in a loss in consumer confidence (and a possible negative impact on a company’s reputation).

It is the view of the industry sector association representative that the chemical safety assessment has led to a greater awareness of manufacturers to the importance of a structured and traceable supply chain. The direct consequence of this is that it is possible to react to chemical risks before products are placed on the market. The association also indicates that they support the way the chemical safety assessment could be used and integrated into manufacturers’ quality assurance processes. A Public Health Authority notes that the chemical safety assessment has to be an obligation considering that consumers of toys are children, and thus a vulnerable population group. A Member State Competent Authority indicates that the obligation to undertake a chemical safety assessment is an important step and improves the protection of children from exposure to hazardous substances. The assessment forces manufacturers to evaluate and assess the chemicals used in toys in relation to how the toy will be used by the consumer. Another Member State Competent Authority notes that a lack of a requirement to undertake a chemical safety assessment could lead to severe dangers to children, with economic costs resulting from medical treatment and potential demographic damage to society (e.g. infertility caused by phthalates). In the case of neurotoxic lead it has been proven via an impact assessment that the costs of expected health effects resulting from deficient limit values are distinctly higher by some orders of magnitude than the economic costs for changes in production. The same is also expected for other long term health effects, such as allergies and cancer.

Is the Toy Safety Directive suitably flexible to allow changes to the chemical requirements in light of technological, scientific and social developments?

As part of this case study it was also deemed appropriate to determine whether, from the perspective of relevant stakeholders, the Toy Safety Directive is suitably flexible to allow changes to

the chemical requirements in light of technological, scientific and social developments as this can have a direct impact on economic operators' understanding of their obligations.

Consultation with an industry association indicates that, in their view, the Toy Safety Directive does sufficiently address emerging areas of concern (e.g. arising from advances in science and technology). If new scientific evidence demonstrates that a substance needs to be restricted then the Toy Safety Directive allows for additional restrictions whenever necessary. Also, toy manufacturers have the obligation to undertake mandatory safety (including chemical) assessments, which allow operators to identify potential new hazards. In addition the Toy Safety Directive includes the sale of products via the internet, which is one of the main emerging areas of 'concern'. Therefore, the safety requirements outlined in the Directive also apply to toys sold online and the accompanying explanatory guidance document outlines details of how warnings, markings and other information should be displayed on websites. However, it is clear that market surveillance in this context is more difficult, thus it is considered important that authorities enforce the Directive by monitoring internet channels.

The 2015 evaluation of the Toy Safety Directive notes that economic operators widely acknowledge the value of the adaptation mechanisms, which make the Directive flexible to adapt to new safety hazards. This is also supported by the targeted consultation undertaken specifically for this case study, whereby a Member State Competent Authority, an industry sector association representative, a Public Health Authority and a Market Surveillance Authority agree that the Directive is flexible to allow changes to the chemical requirements in light of technological, scientific and social developments.

However, a number of suggestions have been made regarding ways in which the chemical requirements of Toy Safety Directive can be altered to better ensure adaptability to new hazards. A German industry association claims that the Directive is not flexible enough to track scientific progress, so that both its scope and the chemical requirements can easily become outdated. The stakeholder therefore suggests setting the chemical limit values in a harmonised standard rather than in an annex to the Directive, so as to update them in a quicker and more transparent way (Technopolis et al., 2015).

Consumer associations stress that the Toy Safety Directive is not flexible enough to address possible changes and new risks. They also question the too limited scope of the Committee procedure (Article 46 of the Directive) as it only applies to Annex I⁴; points 11 and 13 of Part III of Annex II⁵; Annex V⁶; Appendix A on the permitted use of CMR substances and Appendix C on the specific limit values for chemicals intended for use by children under 36 months or in toys intended to be placed in the mouth. This is deemed insufficient as, for example, the acceptance of lower limits in Germany for nitrosamines and nitrosable substances by the European Commission on health grounds implies that lower limits are warranted for certain toys (some Member State Competent Authorities have also highlighted the same issue with regards to lead and barium in the case of Germany).

⁴ Annex I provides a list of products that are not considered as toys within the meaning of the Directive.

⁵ Part III of Annex II concerns chemical properties of materials used for toys.

⁶ Annex V regards warnings.

Box 3-1 provides further details of the German case. It is important to note that on the 9th July 2015, the European Court of Justice rejected the German Government's request to maintain different limits for arsenic, antimony and mercury in toys (Technopolis et al., 2015).

Box 3-1: The German case (Technopolis et al., 2015)

On the 20th January 2011, the German Federal Government requested permission to the Commission to maintain the existing national provisions for five elements: lead, arsenic, mercury, barium and antimony, and for nitrosamines and nitrosatable substances released from toy material.

With decision 160 of the 1st March 2012, the Commission rejected the permission for antimony, arsenic and mercury. The values established by the Directive were considered to be *'based on a consistent and transparent scientific-toxicological approach to ensure safety'* (Decision 2012/160/EU, par. 60), and therefore more appropriate. Measures for nitrosamines and nitrosatable substances were approved by the Commission as the request was recognised to be *'based on a real concern with regard to children's health and not constituting a disguised restriction on trade between Member States'* (Decision 2012/160/EU, par. 88). Finally, as regards lead and barium, the German limit values were approved *'since the scientific background for setting the values evolved'* (par. 86) and uncertainties existed *'with regard to the level of protection offered by the Directive'* (par. 87). The German request was thus considered to be based on a real concern for children's health and at the same time not hampering the functioning of the internal market. The Commission therefore approved the national values. This approval was nonetheless subject to a limitation in time, namely the date of entry into force of EU provisions setting updated limits for lead and barium in toys or 21 July 2013, whichever would come first.

Germany applied for annulment of Decision 2012/160/EC. The General Court issued its judgment on the annulment request on the 14th May 2014 that confirmed the Commission Decision with regard to antimony, arsenic and mercury. The German Federal Government appealed against the judgement; however the Court confirmed the Commission's refusal to allow Germany to retain its limit values for arsenic, antimony and mercury in toys on the 9th July 2015 (Court of Justice of the European Union, 2015)

Migration limits according to the Toy Safety Directive are 0.05 mg/kg for nitrosamines and 1 mg/kg for nitrosable substances for toys intended for use by children under 36 months or in other toys intended to be placed in the mouth. There are lower limits given in the German Consumer Goods Ordinance, namely 0.01 mg/kg for N-nitrosamines and 0.1 mg/kg for N-nitrosatable substances for toys made of natural or synthetic rubber designed for children under 36 months and intended or likely to be placed in the mouth. In reference to Commission Decision 2012/160/EU⁷ the Commission concludes that these German measures are justified by the need to protect human health and the Commission will require CEN to consider the mouthing behaviour of children to lower the limit values within the standardisation procedure. Therefore this will result in different limits within the Toy Safety Directive and in harmonised standard EN 71-12, which may in turn cause issues for economic operators in understanding the requirements. In addition, the adoption by Germany of different chemical rules than those established in the Directive is deemed as a barrier to trade by two Member States (Technopolis et al., 2015).

⁷ European Commission (2012): Commission Decision of 1 March 2012 concerning the national provisions notified by the German Federal Government maintaining limit values for lead, barium, arsenic, antimony, mercury, and nitrosamines and nitrosatable substances in toys beyond entry into application of Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys. Official Journal of the European Union. Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:080:0019:0029:en:PDF>

It is also the view of four Member State Competent Authorities that the current provisions of Article 46 should be broadened with a view to allow the setting of chemical provisions for all kinds of toys and all kinds of chemicals. It is suggested that there is no flexibility within the Toy Safety Directive for the Commission to amend measures on CMR substances in toys for children over 36 months of age. Therefore, in contrast to Article 46 of the Directive, the Commission should be allowed to amend measures on CMR substances resulting from new scientific knowledge in accordance with the regulatory procedure with scrutiny referred to in Article 47 (paragraph 2) and on a risk-based approach. In particular, chemicals used in toys that are intended for children older than 36 months or in toys not intended to be placed in the mouth could be problematic (e.g. preservatives in toys for children over 36 months can pose a health risk).

A Member State Competent Authority also notes that there is a lack of suitable flexibility for specific limit values. In the case of Appendix C of Annex II, Part III of the Toy Safety Directive the specific limit values only relate to oral exposure via mouthing behaviour. Therefore these limit values are restricted to toys for children younger than 36 months and for toys intended to be placed in the mouth. However, there is no flexibility to fix specific limit values addressing the risk of dermal exposure to hazardous substances, which is not restricted to children under 36 months of age. It is therefore the view of the authority that the age restriction for the specific limit values outlined in Appendix C should be removed.

To summarise, the information obtained from desk-based research and stakeholder consultation suggests that the adaptation mechanisms of the Directive have, in general, proved to be an effective policy tool to align the Toy Safety Directive to steady scientific and technological developments. While economic operators and some Member State Authorities generally confirm this, consumer associations and other Member State Authorities identify the need to broaden the scope of the comitology procedure (outlined in Article 46 of the Directive), to include all kinds of toys and all kinds of dangerous substances. Moreover, consumer associations ask to use available adaptation mechanisms to amend current limits for some chemicals (e.g. nitrosamines and nitrosable substances) in order to ensure these are consistent with national limits. In addition, consumer associations are of the view that, as standardisation is a long process, there could be new risks temporarily not covered by any harmonised standard. However, a transition period is unavoidable for each legislative process and the research undertaken by Technopolis et al. (2015) has not provided any evidence of major safety risks that could not be addressed by the available adaptation mechanisms (which include comitology amendments, standardisation mandates to CEN and CENELEC and protocols and recommendations by the notified bodies) (Technopolis et al., 2015).

Do toy manufacturers, in particular SMEs, understand their obligations with regards to toys that are mixtures?

As outlined in section A1.1 of Annex 1, Part III of Annex II of the Toy Safety Directive sets out requirements for toys that are themselves substances or mixtures and indicates that these must comply with the CLP Regulation. As part of the consultation process stakeholders have been asked whether manufacturers understand their obligations with regards to toys that are substances/mixtures.

Consultation with an industry association indicates that, from their perspective, the requirements for substances and mixtures are clear and fit for purpose with regards to toys where the toy is a substance or mixture. The majority of toys are articles and are therefore not subject to classification rules. For chemical toys there are three harmonised standards that can be applied and include requirements for classification and labelling. These are summarised in Table 3-3. For other toys that

may be substances or, more likely, mixtures (including finger paints, dough, play sand, crayons and bubble solutions) the requirements of the Toy Safety Directive clearly indicate that these should not be or contain hazardous chemicals including CMRs except where the specific derogations allow for their use. This is assessed either through application of the standard EN 71-7 (Safety of toys – Part 7: Finger paints – Requirements and test methods) or the chemical safety assessment outlined in Article 18 of the Toy Safety Directive.

Another industry association indicates that in order to understand their obligations related to such specialised legislation SMEs need support in the form of a contact-point that companies can use to obtain information to facilitate their understanding of the requirements and direct them where appropriate. It is suggested by the association that it could be useful to have local meetings that SMEs within the toy sector can attend and ask concrete questions relating to their specific situation.

Table 3-3: Harmonised standards that can be applied to chemical toys	
Standard	Details
EN 71-4:2013 Safety of toys – Part 4: Experimental sets for chemistry and related activities	For chemicals included in experimental sets there is a normative list of substances and mixtures that can only be used in prescribed amounts and concentrations included in the standard along with the GHS pictogram and appropriate signal word. Furthermore, the GHS pictogram and signal word marking is required for all dangerous substances and dangerous mixtures supplied in experimental sets even if a derogation from labelling is permitted by EU legislation (e.g. for small quantities of certain dangerous substances). This standard also allows for colourants to be used that are not individually specified, but these must not be substances that have a harmonised classification of acute toxicity, skin corrosion or irritation, serious eye damage or irritation, respiratory or skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, specific organ toxicity (single and repeated exposure) and aspiration hazard
EN 71-5:2013 Safety of toys – Part 5: Chemical toys (sets) other than experimental sets	A similar approach is taken for other chemical toys that do not fit within the scope of the EN 71-4 standard (such as paints, adhesives, oven hardening clays and plaster of paris moulding sets). These products are included in the scope of EN 71-5, which also adopts the approach of providing positive lists of chemicals that may be used. However, as formulations may vary depending on the toy, the manufacturer is required to adopt the requirements of the CLP Regulation in terms of marking the individual containers and packaging with the appropriate Hazard and Precautionary statements (H and P phrases) depending on the classification. As with EN 71-4, the small packaging derogations do not apply and full labelling requirements must be followed. Although not explicit in the standard the CMR requirements of the Toy Safety Directive also apply
EN 71-13:2014 Safety of toys – Part 13: Olfactory board games, cosmetic kits and gustative games	Cosmetic kits within the scope of this standard are a particular case where the Cosmetic Products Regulation takes precedence and cosmetic kits shall only contain components that are cosmetic products. The cosmetic kit is also required to be assessed for safety as outlined in the Cosmetic Products Regulation. For olfactory board games that are covered by this standard some substances and mixtures that are not food ingredients or cosmetic products should be classified and labelled in accordance with the CLP Regulation. Although not explicit in the standard the CMR requirements of the Toy Safety Directive also apply
<i>Source: Consultation with an industry association</i>	

However, a consumer association and four Member State Competent Authorities indicate that obligations outlined in Annex II, Part III of the Toy Safety Directive (regarding particular chemical safety requirements) are not sufficiently clear. With one noting that, in their experience, small enterprises do not understand the requirements resulting in some choosing to ignore them. In order

to improve stakeholders' understanding of the requirements it is suggested that specific limits for dangerous substances (not only for elements, allergenic fragrances and nitrosamines) could be set, so that the requirements for specific substances are clearer. It is also noted by a Public Health Authority that, given consumers of toys are children and therefore present a vulnerable population and to facilitate stakeholders understanding of their obligations, the requirements for chemicals to be used in toy production (e.g. types, limits) should be completely laid down in the Toy Safety Directive. It is also suggested that the reference to other pieces of legislation within the Directive should be avoided as this can hinder the understanding of the requirements. The Member State Competent Authorities and a Market Surveillance Authority also note that obligations under the provisions laid down in Annex II, Part III of the Toy Safety Directive are complex and can be difficult to understand, particularly as there is a need to refer to several parts of different Directives/Regulations. One Member State Competent Authority indicates that, in their experience, many economic operators are unaware of or do not understand their obligations to ensure that toys comply with chemical requirements set out in other chemicals legislation (e.g. restrictions in Annex XVII of the REACH Regulation).

As part of the consultation process, stakeholders were asked to indicate the main reasons for products not conforming to the chemical requirements laid down in the Toy Safety Directive. A number of stakeholders (including a consumer association, an industry sector association representative, a Market Surveillance Authority and five Member State Competent Authorities) indicated that the failure to adhere to restrictions on substances in the toy is one of the main reasons for non-conformity. Examples of products in which failure to adhere to substance restrictions has occurred include toys made of soft plastic (e.g. dolls) manufactured outside of the EU (particularly in relation to phthalates (e.g. DEHP), balloons and finger paints manufactured inside and outside of the EU and other various types of toy manufactured both inside and outside of the EU).

Stakeholders have also identified failure to adhere to the safety requirements set out in Annex II of the Directive in relation to chemical properties in general as a reason for non-compliance with the Toy Safety Directive. Particular product examples include balloons and finger paints, clay and slime elements of toys and intensive colour polymer toys.

Two Member State Competent Authorities have indicated that one of the main reasons for products not conforming to the chemical requirements of the Toy Safety Directive is failure to adhere to the safety requirements set out in Annex II in relation to chemical properties with regard to allergenic fragrances, with cases relating to scented toys and olfactory games highlighted as an example. In addition, three Member State Competent Authorities and a Market Surveillance Authority indicate that failure to adhere to requirements in relation to the use of CMRs in toys as another reason for non-conformity. Particular examples of toys not conforming to the CMR requirements outlined in the Directive include the use of formaldehyde in puzzles made of wood, phthalates (DIBP) used in plastic balls that have been manufactured outside of the EU and Ethylene vinyl acetate (EVA) foams.

This therefore indicates that failure to adhere to the chemical requirements of the Toy Safety Directive is an issue (which is supported by findings from the RAPEX data discussed earlier in this section) with cases identified for products manufactured both inside and outside of the EU. Given that some concerns have been raised by stakeholders with regards to economic operators' understanding of the chemical requirements it may be the case that a proportion of the 'product failures' could be attributed to a lack of understanding. It is suggested by a number of stakeholders that all requirements (including those relating to chemicals) concerning toys should be manifested in one regulation (rather than requirements relating to toys being referred to several different pieces of legislation) to ensure that the obligations are clear from the perspective of economic operators, thus enabling these requirements to be effectively and efficiently implemented.

Do toy manufacturers, in particular SMEs, understand when chemical requirements (including those related to labelling) under other pieces of legislation apply (e.g. under the CLP Regulation, Cosmetics Regulation, Directive 2002/95/EC restricting the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive), and Directive 2002/96/EC on waste electrical and electronic equipment (WEEE Directive))?

As outlined in Annex 1, there are chemical and labelling requirements provided in a number of pieces of legislation that are applicable to toys in addition to those presented in the Toy Safety Directive. The purpose of this section is to consider whether the chemical requirements (including those related to labelling) are clear under the various Directives/Regulations (in addition to the Toy Safety Directive) from the perspective of economic operators. Where appropriate, any inconsistencies or overlaps that may exist will be identified along with potential ways of improving the situation.

In the case of the Cosmetic Products Regulation, consultation with an industry association indicates that, in their view, the Toy Safety Directive makes it clear that cosmetic toys are to be regarded as cosmetic products and should be assessed as such. In the case of cosmetic kits (as defined by the Toy Safety Directive) the most stringent requirements of both the Toy Safety Directive and Cosmetic Products Regulation apply. Where other cosmetic products may be regarded as toys then the same situation applies. It is explicit in the manual for the scope of application of the Cosmetic Products Regulation that 'play value' would not exempt a product from the Regulation and may well be a 'dual-scope' product. Temporary tattoos are a particular example of this where the tattoo that is applied to the skin is a mixture and not an article. In all of these cases it is the view of the association that these are not considered an overlap, but a complementary solution.

However, the industry association indicates that there may be a potential inconsistency between the Toy Safety Directive and the Cosmetic Products Regulation as the risk assessment principles between the implementation of the two pieces of legislation differ in approach with regards to the treatment of children. The SCCS opinion that covers risk assessment for children indicates that in general no additional safety factors are employed during the risk assessment process. However, according to the industry association, the Toy Safety Directive requires that an additional safety factor of 10 or more is used to account for other exposures. This can lead to a potential compliance issue when borderline products that may include cosmetic toys are subject to a safety assessment.

A study undertaken by Technopolis et al. (2015) to evaluate the Toy Safety Directive indicates that confusion is likely to arise when toys are 'indirectly' regulated via legislation other than the Toy Safety Directive, with requirements relating to CMR substances cited as an example. The Toy Safety Directive sets a limit for CMR substances in toys corresponding to the relevant concentration limit established in the CLP Regulation. However, specific (usually lower) limits for certain CMR

substances, which are specifically applicable to toys, are also set in the REACH Regulation. It is suggested that economic operators may find it difficult to identify the proper requirements to comply with, particularly when reference is made to several pieces of legislation. One Member State indicates that economic operators often find it difficult to understand which regulation (e.g. the Toy Safety Directive rather than REACH) should apply for limits in chemicals (Technopolis et al., 2015). A Member State Competent Authority suggests that, in their experience, many economic operators are unaware of or do not understand their obligations to ensure that toys comply with chemical requirements set out in other chemicals legislation (e.g. restrictions in Annex XVII of the REACH Regulation).

Box 3-2 provides some examples of relevant provisions for toys that are indirectly addressed in other EU legislation (Technopolis et al., 2015).

Box 3-2: Examples of relevant provisions for toys that are indirectly addressed in other EU legislation (Technopolis et al., 2015)

- Benzene is banned according to REACH in toys or parts thereof ‘where the concentration of benzene in the free state is in excess of 5 mg/kg of the weight of the toy or part of toy’ (REACH Regulation, Annex XVII, point 5);
- Bis (2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) and benzyl butyl phthalate (BBP) are limited in REACH to concentrations not higher than 1,000 mg/kg by mass of the plasticised material, in toys and childcare articles (REACH Regulation, Annex XVII, point 51). Di-“isononyl” phthalate (DINP), di “isodecyl” phthalate (DIDP) and di-n-octyl phthalate (DNOP) are limited in REACH to the same concentrations if the toy or childcare article can be placed in the mouth by children (REACH Regulation, Annex XVII, point 52);
- Wood treated with creosote⁸ is explicitly banned from toys in REACH (Annex XVII, point 31);
- Azo dyes: textile or leather toys and toys which include textile or leather garments may not contain more than 30 mg/kg of listed carcinogenic aromatic amines released from azo dyes after reductive cleavage (REACH Annex XVII, point 43); and
- Polycyclic-aromatic hydrocarbons (PAH): as of 27 December 2015, rubber or plastic components on toys intended to come into contact with the skin may not contain more than 0.5 mg/kg of any of the listed carcinogenic PAHs (REACH Annex XVII, point 50)

Consultation with stakeholders has also indicated that failure to adhere to requirements under the Cosmetic Products Regulation (as identified by a Member State Competent Authority and a Public Health Authority) and the restrictions on the use of certain chemicals under the RoHS Directive (as identified by an industry sector association representative and a Member State Competent Authority) have resulted in toy products not conforming to the chemical requirements laid down in the Toy Safety Directive. The examples provided in the case of cosmetic toys were face paints and children’s cosmetic kits and in the case of toys that fall under the scope of the RoHS Directive the example provided was lead used in the solder of circuit boards that were manufactured outside of the EU. Hence, there have been problems with regard to toy products failing to meet the requirements outlined in legislation other than the Toy Safety Directive.

As part of the consultation process stakeholders were asked whether the need for toys to meet the requirements laid down under the RoHS Directive are considered to be appropriate and whether manufacturers understand these obligations. Responses received from a consumer association,

⁸ Relating to wood treated in industrial installations or by professionals, which is placed on the market for the first time or retreated in-situ. This is permitted for professional and industrial use only, e.g. on railways, in electric power transmission and tele-communications, for fencing, for agricultural purposes (e.g. stakes for tree support) and in harbours and waterways.

three Member State Competent Authorities, an industry sector association representative and a Market Surveillance Authority indicate that, in their view, a toy that is also classed as electrical and electronic equipment should fulfil the requirements of the RoHS Directive. A Member State Competent Authority notes that toys that are within the scope of the RoHS Directive will pose the same risks and hazards as other articles (that are not toys) covered by this Directive. It is therefore deemed appropriate that toys within the scope of the RoHS Directive should meet the requirements laid down under this Directive. However, three Member State Competent Authorities and a Market Surveillance Authority indicate that many toy manufacturers do not understand their obligations under the RoHS Directive. One Member State Competent Authority notes that there are a number of small enterprises producing toys, which often ignore obligations under EU legislation because they do not understand them or, as in the case of the RoHS Directive, are unaware of its existence. A Market Surveillance Authority also notes that this lack of understanding can be a particular issue for manufacturers that are based outside of the EU. They have experienced many cases in which manufacturers (often where these are located in China) are not aware that electrical toys are regulated under the RoHS Directive and, depending on the type of toy, other EU legislation (e.g. Electromagnetic Compatibility (EMC) Directive, Low Voltage Directive (LVD), Radio and Telecommunication Terminal Equipment (R&TTE) Directive).

Stakeholders were also asked whether it is clear to toy manufacturers when the requirements laid down in the Toy Safety Directive or the Cosmetics Regulation or any other applicable EU legislation apply to toys. A consumer association and an industry sector association representative are of the view that it is clear to toy manufacturers when the requirements laid down in the Toy Safety Directive or the Cosmetics Regulation or any other applicable EU legislation apply to toys. However, three Member State Competent Authorities and a Public Health Authority disagree with this viewpoint and do not consider the requirements laid down in legislation applicable to toys to be clear to manufacturers, especially for smaller enterprises.

In order to increase the clarity of requirements it is suggested that including all requirements relating to toys in the Toy Safety Directive would make it much easier and clearer for manufacturers (and in particular SMEs) to understand their obligations. It is also suggested that the inclusion of a list within the Toy Safety Directive indicating which other Regulations/Directives must be taken into account (and for which types of toy these apply) would provide greater clarity⁹.

As indicated in a study undertaken by Milieu in 2012¹⁰, legislative confusion increases administrative costs for economic operators (particularly manufacturers) who have to double-check the requirements that are applicable to them. For example, as regards the relation between the Toy Safety Directive and REACH, a first assessment is required to identify the requirements manufacturers are subject to under the Toy Safety Directive and a second is required in relation to restrictions under other legislative texts. This double-check has been indicated as a duplication of costs (Technopolis et al., 2015). The consultation exercise undertaken as part of the evaluation of the Toy Safety Directive indicates that a large Belgian manufacturer notes that several pieces of legislation relevant for the toy sector require the drafting of the EC declaration of conformity (e.g.

⁹ It is worth noting that Appendix II of the Technical Documentation guidance document (European Commission, 2016e) accompanying the Toy Safety Directive contains a list of legislation that also applies to toys.

¹⁰ Milieu (2012). Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps. Final Report.

RoHS Directive and the Radio and Telecommunication Terminal Equipment Directive (R&TTE Directive)) (Technopolis et al., 2015).

However, it should be noted that the European Commission ‘Blue Guide’ indicates that “where several pieces of Union harmonisation legislation apply to a product, the manufacturer or authorised representative has to provide a single declaration of conformity in respect of all such Union acts. In order to reduce the administrative burden on economic operators and facilitate its adaptation to the modification of one of the applicable Union acts, the single declaration may be a dossier made up of relevant individual Declarations of conformity” (European Commission, 2016f). A number of different stakeholders (three consumer associations, an Italian industry association, a large Italian manufacturer and a Czech Notified Body) have stated that, bearing in mind the vulnerability of the target group (i.e. children) the current framework should be maintained even if it is sometimes cumbersome and time-consuming. This is important given that respondents to the evaluation of the Toy Safety Directive do not experience any major contradictions or overlaps between the Directive and other pieces of EU legislation. Also some economic operators (an Italian industry association, a large Italian manufacturer, a Belgian and a Danish manufacturer) stressed that all current pieces of legislation are necessary as they regulate different products or products serving different purposes (Technopolis et al., 2015).

Given that the findings of the Toy Safety Directive evaluation suggest no major contradiction or overlapping, only a small number of points have been raised with regard to the link between the Toy Safety Directive and the other EU relevant legislation for toys (Technopolis et al., 2015).

A horizontal legislative framework has been suggested in order to better regulate chemicals in products¹¹. Moreover, economic operators deem it necessary to develop common EU testing methodologies, in order to ensure their uniform interpretation – thus enhancing intra-EU trade, lowering costs for testing laboratories and manufacturers, and ensuring an increased level of toy safety (Technopolis et al., 2015).

A large UK manufacturer argues that it would be better if the same chemical limits were applied in general to all consumer products. Similarly, a UK association of distributors suggests it would be beneficial to have the same chemical limit values for the same material across all consumer products, as this would ease the compliance with chemical regulation. Coherence could be improved accordingly if the same testing methodologies were implemented across different legislation, thus the same approach would be used not only to ensure toy safety, but the safety of all consumer products (Technopolis et al., 2015).

Although the work undertaken to evaluate the Toy Safety Directive did not identify any contradictions between the Directive and other legislation, a European consumer association suggests that the legislation on toys should be aligned as much as possible to that of other products, such as food and cosmetics. It is the view of the association that it should not be tolerable that some chemical substances (e.g. CMRs and allergens) are allowed in toys at higher levels than in other products (Technopolis et al., 2015).

¹¹ ANEC (2014): Position paper – Hazardous chemicals in products: the need for enhanced EU regulations. Available at: <http://www.anec.eu/attachments/ANEC-PT-2014-CEG-002.pdf>

In summary, the legislative links between the Toy Safety Directive and other Directives/Regulations applicable to toys are considered to be appropriate and necessary for ensuring the health and safety of consumers (and in particular children). However, issues have been identified with regards to manufacturers and, in particular, SMEs understanding of these requirements. Cases have been identified whereby manufacturers are unaware of their obligations under other pieces of legislation aside from the Toy Safety Directive. In some cases manufacturers are choosing to ignore these requirements because they do not understand them. This suggests that there is a need to provide greater clarity within the Toy Safety Directive of the chemical requirements that are applicable to toys under other pieces of legislation, with a number of stakeholders recommending the inclusion of all requirements relating to toys in the Toy Safety Directive itself.

Do toy manufacturers, in particular SMEs, consider the labelling requirements outlined in the Toy Safety Directive to be clear and understandable? Is it clear when labelling requirements under other legislation apply to toys (e.g. under the Cosmetics Regulation)? If not, which aspects are unclear?

As outlined in Annex 1, labelling in the context of the Toy Safety Directive also includes marking and warnings relevant to the mechanical and physical hazards in addition to specific warnings for chemical toys and fragrance allergens. It is the view of an industry association involved in the toy sector that the specific text and applicability of these labelling requirements is clearly set out in the standards accompanying the Directive and the majority of manufacturers have considerable experience in applying these. With regards to the CLP Regulation, the labelling requirements for chemical toys are also clearly set out in relevant standards. In the case of the Cosmetic Products Regulation it is, in general, clear when the labelling requirements apply to toys. The manufacturers and importers of these types of products often specialise in this area and are aware of the different requirements.

As part of the consultation process stakeholders were also asked whether labelling requirements outlined in the Toy Safety Directive are considered to be clear and understandable. In general the majority of stakeholders consulted¹² considered the obligations (including those related to product labels) for manufacturers (Article 4), importers (Article 6) and distributors (Article 7) to be clear.

Evidence obtained from the evaluation of the Toy Safety Directive suggests that issues have been raised with regards to a lack of clarity of the rules to affix the CE marking on toy products, especially when imported goods are concerned (Technopolis et al., 2015). However, the findings from the consultation undertaken as part of this study indicates that there is general consensus that most stakeholders understand the obligations relating to warnings for safe use of toys (Article 11 and Annex V) and obligations relating to CE marking (Article 17).

Stakeholders were also asked whether there are any aspects of the labelling requirements outlined in the Toy Safety Directive that are particularly burdensome or could be improved. Although the majority of respondents do not consider the labelling requirements to be particularly burdensome for manufacturers, one Member State Competent Authority indicates that, in their view, it is not clearly stated within the Toy Safety Directive that the list of warnings in Annex V is not exhaustive and additional warnings that are given the EN 71 standards must also be taken into account. In this

¹² This is the view of an industry association consumer association, a Market Surveillance Authority and four Member State Competent Authorities.

respect it is suggested that specific reference to the additional warnings in the EN71 standards should be included within the Directive. A Public Health Authority notes that the labelling requirements outlined in the Toy Safety Directive need to be comprehensive, clear, concise and precise. It is suggested that the label should bear all information about any toxic substances present in the toy even if the substance is hidden inside the toy as parents have the right to know such information.

In summary, there is general consensus that the labelling requirements outlined in the Toy Safety Directive, including those that relate to other pieces of legislation, are clear and therefore understood by most stakeholders. However, in the case of warnings, it is suggested that greater clarity could be provided with regards to the additional warning requirements included in standards by ensuring that specific reference is made in the Directive to the relevant standards.

Is the current system of labelling toy products considered to be effective at communicating the hazards and risks associated with chemical substances/mixtures contained in toys? If not, what changes could be made to ensure that the hazards/risks of chemicals used in toys are communicated more effectively?

Targeted consultation with relevant stakeholders has been undertaken to obtain their views regarding whether or not the labelling system for toys is deemed to be effective at communicating the hazards and risks associated with chemical substances/mixtures contained in toys. It is the view of an industry association that the system of labelling toy products is effective at communicating the hazards and risks associated with chemical substances/mixtures contained in toys. The association indicates that the requirements for chemical toys specifically reference the CLP Regulation and actually go beyond what is required, as the small packaging derogation for normal consumer products does not apply. Since the Toy Safety Directive requires that toys are safe, there is no justification for further communication of hazards beyond the scenario where chemicals and mixtures that would require a classification are allowed. The proportion of toys that fall within this category is very small when compared to all toys on the market.

It is also the view of two Member State Competent Authorities, an industry sector association representative and a Market Surveillance Authority that the current system of labelling toys is effective at communicating the hazards and risks associated with chemical substances/mixtures contained in toy products. However, one Member State Competent Authority disagrees and is of the view that the current system of labelling toys does not effectively communicate the hazards and risks associated with chemical substances/mixtures contained in toys as most labelling requirements concern mechanical hazards and risks. Another Member State Competent Authority also notes that there are no specific labelling requirements in the Toy Safety Directive with regards to communicating the hazards and risks related to the content of chemicals in toys, unless the toy is defined as a chemical toy or included on the packaging for fragrances in olfactory board games, cosmetic kits and gustative games (in line with Paragraphs 4 and 10 of Annex V of the Toy Safety Directive). A similar view is also held by a Public Health Authority which indicates that the labelling requirements are not currently precise enough with regards to the presence of potentially dangerous substances which may be present, especially in hidden parts of the toy. A Member State Competent Authority notes that allergens, other than fragrances, are not covered by the labelling requirements of the Directive. Also, toys are exempt from the biocides regulation, which means that toys containing biocides (e.g. toy tents with an antibacterial or mosquito-repellent surface) will not be labelled with the substance(s) that has/have been applied.

During the consultation exercise stakeholders were asked whether the linkages set out in Annex II, Part III point 10 (of the Toy Safety Directive) for cosmetic toys in relation to the compositional and

labelling requirements for cosmetic products (where the reference is to Council Directive 76/768/EEC) are considered to be appropriate for ensuring adequate protection of children's health. It is the view of a consumer association, four Member State Competent Authorities, an industry sector association representative and a Market Surveillance Authority that these linkages are in principle appropriate and, assuming that cosmetics for toys will be applied to the skin of children, it seems natural to apply the requirements of the Cosmetics Regulation. It is noted by a Member State Competent Authority that chemicals in cosmetic products are assessed in relation to their use and exposure which is very different from the exposure from most toys. It is therefore considered reasonable for the protection of children that cosmetic toys comply with both pieces of legislation (i.e. the Toy Safety Directive and the Cosmetic Products Regulation). However, stricter limits have to be applied in some cases, for example, where Appendix C of the Toy Safety Directive establishes stricter limits compared to the Cosmetics Regulation or in the case of fragrances where the requirements in Annex II, Part III point 11 obviously deviate from those outlined in the Cosmetics Regulation. It is the view of the consumer association that this needs clarification in Annex II, Part III point 10 of the Toy Safety Directive.

Information obtained from the evaluation of the Toy Safety Directive undertaken by Technopolis et al. in 2015 indicates that allergens are an issue considered as too softly regulated (expressed as a concern by three Member States and a consumer representative). The issue raised is that the list of sensitising fragrances set out in the Toy Safety Directive is "*clearly outdated*", while all 129 contact allergens identified by the Scientific Committee on Consumer Safety (SCCS)¹³ should be banned from toys (Technopolis et al., 2015). As part of the consultation process, stakeholders were specifically asked whether the requirements (including those related to labelling) laid down in the Toy Safety Directive with regard to allergenic fragrances are appropriate for ensuring adequate protection of children's health. Information obtained from a consumer association indicates that the list of allergenic fragrances included in Annex II, Part III of the Toy Safety Directive is outdated and should be updated in line with the findings of the SCCS in its opinion of fragrance allergens in cosmetic products (SCCS/1459/11, 2011)¹⁴. This concluded that many more fragrance substances (129 instead of the 26 substances identified previously and subject to labelling requirements if exceeding 0.001%/0.1% according to the Cosmetic Products Regulation) have been shown to be human sensitisers and consequently need to be subject to additional labelling provisions in the Cosmetic Products Regulation. Hence, an additional 103 substances should be subject to regulatory provisions for toys (the list in the Toy Safety Directive is based on the Cosmetics Regulation) either in the form of a ban or labelling provisions.

It is the view of a Member State Competent Authority that the requirements laid down in the Toy Safety Directive with regards to allergenic fragrances are not appropriate for ensuring adequate protection of children's health. Children playing with scented toys can be exposed to allergens as a result of long term skin contact. Annex II, Part III, Paragraph 11 of the Toy Safety Directive provides a list of allergenic fragrances that should not be contained in toys unless technically unavoidable under good manufacturing practice and must not exceed 100 mg/kg. Paragraph 11 also provides a list of 11 allergenic fragrances that should be affixed on a product label, on the packaging or in an accompanying leaflet if added to a toy (or associated components) in concentrations exceeding 100

¹³ SCCS (2011): Opinion on fragrance allergens on cosmetic products. Available at: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf

¹⁴ SCCS (2011): Opinion on fragrance allergens in cosmetic products. Scientific Committee on Consumer Safety (SCCS). Available at: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf

mg/kg. However, these do not correspond to the limits set out in the Cosmetic Products Regulation for leave-on products (long term skin contact) in which a declaration level of 10 mg/kg (0.001%) is stipulated. It is the view of the authority that the declaration level for leave-on products given in the Cosmetic Products Regulation should be adopted in the Toy Safety Directive.

Another Member State Competent Authority is of the view that there should be a general ban on the use of fragrances in toy products given that these can be allergenic. Allergies towards fragrances are one of the most common reasons for contact allergies. It is therefore the opinion of the authority that fragrances are not necessary and should not be used in toy products. As an alternative to a complete ban on all fragrances used in toys, it is suggested that they should be labelled with either the specific chemical name of the fragrance or a label “containing fragrances”, so that consumers have an opportunity to avoid these toys.

The evaluation of the Toy Safety Directive undertaken by Technopolis et al. in 2015 indicates that three Member States and a consumer representative consider the requirements regarding allergenic fragrances outlined in the Directive to be deficient as in some cases only labelling is required, and sensitisers other than allergenic fragrances are not covered (Technopolis et al., 2015). In addition, consumer associations and six Member States express concerns as regards the regulation of preservatives under the Toy Safety Directive. This is further confirmed in a study by the Austrian Federal Ministry of Labour, Social Affairs and Consumer Protection stating that *“no specific requirements for preservatives are set in the new Toy Safety Directive – except for preservatives classified as CMRs and except for the general statement that chemical substances used in toys must not present a risk of adverse effects to human health”*¹⁵ (Technopolis et al., 2015). Consultation with a Member State Competent Authority also notes that other allergens (i.e. those that are not fragrances) are not included within the Toy Safety Directive, and there are no labelling requirements for these (e.g. allergenic preservatives). It is therefore suggested that other allergens (in addition to allergenic fragrances) should be included within the Directive to ensure adequate protection of consumers’ health.

It is important to note that a Member State Competent Authority and an industry sector association representative consider the requirements (including those related to labelling) laid down in the Toy Safety Directive with regards to allergenic fragrances to be appropriate for ensuring adequate protection of children’s health. The industry sector association representative notes that compared with the standards for cosmetics the Toy Safety Directive offers clear protection of children’s health at a very low exposure potential. International Fragrance Association (IFRA) Standards and all recommendations for prohibitions are followed. It is also indicated that the labelling requirement outlined in the Toy Safety Directive with regard to the use of allergenic fragrances above 100 mg/kg is clearly regulated and constitutes a high level of protection for children.

As part of the consultation process stakeholders were asked whether they consider the Toy Safety Directive and CLP Regulation to work well together and with other legislation (e.g. the Cosmetic Products Regulation) to reduce child exposure to hazardous chemical substances and mixtures in toys. Four Member State Competent Authorities, an industry sector association representative and a Market Surveillance Authority indicate that in general the Toy Safety Directive does work well together with other legislation to reduce child exposure to hazardous chemical substances and mixtures in toys. It is the view of a Member State Competent Authority that the Toy Safety Directive and CLP Regulation work well together and with other legislation to reduce exposure to hazardous

¹⁵ Bmask (2013). Chemical Requirements for toys, European Parliament (2010), p. 97.

chemical substances and mixtures in toys, but not to eliminate or minimise exposure. Hence, from their perspective there is still room for improvement in this regard.

However, it is noted by a consumer association that the thresholds outlined in the CLP Regulation for CMR substances were never intended to be used as a safe limit for consumer products. It is therefore not deemed appropriate to use these thresholds as product limits, in particularly for products for children. A Member State Competent Authority also notes that the CLP Regulation follows a hazard-based approach and the generic classification limits of 0.1% for human carcinogens are too high meaning that health risks to children cannot be excluded.

To summarise, there is a general view that the current system of labelling toys is considered to be effective at communicating the hazards and risks associated with chemical substances/mixtures contained in toy products. However, there are no specific labelling requirements in the Toy Safety Directive with regard to communicating the hazards and risks related to the content of chemicals in toys except where a toy is defined as a chemical toy or where labelling is required on packaging for fragrances in olfactory board games, cosmetic kits and gustative games. Thus, it is suggested by some stakeholders that product labels should contain information regarding the presence of potentially dangerous substances which may be present, especially in hidden parts of the toy.

The majority of stakeholders consulted are of the view that the linkages set out in Annex II, Part III point 10 (of the Toy Safety Directive) for cosmetic toys in relation to the compositional and labelling requirements for cosmetic products (where the reference is to Council Directive 76/768/EEC) are appropriate for ensuring adequate protection of children's health. However, a number of respondents have noted that allergens are an issue considered as too softly regulated under the Toy Safety Directive. It is also suggested that other allergens that are not specifically fragrance allergens should be regulated by the Toy Safety Directive to ensure that the health of consumers (and in particular children) is adequately protected.

It is also the general view of the stakeholders consulted that the Toy Safety Directive and CLP Regulation are considered to work well together and with other legislation (e.g. the Cosmetic Products Regulation) to reduce child exposure to hazardous chemical substances and mixtures in toys (thus suggesting a suitable level of coherence). However, some stakeholders have indicated that the thresholds outlined in the CLP Regulation for CMR substances were not originally intended to be used as a safe limit for consumer products and are therefore not appropriate for application to consumer products (and in particular toys as children are a vulnerable population).

Are there issues with toy products not meeting the labelling requirements outlined in the Toy Safety Directive (e.g. missing information, lack of a CE mark, labelling not in the correct language? Is there a particular issue with products imported from outside the EU not conforming to the labelling requirements outlined in the Toy Safety Directive?

In order to answer this question desk-based research has been undertaken alongside stakeholder consultation to determine whether there are any issues with toy products not meeting the labelling requirements outlined in the Toy Safety Directive (e.g. missing information, lack of a CE mark, labelling not in the correct language). In addition stakeholders were also asked whether the procedures in place to monitor the safety of toys and respond to cases of non-compliance with regard to chemical requirements and labelling requirements are considered to be suitable and effective (e.g. market surveillance).

Issues with toy products not meeting the labelling requirements outlined in the Toy Safety Directive

Consultation with an industry association indicates that, in their experience, the majority of toys are correctly labelled for both physical and chemical hazards, although it is recognised that there will always be a proportion of products that may be marked incorrectly. However this is not considered to be an issue specifically associated with imported toys. In general the majority of toys are imported and there is no evidence of a major issue with regards incorrect labelling. It is important to consider that a large proportion of toys are designed by EU companies (who are manufacturers under the Toy Safety Directive), but are physically made outside of the EU. In these cases, the labelling of toys will be specified by the operators who are experienced and knowledgeable in the application of the requirements of the Toy Safety Directive. The requirements of the Toy Safety Directive also place obligations on importers and distributors to check that the warnings are correct. This further minimises the risk that toys will be incorrectly labelled.

As part of the consultation exercise stakeholders were asked whether they were aware of any issues with regard to the labelling of toys (e.g. incorrect labelling), and in particular in relation to chemical substances/mixtures contained in toys. Stakeholders were also asked to identify the magnitude of any labelling issues in terms of the percentage of toys affected. A minor problem was defined as affecting less than 7% of toys on the EU market; a moderate problem was defined as affecting more than 7% of toys on the EU market and a major problem was defined as affecting more than 20% of toys on the EU market.

Information received from stakeholders indicates that issues have been identified with regards to the size of the product labels (e.g. lettering too small) with the same number of respondents identifying this as a major and minor problem. Missing information on the product label, incorrect information on the label and a lack of the manufacturer's contact details have been identified as issues for the labelling of toys with the majority of respondents identifying these as a moderate problem. There have also been issues with product labels being included in incorrect languages and also the failure to label or incorrect labelling of allergenic fragrances contained in toys with the majority of respondents identifying these issues as either a moderate/minor problem. There have also been cases in which the CE mark has not been included on a toy product; however, the majority of respondents consider this to be a moderate or minor problem. One Member State Competent Authority indicates that overall across all toys within the EU there is a non-compliance rate of 12% with regards to the labelling of toys.

Stakeholders were also asked to indicate the types of impacts that occur as a result of these labelling issues. A Member State Competent Authority notes that manufacturers may be impacted by having to deal with complaints from market surveillance authorities and, where necessary, undertake remedial action to ensure the labelling requirements of the Toy Safety Directive are complied with. Another Member State Competent Authority notes that manufacturers that comply with the labelling requirements have a competitive advantage as the lack of correct information on product labels and the need to take corrective action may damage a manufacturer's reputation.

The lack of certain information on a label or the presence of incorrect information can also impact consumers as there could be a safety risk if, for example, warnings are incorrect or missing leading to inappropriate use of a toy product. A Market Surveillance Authority notes that toys containing labels of unsuitable size or including incorrect/missing information can result in users (i.e. children) and their supervisors using the toy incorrectly or not in accordance to the manufacturer's intended use, thus endangering health and safety. A lack of a CE mark indicates that the manufacturer has not carried out the applicable conformity assessment procedure and has therefore not ensured that the toy complies with the requirements of the Toy Safety Directive. This could also mean that the product is not suitable for use and may present a hazard to consumers. The lack of

manufacturer/importer contact details means that, in the case of a toy that does not conform with the requirements of the Directive or is unsafe, it is not possible to contact the responsible economic operator to inform them of the non-compliance and thus enable them to take corrective action in order to bring the toy into conformity, withdraw it from the market or to recall it.

The information received from consultation with relevant stakeholders regarding the labelling issues experienced is supported by the evidence obtained from the evaluation of the Toy Safety Directive undertaken by Technopolis et al. (2015). The study notes that twelve Member States indicate problems with the warnings required to be placed on toy products or their associated documentation, in particular concerning the language of the labels, their clarity and legibility. The Toy Safety Directive requires the warning to be legible, but does not establish a specific font size. This is perceived by five Member States as a relevant problem for the marketing departments in charge of the labels (Technopolis et al., 2015).

Only seven Member States responding to the evaluation of the Toy Safety Directive reported that they have not experienced any issues with the use of warnings on toy products. However, the evaluation report concludes that warnings are often written in too small a font size, which is not easily readable, and are not always provided in all relevant languages. This is an issue raised by a large German manufacturer, which indicates problems when small products need to be labelled in a number of different languages resulting in very small text that is not easily readable (Technopolis et al., 2015).

A position paper regarding the application and effectiveness of the Toy Safety Directive published by ANEC also indicates that warnings on toys are often too small, hidden by other text or hidden under crumples in packaging, thus making it difficult for consumers to read and understand them. It is also noted that some authorities have experienced problems in enforcing the presentation of warnings on toys because of the lack of specified requirements in the Directive and associated standards (e.g. a minimum letter size). A definitive letter size is only defined in the explanatory guidance document to the Directive (ANEC, 2014).

In 2008, during the revision of the previous version of the Toy Safety Directive from 1988, ANEC and BEUC asked for stricter requirements for warnings in the Toy Safety Directive. An amendment to the toy safety standard EN-71-1:2011 for the presentation of warnings on toys was undertaken based on suggestions made by ANEC and BEUC and the updated standard was published in March 2014. However, this amendment did not contain any specific requirements on how to improve the presentation of warnings (there is only advice in the informative part of the standard - the rationale). The rationale is voluntary and not normative and there are, for example, no requirements on minimum sizes of letters. ANEC indicates that, in the interest of legal certainty, it is important that Member States have normative criteria at their disposal of how to enforce the requirements for visibility and legibility of warnings on toys (ANEC, 2014).

Seven Member States, three consumer associations and a large German manufacturer that contributed to the evaluation of the Toy Safety Directive request that language and font size requirements are better regulated at the EU level. A Dutch SME notes that, in their view, a compromise needs to be found between the requirement for warnings to be readable and the size of warnings on small toys (Technopolis et al., 2015).

As noted in the evaluation of the Toy Safety Directive, a UK expert on toy safety and a large Italian manufacturer indicate that there is not always complete correspondence between the actual risk identified in toys and the warnings placed on them. This is particularly the case with regards to the pictogram indicating that a toy is not intended for use by children under 36 months of age. If the pictogram is missing, manufacturers incur strict sanctions, but they often place the pictogram on

toys that do not raise any risks for children under 36 months in order to protect themselves from infringement sanctions (Technopolis et al., 2015). In addition, consultation with a Member State Competent Authority indicates that toys sometimes bear one or more of the specific warnings set out in Part B of Annex V of the Toy Safety Directive even though these warnings conflict with the intended use of the toy, as determined by virtue of its function, dimension and characteristics.

Consultation with a Member State Competent Authority indicates that in some cases manufacturers label products in order to avoid complying with certain requirements of the Toy Safety Directive. For example, products may be labelled as “not intended for children under 36 months”, however, these products are clearly intended for very young children. This can mislead consumers and in a worst case scenario result in consumers buying products irrespective of the age labelling. This could result in toys that do not conform to the requirements for the age group they are suitable for being used inappropriately, thus posing a risk to users.

Also, a Member State has highlighted an issue with regards to imported toys, as inspectors are sometimes unable to determine whether the labels have been placed on the toy before or after import. A German industry association and a German SME suggest identifying more age categories for toys instead of only one for children less than 36 months of age. This may solve the problem of manufacturers using the age pictogram even if not appropriate as well as the difficulties encountered by Member States in the age grading of toy products (Technopolis et al., 2015).

Information obtained from the evaluation of the Toy Safety Directive indicates that a Member State criticises the requirement set in Article 11 paragraph 2 of the Toy Safety Directive indicating warnings should be preceded by the word ‘Warning’. It is the view of the Member State that this should not apply in the case that the pictogram is used as this would not have any further impact on consumers. A Spanish industry association and a UK expert also suggest that only the warning pictogram should be used as consumers do not read the whole warning message. Further problems have also been raised in relation to the indication for “adult supervision”, which is often misleading as it suggests dangers that are not actually present. This also points to the low awareness of economic operators about the provisions regarding the warnings. It is suggested by a Spanish industry association and a UK expert on toy safety that in order to increase the impact of warnings on consumers a series of pictograms could be introduced instead of written words (Technopolis et al., 2015).

A Member State responding to the evaluation of the Toy Safety Directive also proposes aligning Annex V of the Directive to the warnings listed in the EN71 standard series (which specify safety requirements for toys), as the translation of the warnings in the Directive into national languages is not always consistent with the warnings in EN71, causing problems for industry and market surveillance authorities. The lack of consistency between the warnings outlined in Annex V of the Toy Safety Directive and the EN71 standards may present a problem in terms of the free marketing and safety of toys as different interpretations of warnings could potentially hinder and slow down business and market surveillance activities. To avoid these coherence issues, the warnings listed in Annex V of the Directive and the EN 71 standards could be aligned, thus ensuring consistency. It is worth noting that a European representative of NB-Toys and a Dutch SME manufacturer consider the harmonisation of warnings between the Toy Safety Directive and standards has improved compared to the past (Technopolis et al., 2015).

Consultation undertaken as part of the evaluation of the Toy Safety Directive indicates that four Member States have experienced problems with CE marking of toys. Specifically, one Member State notes that the marking of dual-purpose products is unclear, while another considered the marking of

toys made of several parts to be unclear. It should be noted that the Toy Safety Directive guidance document¹⁶ that was first published in 2010 and has been frequently updated since then outlines the requirements and procedures relating to CE marking. In addition, Toy Industries of Europe (TIE) published a brochure in 2011 focussing on the scope and rules of CE marking¹⁷. Both of these documents address some of the issues raised by Member States. This therefore suggests that the problem perhaps relates to the insufficient dissemination of existing documents rather than the lack of appropriate guidance. The evaluation report therefore recommends raising awareness of these guidance documents to assist stakeholders in understanding the working mechanisms of the Directive (Technopolis et al., 2015).

To summarise, a number of issues have been raised with regards to toy products not meeting the labelling requirements outlined in the Toy Safety Directive. In particular, problems have been experienced with regards to the use of warnings in that they are, in some cases, applied incorrectly, written in too small a font size which is not easily readable, and/or are not always provided in the relevant languages. Also, problems have been experienced in cases where information is missing from product labels, which can have impacts on product traceability and potentially for consumers' health if toys are not appropriately used. To increase the clarity of the requirements relating to warnings and to ensure that these are clear and understandable from the perspective of the consumer, a number of stakeholders suggest that language and font size requirements should be better regulated at the EU level. The increased use of pictograms instead of written words along with the modification of the font and language requirements could be considered to ensure that warnings are always clear, legible and written in all relevant languages (thus increasing the effectiveness of the Directive). The use of QR codes could also be considered, as a smart tool to provide information while detailing warnings on manufacturer websites (Technopolis et al., 2015).

Effectiveness of procedures to monitor toy safety

During the consultation process stakeholders were asked whether the procedures in place to monitor the safety of toys and respond to cases of non-compliance with regard to chemical and labelling requirements are considered to be effective (e.g. market surveillance). It is the view of three Member State Competent Authorities, an industry sector association representative and a Market Surveillance Authority that the procedures in place to monitor the safety of toys and respond to cases of non-compliance with regard to chemical requirements and labelling requirements are effective.

However, a consumer association indicates that, for a number of years, consumer organisations and economic operators have emphasised the need to establish an effective market surveillance system in the EU internal market. It is noted that most consumers believe that market surveillance will

¹⁶ European Commission (2016): Toy Safety Directive 2009/48/EC – An explanatory guidance document (Rev. 1.9). Available at:

https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0ahUKEWjSi4ehlbHMAhWrLMAKHVLECQgQFggiMAE&url=http%3A%2F%2Fec.europa.eu%2FdocsRoom%2Fdocuments%2F15503%2Fattachments%2F1%2Ftranslations%2Fen%2Frenditions%2Fnative&usg=AFQjCNFxbULztr9ZmQOtStsEPJgfMoldipQ&sig2=CE3LJ_AZcZRqsynHlIm-zQ&cad=rja

¹⁷ TIE (2011): CE Marking for the Toy Industry. Available at:

http://www.tietoy.org/docrestreint.api/379/9ed51b64fe32b5077a992850bf5853b349896fac/pdf/ce_marking_for_the_toy_industry-2.pdf

protect them from buying unsafe products; however this is not true as market surveillance has different meanings in different countries. Even the most stringent legislation and standards become worthless if they are not applied or enforced. Once a product enters a Member State it is free to circulate to all Member States, hence the overall effectiveness of market surveillance throughout Europe is dependent on the quality of market surveillance in the weakest Member State. Market surveillance activities are undertaken by Member States exclusively and individually at the national level as market surveillance falls under shared competence. This leads to inconsistencies and sees insufficient resources being made available to police the many products on the market. As a result, the consumer expectation of safe products is not always met. The consumer association therefore considers there to be an urgent need to establish a European framework for market surveillance in order to ensure a coherent approach to market surveillance activities across all EU Member States and to make more resources available.

A Member State Competent Authority suggests that more inspections on EC declaration of conformity and technical documentation should be undertaken to ensure compliance with the Toy Safety Directive. Another Member State Competent Authority indicates that there should be greater capacity to monitor the safety of toy products. It is noted that currently there is rarely time to control all the information and documentation that has to be provided by the manufacturer and is necessary to demonstrate conformity of the toy.

Stakeholders were also asked whether the level of market surveillance of toy safety with regard to chemical requirements and labelling are consistent across Member States. A Market Surveillance Authority indicates that, in their view, the level of market surveillance is consistent across Member States. However, an industry sector association representative and a Member State Competent Authority indicate that this is not consistent in terms of the number of controls and the strictness of sanctions. It is noted that, in some countries, reputable manufacturers are checked and proven to be compliant again and again instead of focussing efforts on hazardous products that are produced by manufacturers that are not aware of (or do not understand) their obligations regarding placing products on the market.

As part of the stakeholder consultation process stakeholders were asked whether they are aware of any significant differences in enforcement of the Toy Safety Directive across Member States. Two Member State Competent Authorities indicate that in Germany there are different limits for the same elements (e.g. lead and in particular nitrosamines). An industry sector association representative also indicates that there are different limits for lead and barium in Germany. It is the view of a Member State Competent Authority that these differences have an impact on the effectiveness of the Toy Safety Directive in protecting children's health, in ensuring free movement of goods within the single market and on the efficiency of the Directive for companies placing toys on the market.

Another important issue highlighted by an industry association is that there can be difficulties in enforcing risk management measures when very low limits that are below the limits of quantification are introduced, which means that most laboratories are unable to determine if a product is in compliance. This is likely to be the case with Cr(VI) limits as laboratory determination in the majority of toy matrices will be extremely difficult. A similar but different example is the introduction of lower limits for the isothiazolinone preservatives in Appendix C of the Toy Safety Directive. There is no validated method by inter-laboratory comparison that is available to enforce the limits. It is extremely important both for industry and market surveillance authorities that when risk management limit values are agreed there is a validated test method that can be used to enforce the requirement for the wide range of materials/matrices used in toys.

To summarise, there is considered to be a need to further enhance market surveillance and better coordinate activities to ensure consistency across EU Member States. It is suggested that establishing a European framework for market surveillance and increasing the resources available would help ensure a coherent approach to market surveillance activities is undertaken. It is also noted that there is a need to ensure that validated test methods are available when new risk management limit values are introduced to ensure that these can be effectively and efficiently enforced.

4 Conclusions

It can be concluded that extensive efforts have been made by industry (in particular associations) to ensure that economic operators are aware of their requirements under the Toy Safety Directive to undertake chemical safety assessments and ensure that toys and the chemicals they contain do not jeopardise the safety and health of consumers. In general, the obligations to perform a chemical safety assessment are considered to be clear and understandable for most stakeholders. However, the obligations outlined in Part III of Annex II of the Toy Safety Directive (regarding particular safety requirements in relation to chemical properties) are not in general considered to be sufficiently clear. The complexity of these requirements means that some economic operators (particular SMEs) are choosing to ignore them because they are not easily understandable. This therefore suggests that simplifying the obligations outlined in Annex II, Part III of the Toy Safety Directive could assist in the ensuring effective communication and understanding of the requirements by relevant stakeholders.

Information obtained from desk-based research and stakeholder consultation indicates that whilst the chemical safety assessment is considered to be critical for ensuring the protection of consumers (and in particular children's) health when using toys, the requirements can be burdensome for economic operators, especially SMEs. SMEs are particularly concerned with the costs related to the safety assessments (including those relating to chemicals specifically) under the Toy Safety Directive and that this hinders the overall quality of the assessment procedures that are often incomplete and missing relevant information. The chemical safety assessment requires knowledge of all the chemicals used throughout the entire production of a toy product. It can be difficult for the toy manufacturer to obtain information on all chemicals in every raw material used during production, thus leaving it to the manufacturer of the toy to determine when and what to test to ensure an appropriate chemical safety assessment is undertaken and the safety of the toy. It is also indicated that Member States have experienced difficulties in obtaining information to be included in the technical documentation (such as safety assessment, test reports, names of supplier, etc.) from economic operators, particularly when imported toys are concerned. Safety assessments are often not included in the technical documentation, as they are seen to be too complex and merely a formal requirement or because there is a lack knowledge regarding the information required.

Information obtained from desk-based research and stakeholder consultation further suggests that the adaptation mechanisms of the Directive have, in general, proved to be an effective policy tool to align the Toy Safety Directive to scientific and technological developments. While economic operators and some Member State Authorities generally confirm this, consumer associations and other Member State Authorities identify the need to broaden the scope of the comitology procedure (outlined in Article 46 of the Directive) to include all kinds of toys and all kinds of dangerous substances.

In general the legislative links between the Toy Safety Directive and other Directives/Regulations applicable to toys are considered to be appropriate and necessary for ensuring the health and safety of consumers (and in particular children). However, issues have been identified with regards to manufacturers' and, in particular, SMEs' understanding of these requirements. Cases have been identified whereby manufacturers are unaware of their obligations under other pieces of legislation aside from the Toy Safety Directive or are choosing to ignore these requirements because they do not understand them. This suggests that there is a need to provide greater clarity within the Toy Safety Directive of the chemical requirements that are applicable to toys under other pieces of legislation, with a number of stakeholders recommending the inclusion of all requirements relating

to toys within the Toy Safety Directive itself. A number of stakeholders also consider it necessary to include all requirements for chemicals to be used in toy production (e.g. types, limits) to be completely laid down in the Toy Safety Directive in order to avoid references to other pieces of legislation within the Directive as this would facilitate understanding of the obligations by economic operators and other relevant stakeholders. In addition, there are cases in which different limit values are applied to the same substances (e.g. for nitrosamines and nitrosatable substances in Germany compared to those outlined in the Toy Safety Directive). It is therefore considered important to ensure consistent and coherent requirements, thus facilitating understanding of these requirements and helping to reduce the possibility of misinterpretation.

With regard to labelling of toy products, information obtained from desk-based research and stakeholder consultation suggests that in general the labelling requirements outlined in the Toy Safety Directive, including those that relate to other pieces of legislation, are clear and therefore understood by most stakeholders. However, in the case of warnings, it is suggested that greater clarity could be provided in relation to the additional warning requirements included in standards by ensuring that specific reference is made in the Directive to the relevant standards.

However, a number of issues have been raised with regard to toys not meeting the labelling requirements outlined in the Toy Safety Directive. In particular, problems have been experienced relating to the use of warnings in that they are, in some cases, applied incorrectly, written in too small a font size, and/or are not always provided in the relevant languages. Also, problems have been experienced in cases where information is missing from product labels, which can have impacts on product traceability and potentially for consumers' health if toys are not used by the intended age group in the appropriate way. To increase the clarity of the requirements relating to warnings and to ensure that these are clear and understandable from the perspective of the consumer, a number of stakeholders suggest that language and font size requirements should be better regulated at the EU level. Also, increasing the use of pictograms instead of written words along with the modification of the font and language requirements would help ensure that warnings are always clear, legible and written in all relevant languages (thus increasing the effectiveness of the Directive). It is also suggested that the use of QR codes could be considered as a smart tool to provide further detailed information relating to warnings on manufacturer websites (Technopolis et al., 2015).

In general the current system of labelling toys is considered to be effective at communicating the hazards and risks associated with chemical substances/mixtures contained in toys. However, there are no specific labelling requirements in the Toy Safety Directive with regards to communicating the hazards and risks related to the content of chemicals in toys except where a toy is defined as a chemical toy or where labelling is required on packaging for fragrances in olfactory board games, cosmetic kits and gustative games. It is therefore suggested by some stakeholders that product labels should contain information regarding the presence of potentially dangerous substances, especially in hidden parts of the toy.

The majority of stakeholders consulted are of the view that the linkages set out in Annex II, Part III point 10 (of the Toy Safety Directive) for cosmetic toys in relation to the compositional and labelling requirements for cosmetic products are appropriate for ensuring adequate protection of children's health. However, a number of respondents have noted that allergens are an issue considered as too softly regulated under the Toy Safety Directive. It is also suggested that other allergens that are not specifically fragrance allergens should be regulated by the Toy Safety Directive to ensure that the health of consumers (and in particular children) is adequately protected.

It is the general view of the stakeholders consulted that the Toy Safety Directive and CLP Regulation are considered to work well together and with other legislation (e.g. the Cosmetic Products Regulation) to reduce child exposure to hazardous chemical substances and mixtures in toys (thus

suggesting a suitable level of coherence). However, some stakeholders have indicated that the thresholds outlined in the CLP Regulation for CMR substances were not originally intended to be used as a safe limit for consumer products and are therefore not appropriate for application to consumer products (and in particular toys as children are a vulnerable population).

There is also considered to be a need to establish an effective market surveillance system in the EU internal market. Market surveillance activities are undertaken by Member States at the national level, which results in inconsistencies in approach and insufficient resources being made available to effectively police the products available on the market. It is also noted that there is a need to ensure that validated test methods are available when new risk management limit values are introduced for chemical substances/mixtures to ensure that these can be effectively and efficiently enforced.

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Annex 1: Overview of the Chemical Requirements and Labelling Requirements Relevant to Toys

A1.1 Toy Safety Directive (2009/48/EC)

A1.1.1 Chemical safety assessment obligations/chemical requirements

Chemical requirements

The following provides details of the chemical safety assessment obligations and chemical requirements outlined in the Toy Safety Directive.

Recital 21 of the Toy Safety Directive notes that to ensure a high level of protection of children against risks caused by chemical substances in toys, the use of dangerous substances, in particular substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR), and allergenic substances and certain metals, should be subject to careful attention. Chemical substances in toys should comply with general chemicals legislation (in particular the REACH Regulation), although the provisions should be adapted to the particular needs of children, who are a vulnerable group of consumers. Therefore, new restrictions on CMR substances, in accordance with applicable Community legislation on classification, labelling and packaging of substances and mixtures (such as the CLP Regulation), and on fragrances in toys should be provided for on account of the special risks that these substances may entail for human health. Nickel in stainless steel has proven to be safe, and consequently can be used in toys despite it being a CMR (carcinogenic when in vapour form) (SCHER, 2012).

Recital 25 of the Toy Safety Directive notes that “the general and specific chemical requirements laid down by the Directive should aim at protecting the health of children from certain substances in toys, while the environmental concerns presented by toys are addressed by horizontal environmental legislation applying to electrical and electronic toys, namely Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment [RoHS Directive] and Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment [WEEE Directive]”. In addition, environmental issues on waste are regulated by Directive 2006/12/EC (Waste Framework Directive), those on packaging and packaging waste by Directive 94/62/EC and those on batteries and accumulators and waste batteries and accumulators by Directive 2006/66/EC.

Recital 35 of the Directive indicates that “in order to ensure compliance with the essential safety requirements, it is necessary to lay down appropriate conformity assessment procedures to be followed by the manufacturer. To complete the legal obligations of the manufacturer which aim at ensuring the safety of toys, an explicit obligation to carry out an analysis of the various hazards that the toy may present and an assessment of the potential exposure to them, which for chemicals includes an assessment of the likelihood of the presence in the toy of prohibited or restricted substances, should be included in this Directive, and manufacturers should be obliged to keep this safety assessment in the technical documentation to allow market surveillance authorities to perform their tasks efficiently”.

Article 10 of the Directive relates to ‘essential safety requirements’ with **paragraph 1** indicating that Member States should take “all measures necessary to ensure that toys may not be placed on the

market unless they comply with the essential safety requirements set out, as far as the general safety requirement is concerned, in paragraph 2, and, as far as the particular safety requirements are concerned, in Annex II”.

Paragraph 2 of Article 10 states that toys, including the chemicals they contain, will “not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children”. Paragraph 2 also notes that “the ability of the users and, where appropriate, their supervisors shall be taken into account, in particular, in the case of toys which are intended for use by children under 36 months or by other specified age groups”.

Article 18 of the Toy Safety Directive relates to ‘safety assessments’ and indicates that, before placing a toy on the market, manufacturers are required to “carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards”.

Chapter VII of the Toy Safety Directive relates to committee procedures and Article 46 refers to amendments and implementing measures. **Paragraph 1 of Article 46** indicates that “the Commission may, for the purposes of adapting them to technical and scientific developments, amend 1) Annex I; 2) points 11 and 13 of Part III of Annex II; and 3) Annex V”. Thus, the comitology procedure may be used to amend these parts of the Toy Safety Directive as outlined in Decision 1999/468/EC (laying down the procedures for the exercise of implementing powers conferred on the Commission) – regulatory procedure with scrutiny.

Paragraph 2 of Article 46 notes that “the Commission may adopt specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth, taking into account the packaging requirements for food as laid down in Regulation (EC) No 1935/2004 (relating to materials and articles intended to come into contact with food) and the related specific measures for particular materials, as well as the differences between toys and materials which come into contact with food”.

Paragraph 3 of Article 46 states that “the Commission may decide upon the use in toys of substances or mixtures that are classified as carcinogenic, mutagenic or toxic for reproduction of the categories laid down in Section 5 of Appendix B to Annex II and have been evaluated by the relevant Scientific Committee, and may amend Appendix A to Annex II accordingly”.

Annex II of the Toy Safety Directive provides details of ‘particular safety requirements’ with **part III** outlining specific requirements in relation to **chemical properties**. Box A1-1 provides further details of the requirements outlined in part III of Annex II.

Box A1-1: Selected points from Part III of Annex II (particular safety requirements in relation to chemical properties)

III. Chemical properties

1. Toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain when the toys are used as specified in the first subparagraph of Article 10(2).

Toys shall comply with the relevant Community legislation relating to certain categories of products or to restrictions for certain substances and mixtures.

2. Toys that are themselves substances or mixtures must comply also with Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the

Box A1-1: Selected points from Part III of Annex II (particular safety requirements in relation to chemical properties)

classification, labelling and packaging of dangerous substances, Directive 1999/45/EC of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, labelling and packaging of dangerous preparations and Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures, as applicable, relating to the classification, labelling and packaging of certain substances and mixtures.

3. Without prejudice to the restrictions referred to in the second paragraph of point 1, **substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys.**

4. **By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in Section 3 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one or more of the following conditions is met:**

- a) These substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;
- b) These substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2); and
- c) A decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A.

That decision may be taken if the following conditions are met:

- i) The use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure;
- ii) There are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives; and
- iii) The substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006 [REACH Regulation].

The Commission shall **mandate the relevant Scientific Committee to re-evaluate those substances or mixtures as soon as safety concerns arise and at the latest every five years** from the date that a decision in accordance with Article 46(3) was taken.

5. **By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in Section 4 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one of the following conditions is met:**

- a) These substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;
- b) These substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2); or
- c) A decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A.

That decision may be taken if the following conditions are met:

- i) The use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure; and

Box A1-1: Selected points from Part III of Annex II (particular safety requirements in relation to chemical properties)

- ii) The substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006 [REACH Regulation].

The Commission shall **mandate the relevant Scientific Committee to re-evaluate those substances or mixtures as soon as safety concerns arise and at the latest every five years** from the date that a decision in accordance with Article 46(3) was taken.

6. Points 3, 4 and 5 shall not apply to nickel in stainless steel.

7. Points 3, 4 and 5 shall not apply to materials that comply with the specific limit values set out in Appendix C, or, until such provisions have been laid down, but not later than 20 July 2017, to materials covered by and complying with the provisions for food contact materials set out in Regulation (EC) No 1935/2004 and the related specific measures for particular materials.

10. Cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements laid down in Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.

11. [Provides a list of allergenic fragrances that should not be used in toys, unless their presence is technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg. In addition, point 11 provides a list of fragrances that are required to be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy, as such, at concentrations exceeding 100 mg/kg in the toy or components thereof].

12. The use of fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 and of the fragrances set out in points 1 to 11 of the list set out in the third paragraph of that point shall be allowed in olfactory board games, cosmetic kits and gustative games, provided that:

- a) Those fragrances are clearly labelled on the packaging, and the packaging contains the warning set out in point 10 of Part B of Annex V;
- b) If applicable, the resulting products made by the child in accordance with the instructions comply with the requirements of Directive 76/768/EEC [Cosmetics Directive]; and
- c) If applicable, those fragrances comply with the relevant legislation on food.

Such olfactory board games, cosmetic kits and gustative games shall not be used by children under 36 months and shall comply with point 1 of Part B of Annex V.

13. [Without prejudice to points 3, 4 and 5, point 13 provides a list of substances and associated migration limits, from toys or toy components that should not be exceeded. These limit values do not apply to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin when used as specified in the first subparagraph of Article 10(2)]

Appendix A of Annex II provides a list of CMR substances and their permitted uses in accordance with points 4, 5 and 6 of Part III (of Annex II). This list contains a single substance (nickel) and indicates that it is classified as a category 2 CMR with permitted uses in: 1) toys and toy components made of stainless steel; and 2) toy components which are intended to conduct an electric current.

Appendix B of Annex II refers to the classification of substances and mixtures:

- **Point 2 of Appendix B** refers to “community legal acts governing the use of certain substances for the purposes of points 4(a) and 5(a) or Part III” of Annex II (see Box A1-1 for further details);
- **Point 3 of Appendix B** refers to “categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of point 4 of Part III” of Annex II;
- **Point 4 of Appendix B** refers to “categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of point 5 of Part III” of Annex II; and
- **Point 5 of Appendix B** refers to “categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of Article 46(3)” of Annex II.

As of the 1st of June 2015, the relevant concentrations for the classification of mixtures containing substances shall be those established in accordance with Regulation (EC) No 1272/2008 (CLP Regulation) (with regard to point 2 of Appendix B). In relation to points 3, 4 and 5 of Appendix B, references within the Toy Safety Directive to “categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR)” concerns substances and (from 1 June 2015) mixtures classified as CMRs under the CLP Regulation.

Appendix C of Annex II provides specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth adopted in accordance with Article 46(2). Table A1-1 provides details of the limit values for the chemical substances listed in Appendix C.

Table A1-1: Substances with specific limit values listed in Appendix C of Annex II of the Toy Safety Directive in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth		
Substance	CAS No	Limit value
TCEP	115-96-8	5 mg/kg (content limit)
TCPP	13674-84-5	5 mg/kg (content limit)
TDCP	13674-87-8	5 mg/kg (content limit)
Bisphenol A	80-05-7	0.1 mg/l (migration limit in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005)
Added to Appendix C to Annex II of Directive 2009/48/EC but applicable only as of 24 May 2017 (formamide, 1,2-benzisothiazol-3(2H)-one) and 24 November 2017 (the subsequent 3 substances)		
Formamide	75-12-7	20 µg/m ³ (emission limit) after a maximum of 28 days from commencement of emission testing of foam toy materials containing more than 200 mg/kg (cut-off limit based on content) ¹
1,2-benzisothiazol-3(2H)-one	2634-33-5	5 mg/kg (content limit (in aqueous toys materials, in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005) ²
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9	1 mg/kg (content limit) in aqueous toy materials ³
5-Chloro-2-methyl-isothiazolin-3(2H)-one	26172-55-4	0.75 mg/kg (content limit) in aqueous toy materials ³
2-methylisothiazolin-3(2H)-one	2682-20-4	0.25 mg/kg (content limit) in aqueous toy materials ³

Table A1-1: Substances with specific limit values listed in Appendix C of Annex II of the Toy Safety Directive in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth

Substance	CAS No	Limit value
¹ European Commission (2015e)		
² European Commission (2015f)		
³ European Commission (2015g)		

Chemical safety assessment requirements

Background

The safety requirements in the Toy Safety Directive consist of a general safety requirement in Article 10(2) and the particular safety requirements in Annex II. The Directive also requires that toys comply with relevant EU legislation regarding certain categories of products or restrictions for certain substances and mixtures as well as rules for classification, labelling and packaging of certain substances and mixtures (European Commission, 2016e).

The Toy Safety Directive also requires that a safety assessment is carried out, which involves an analysis of the various hazards that the toy may present and an assessment of the potential exposure to these hazards. In the case of chemicals a key part of this is the assessment of the likelihood of the presence in the toy of prohibited or restricted substances. However, the assessment should also cover other chemical hazards (and the exposure to these) that might be presented by substances currently not prohibited or restricted but are commonly known as undesirable for use in toys. A chemical safety assessment should therefore consider all applicable regulations and directives and additional relevant information on other substances that children may be exposed to when playing with toys. Such additional information is often supplied to toy manufacturers through their industry associations but can also be obtained from other sources (European Commission, 2016e).

A safety assessment may need to be updated with regards to chemicals if for example (European Commission, 2016e):

- New toxicological information becomes available for the chemicals used;
- Changes are made to the product (design, raw materials, additives, paints etc.) that will affect the presence of chemicals and/or the exposure to these;
- Legal requirements change;
- Consumer complaints suggest that the products presents a chemical risk (e.g. allergic reactions); or
- Products were withdrawn from the market due to a chemical risk.

Several requirements in the Toy Safety Directive are fully or partly supported by harmonised standards, the references of which have been published in the OJEU. These standards give presumption of conformity to the Directive, which means that if a toy complies with such standards the manufacturer has no obligation to carry out further assessment or testing with regard to the chemical hazards covered by these standards (European Commission, 2016e).

EC-type examination can be used as a means of assessing whether the toy is in conformity with the Toy Safety Directive, particularly if there is a concern that a chemical hazard exists that is not covered by harmonised standards. However, it is important to note that this route does not release the manufacturer from his obligation to perform the safety assessment. Also, the mandatory safety

assessment is considered to be an alternative to EC-type examination for chemical hazards that are not covered by harmonised standards (European Commission, 2016e).

For several of the chemical requirements outlined in the Toy Safety Directive, there are at present no supporting harmonised standards (the references of which have been published in the OJEU). The safety assessment process must therefore cover, for example (European Commission, 2016e):

- Substances classified as CMR;
- Fragrances;
- Chemical substances prohibited or restricted in other directives/regulations (e.g. REACH); and
- Undesirable chemical substances that are not yet prohibited or restricted.

The starting point for a chemical safety assessment is the gathering of information on the materials and chemicals used in the manufacture of the toy. It is invaluable to have comprehensive information in the form of a bill of materials, a bill of substances and in support of these, safety data sheets where applicable, and finally the results of any analytical testing. Given that in general chemicals cannot be 'seen', the presence of chemical hazards in toys therefore needs to be determined using one or both of the following (European Commission, 2016e):

1. The manufacturer's or supplier's knowledge about the materials and/or substances used in the manufacturing process, and/or;
2. By chemical analysis (testing).

The overall aim of the chemical safety assessment process is to ensure that a manufacturer carefully considers the chemical hazards that the toy, its materials and contained substances might present to the health of the child. If it can be excluded that the toy materials contain excessive amounts of any substances covered by the standards, or substances that are prohibited/restricted, or substance that are well known and under suspicion to be hazardous, there is a high probability that the toy can be considered to be chemically safe. If any of these substances are present in excessive levels, exposure to the substances must be considered: if the substances contained in parts of the toy that are inaccessible under reasonably foreseeable use or if the substances do not migrate or emit from the toy material under reasonably foreseeable use, then there is no exposure and the chemical risk may be regarded as acceptably low (European Commission, 2016e).

Chemical safety assessment process

The chemical safety assessment process comprises three main stages (European Commission, 2016e):

1. **Identification:** relates to the examination of information within documentation to identify materials and substances contained in the toy together with amounts (if known). Each identified material or substance then goes through the characterisation stage;
2. **Characterisation:** the process by which a materials or substance is reviewed against known prohibitions/restrictions, to determine whether it falls within scope, and against scientific knowledge on potentially hazardous substances. The outcome of the characterisation is to place the material or substance into one of two groups:

- Materials or substances subject to legal restrictions or restrictions in safety standards;
or
- Materials or substances not subject to restrictions.

Once a material or substance is characterised it undergoes the appropriate assessment process.

3. **Assessment:** is concerned with establishing the likelihood of a given material containing an undesirable substance in amounts that are high enough to present an unacceptable risk taking into consideration the hazard and exposure of the user.

The conclusion of the safety assessment should be a statement regarding the safety of the toy in relation to the safety requirement of Article 10 of the Toy Safety Directive. For the chemical part of the safety assessment this could be based on a conclusion for each material or substance that has been listed as potentially hazardous, stating whether its exposure results in a risk that must be managed (European Commission, 2016e).

Technical documentation

Article 4 of the Toy Safety Directive outlines the obligations for manufacturers with **paragraph 2** indicating that manufacturers shall draw up the required technical documentation in accordance with Article 21 and carry out or have carried out the applicable conformity assessment procedure in accordance with Article 19.

Paragraph 3 of Article 4 indicates that manufacturers shall keep the technical documentation and the EC declaration of conformity for a period of 10 years after the toy has been placed on the market.

Article 6 of the Directive provides the obligations for importers and **paragraph 2** indicates that importers shall ensure that the manufacturer has drawn up the technical documentation and that the toy bears the required conformity marking and is accompanied by the required documents. **Paragraph 8** indicates that importers shall, for a period of 10 years after the toy has been placed on the market, keep a copy of the EC declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request.

Article 20 of the Toy Safety Directive relates to EC-type examination with **paragraph 5** indicating that the technical documentation and correspondence relating to the EC-type examination procedures shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to that body.

Article 21 refers to technical documentation with **paragraph 1** indicating that the technical documentation mentioned in Article 4 paragraph 2 shall contain all relevant data or details of the means used by the manufacturer to ensure that toys comply with the requirements set out in Article 10 and Annex II. It shall in particular contain the documents listed in Annex IV.

Paragraph 2 indicates that the technical documentation shall be drawn up in one of the official languages of the Community, subject to the requirement set out in Article 20 paragraph 5. Paragraph 3 notes that following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the language of the Member State.

Annex IV of the Toy Safety Directive provides details of the information that should be included in the technical documentation. In particular, the technical documentation shall contain, so far as relevant for assessment:

1. A detailed description of the design and manufacture, including a list of components and materials used in the toy as well as the safety data sheets on chemicals used, to be obtained from the chemical suppliers;
2. The safety assessment(s) carried out in accordance with Article 18;
3. A description of the conformity assessment procedure followed;
4. A copy of the EC declaration of conformity;
5. The addresses of the places of manufacture and storage;
6. Copies of documents that the manufacturer has submitted to a notified body, if involved;
7. Test reports and description of the means whereby the manufacturer ensured conformity of production with the harmonised standards, if the manufacturer followed the internal production control procedure referred to in Article 19 paragraph 2; and
8. A copy of the EC-type examination certificate, a description of the means whereby the manufacturer ensured conformity of the production with the product type as described in the EC-type examination certificate, and copies of the documents that the manufacturer submitted to the notified body, if that manufacturer submitted the toy to EC-type examination and followed the conformity to type procedure referred to in Article 19 paragraph 3.

A1.1.2 Labelling requirements

Toys in general

Point 11 of Part III of Annex II of the Toy Safety Directive provides a list of 55 allergenic fragrances that should not be contained in toys (as outlined in Table A1-2). However, the presence of traces of these fragrances is allowed in toys provided that this is technically unavoidable under good manufacturing practice and does not exceed 100mg/kg.

Table A1-2: Allergenic fragrances that should not be contained in toys		
Number	Name of allergenic fragrance	CAS number
1	Alanroot oil (Inula helemium)	97676-35-2
2	Allylisothiocyanate	57-06-7
3	Benzyl cyanide	140-29-4
4	4 tert-Butylphenol	98-54-4
5	Chenopodium oil	8006-99-3
6	Cyclamen alcohol	4756-19-8
7	Diethyl maleate	141-05-9
8	Dihydrocoumarin	119-84-6
9	2,4-Dihydroxy-3-methylbenzaldehyde	6248-20-0
10	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5
11	4,6-Dimethyl-8-tert-butylcoumarin	17874-34-9

Table A1-2: Allergenic fragrances that should not be contained in toys		
Number	Name of allergenic fragrance	CAS number
12	Dimethyl citraconate	617-54-9
13	7,11-Dimethyl-4.6,10-dodecatrien-3-one	26651-96-7
14	6,10-Dimethyl-3.5,9-undecatrien-2-one	141-10-6
15	Diphenylamine	122-39-4
16	Ethyl acrylate	140-88-5
17	Fig leaf, fresh and preparations	68916-52-9
18	trans-2-Heptenal	18829-55-5
19	trans-2-Hexenal diethyl acetal	67746-30-9
20	trans-2-Hexenal dimethyl acetal	18318-83-7
21	Hydroabietyl alcohol	13393-93-6
22	4-Ethoxy-phenol	622-62-8
23	6-Isopropyl-2-decahydronaphthalenol	34131-99-2
24	7-Methoxycoumarin	531-59-9
25	4-Methoxyphenol	150-76-5
26	4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4
27	1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8
28	Methyl trans-2-butenolate	623-43-8
29	6-Methylcoumarin	92-48-8
30	7-Methylcoumarin	2445-83-2
31	5-Methyl-2,3-hexanedione	13706-86-0
32	Costus root oil (Saussurea lappa Clarke)	8023-88-9
33	7-Ethoxy-4-methylcoumarin	87-05-8
34	Hexahydrocoumarin	700-82-3
35	Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch)	8007-00-9
36	2-Pentylidene-cyclohexanone	25677-40-1
37	3.6,10-Trimethyl-3.5,9-undecatrien-2-one	1117-41-5
38	Verbena oil (Lippia citriodora Kunth)	8024-12-2
39	Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)	83-66-9
40	4-Phenyl-3-buten-2-one	122-57-6
41	Amyl cinnamal	122-40-7
42	Amylcinnamyl alcohol	101-85-9
43	Benzyl alcohol	100-51-6
44	Benzyl salicylate	118-58-1
45	Cinnamyl alcohol	104-54-1
46	Cinnamal	104-55-2
47	Citral	5392-40-5
48	Coumarin	91-64-5
49	Eugenol	97-53-0
50	Geraniol	106-24-1
51	Hydroxy-citronellal	107-75-5
52	Hydroxy-methylpentylcyclohexenecarboxaldehyde	31906-04-4
53	Isoeugenol	97-54-1
54	Oakmoss extracts	90028-68-5
55	Treemoss extracts	90028-67-4

Table A1-2: Allergenic fragrances that should not be contained in toys

Number	Name of allergenic fragrance	CAS number
<i>Source: European Commission (2014)</i>		

In addition, the Toy Safety Directive lists 11 allergenic fragrances that are required to be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy or components thereof at concentrations exceeding 100 mg/kg (as presented in Table A1-3).

Table A1-3: Allergenic fragrances that are required to be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy or components thereof at concentrations exceeding 100 mg/kg

Number	Name of allergenic fragrance	CAS number
1	Anisyl alcohol	105-13-5
2	Benzyl benzoate	120-51-4
3	Benzyl cinnamate	103-41-3
4	Citronellol	106-22-9
5	Farnesol	4602-84-0
6	Hexyl cinnamaldehyde	101-86-0
7	Lilial	80-54-6
8	d-Limonene	5989-27-5
9	Linalool	78-70-6
10	Methyl heptine carbonate	111-12-6
11	3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5
<i>Source: European Commission (2014)</i>		

Olfactory board games, cosmetic kits and gustative games

Point 12 of Part III of Annex II states that the use of fragrances set out in points 41 to 55 of Table A1-2 and points 1 to 11 in Table A1-3 is allowed in olfactory board games, cosmetic kits and gustative games, provided that:

- The fragrances are clearly labelled on the packaging, and the packaging contains the warning set out in point 10 of Part B of Annex V;
- If applicable, the resulting products made by the child in accordance with the instructions comply with the requirements of Directive 76/768/EEC (Cosmetics Directive now the Cosmetics Regulation (EC) No 1223/2009); and
- If applicable, the fragrances comply with the relevant legislation on food.

However, these olfactory board games, cosmetic kits and gustative games shall not be used by children under 36 months and shall comply with point 1 of Part B of Annex V (further details outlined under the 'Warnings' section below).

Cosmetic toys

As outlined in **Point 10, Part III of Annex II** of the Toy Safety Directive (regarding 'chemical properties') cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements laid down in Council Directive 76/768/EEC of 27 July 1976 on the

approximation of the laws of the Member States relating to cosmetic products (now the Cosmetics Regulation (EC) No 1223/2009).

Warnings

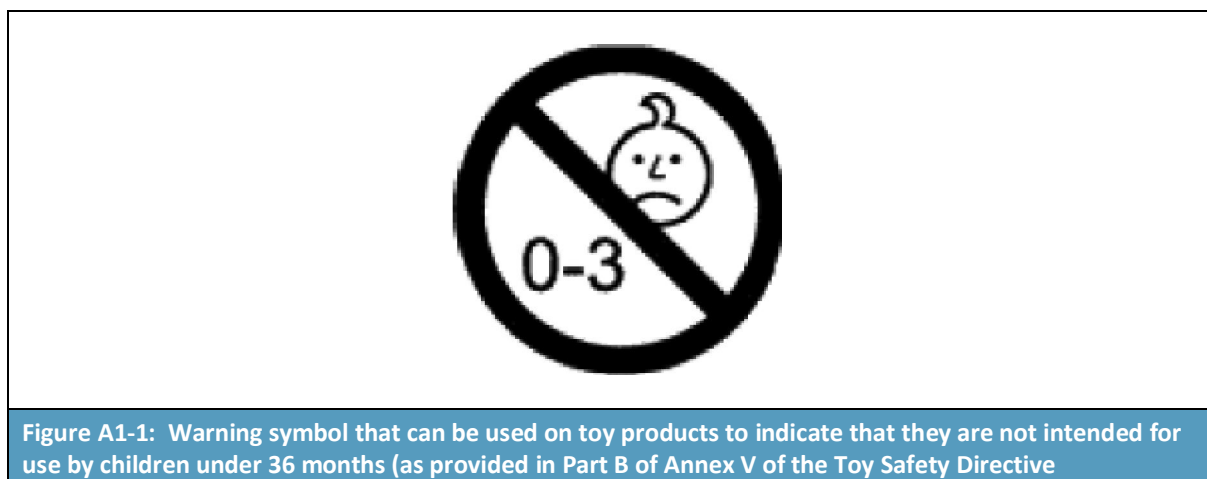
Paragraph 1 of Article 11 of the Toy Safety Directive indicates that, where appropriate for safe use, warnings made for the purposes of Article 10(2) shall specify appropriate user limitations in accordance with Part A of Annex V.

Part A of Annex V of the Toy Safety Directive relates to ‘general warnings’ and stipulates that the user limitations referred to in paragraph 1 of Article 11 shall include at least the minimum or maximum age of the user and, where appropriate, the abilities of the user, the maximum or minimum weight of the users and the need to ensure that the toy is used only under adult supervision.

For the categories of toy listed in Part B of Annex V the warnings outlined in this Annex are required to be used. Article 11 also notes that toys shall not bear one or more of the specific warnings set out in Part B of Annex V where the warning conflicts with the intended use of the toy, as determined by virtue of its function, dimension and characteristics.

Part B of Annex V of the Toy Safety Directive provides specific warnings and indications of precautions to be taken when using certain categories of toys. The requirements that are specifically relevant to chemicals used in toys are outlined in points 1, 4 and 10.

Point 1 relates to toys not intended for use by children under 36 months and requires toys that might be dangerous for children under 36 months of age to bear a warning such as ‘Not suitable for children under 36 months’ or ‘Not suitable for children under three years’ or a warning in the form of a graphic (as presented in Figure A1-1).



The warnings are required to be accompanied by a brief indication, which may appear in the instructions for use, of the specific hazard calling for this precaution. This point does not apply to toys which, on account of their function, dimensions, characteristics or properties, or on other cogent grounds, are manifestly unsuitable for children under 36 months.

Point 4 relates to chemical toys and indicates that, without prejudice to the application of the provisions laid down in applicable Community legislation on the classification, packaging and labelling of certain substances and mixtures, the instructions for use of toys containing inherently dangerous substances or mixtures and an indication of the precautions to be taken by the user in

order to avoid hazards associated with them, shall be specified concisely according to the type of toy. The first aid to be given in the event of serious accidents resulting from the use of this type of toy shall also be mentioned. It shall also be stated that the toy must be kept out of reach of children under a certain age, which shall be specified by the manufacturer.

In addition to the above requirements relating to the toys instructions, chemical toys are required to bear the following warning on their packaging: ‘Not suitable for children under ⁽¹⁸⁾ years. For use under adult supervision’.

Point 4 also indicated that, in particular, the following are regarded as chemical toys: chemistry sets, plastic embedding sets, miniature workshops for ceramics, enamelling or photography and similar toys which lead to a chemical reaction or similar substance alteration during use.

Point 10 relates to packaging for fragrances in olfactory board games, cosmetic kits and gustative games and indicates that these toys containing the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 of Part III of Annex II and the fragrances set out in points 1 to 11 of the list set out in the third paragraph of that point shall contain the following warning message: ‘Contains fragrances that may cause allergies’.

Paragraph 2 of Article 11 indicates that the manufacturer is required to mark the warnings in a clearly visible, easily legible and understandable and accurate manner on the toy, on an affixed label or on the packaging and, if appropriate, on the instructions for use which accompany the toy. Small toys that are sold without packaging are required to have appropriate warnings affixed to them. The warnings attributed to a toy shall be preceded by the words ‘Warning’ or ‘Warnings’ as appropriate. Paragraph 2 of Article 11 also indicates that warnings which determine the decision to purchase the toy, such as those specifying the minimum and maximum ages for users and the other applicable warnings set out in Annex V, shall appear on the consumer packaging or be otherwise clearly visible to the consumer before the purchase, including cases where the purchase is made online.

Paragraph 3 of Article 11 indicates that, in accordance with Article 4(7), a Member State may, within its territory, stipulate that the warnings and safety instructions shall be written in a language or languages easily understood by consumers, as determined by the Member State.

It should also be noted that **Paragraph 2 of Article 10** states that toys, including the chemicals they contain, will not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children. Paragraph 2 also indicates that the ability of the users and, where appropriate, their supervisors shall be taken into account, in particular, in the case of toys which are intended for use by children under 36 months or by other specified age groups. In addition, labels affixed in accordance with Article 11(2) and instructions for use which accompany toys should draw the attention of users or their supervisors to the inherent hazards and risks or harm involved in using the toys, and to the ways of avoiding such hazards and risks.

CE marking

By affixing a CE mark to a toy the manufacturer declares that the toy is in conformity with all applicable requirements outlined in the Toy Safety Directive and that the manufacturer takes full responsibility thereof.

¹⁸ Age to be specified by the manufacturer.

Article 16 of the Toy Safety Directive outlines the general principles of CE marking and indicates that toys made available on the market are required to bear the CE mark.

Article 17 of the Directive establishes the rules and conditions for affixing the CE mark of toy products. **Paragraph 1** indicates that the CE mark is required to be affixed visibly, legibly and indelibly to the toy, to an affixed label or to the packaging. In the case of small toys and toys consisting of small parts, the CE marking may alternatively be affixed to a label or an accompanying leaflet. Where, in the case of toys sold in counter displays, that is not technically possible, and on condition that the counter display was originally used as packaging for the toy, the CE marking may be affixed to the counter display. Paragraph 1 also states that where the CE marking is not visible from outside the packaging, if any, it shall as a minimum be affixed to the packaging.

Paragraph 2 of Article 17 indicates that the CE marking shall be affixed before the toy is placed on the market and it may be followed by a pictogram or any other mark indicating a special risk or use.

Labelling of contact details, instructions and traceability information

Recital 16 of the Toy Safety Directive indicates that when placing a toy on the market, importers should indicate on the toy their name and the address at which they can be contacted. Exceptions should be provided for in cases where the size or nature of the toy does not allow for such an indication. This includes cases where importers would have to open the packaging to put their name and address on the product.

Recital 19 highlights the importance of ensuring traceability of a toy throughout the whole supply chain as this helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant toys available on the market.

Article 4 of the Toy Safety Directive outlines obligations for manufacturers. **Paragraph 5** indicates that manufacturers shall ensure that their toys bear type, batch, serial or model number or other element allowing their identification, or, where the size or nature of the toy does not allow it, that the required information is provided on the packaging or in a document accompanying the toy.

Paragraph 6 notes that manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy or, where that is not possible, on its packaging or in a document accompanying the toy. The address shall indicate a single point at which the manufacturer can be contacted.

Paragraph 7 states that manufacturers shall ensure that the toy is accompanied by instructions and safety information in a language or languages easily understood by consumers, as determined by the Member State concerned.

Article 6 of the Toy Safety Directive outlines obligations for importers. **Paragraph 3** states that importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy, or, where that is not possible, on its packaging or in a document accompanying the toy. **Paragraph 4** indicates that importers shall ensure that the toy is accompanied by instructions and safety information in a language or languages easily understood by consumers, as determined by the Member State concerned.

Article 7 of the Directive outlines the obligations of distributors with **paragraph 2** indicating that, before making a toy available on the market, distributors shall verify that the toy bears the required conformity marking, that it is accompanied by the required documents and by instructions and

safety information in a language or languages easily understood by consumers in the Member State in which the toy is to be made available on the market, and that the manufacturer and importer have complied with the requirements set out in Article 4 paragraphs 5 and 6 and Article 6 paragraph 3 of the Directive.

A1.2 Cosmetics Regulation (1223/2009/EC)

A1.2.1 Chemical requirements (relevant to toys)

In Annex II of the Toy Safety Directive, point 10 of Section III (which relates to chemical properties) indicates that cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements laid down in Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (now the Cosmetics Regulation (EC) No 1223/2009) (European Parliament and the Council, 2014).

As indicated in **Article 1**, the Cosmetics Regulation establishes rules to be complied with by any cosmetic product made available on the market to ensure the functioning of the internal market and a high level of protection of human health (European Commission, 2016a).

Article 3 of the Cosmetics Regulation indicates that a cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use, taking account, particular, of the following (European Commission, 2016a):

- Presentation including conformity with Directive 87/357/EEC (on food imitating products);
- Labelling;
- Instructions for use and disposal; and
- Any other indication or information provided by the responsible person defined in Article 4.

Article 10 of the Regulation refers to the safety assessment with **paragraph 1** indicating that in order to demonstrate that a cosmetic product complies with Article 3, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up in accordance with Annex I (European Commission, 2016a).

Article 11 of the Regulation outlines the requirements for a product information file with **paragraph 1** indicating that when a cosmetic product is placed on the market, the responsible person shall keep the product information file for it. This file should be kept for a period of 10 years following the date on which the last batch of the cosmetic product was placed on the market. Paragraph 2 notes that the product information file shall contain the following information and data which shall be updated as necessary (European Commission, 2016a):

- A description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product;
- The cosmetic product safety report referred to in Article 10 paragraph 1;
- A description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 8;
- Where justified by the nature or the effect of the cosmetic product, proof of the effect for the cosmetic product; and
- Data on animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including

any animal testing performed to meet the legislative or regulatory requirements of third countries.

Chapter IV of the Cosmetics Regulation refers to **restrictions for certain substances** with Article 14 outlining requirements for restrictions for substances listed in the Annexes. **Paragraph 1 of Article 14** indicates that, without prejudice to Article 3, cosmetic products shall not contain any of the following (European Commission, 2016a):

- a) Prohibited substances (as listed in Annex II);
- b) Restricted substances (which are not used in accordance with the restrictions laid down in Annex III);
- c) Colorants:
 - i) Colorants other than those listed in Annex IV and colorants which are listed there but not used in accordance with the conditions laid down in that Annex, except for hair colouring products referred to in paragraph 2;
 - ii) Without prejudice to points b), d) (i) and e) (i), substances which are listed in Annex IV but which are not intended to be used as colorants, and which are not used in accordance with the conditions laid down in that Annex;
- d) Preservatives:
 - i) Preservatives other than those listed in Annex V and preservatives which are listed there but not used in accordance with the conditions laid down in that Annex;
 - ii) Without prejudice to points b), c) (i) and e) (i), substances listed in Annex V but which are not intended to be used as preservatives, and which are not used in accordance with the conditions laid down in that Annex;
- e) UV filters:
 - i) UV-filters other than those listed in Annex VI and UV-filters which are listed there but not used in accordance with the conditions laid down in that Annex; and
 - ii) Without prejudice to points b), c) (i) and d) (i), substances listed in Annex VI but which are not intended to be used as UV-filters and which are not used in accordance with the conditions laid down in that Annex.

Article 15 outlines the rules regarding substances that are classified as CMRs. **Paragraph 1** indicates that the use in cosmetic products of substances classified as CMR substances, of category 2, under Part 3 of Annex VI to Regulation (EC) No 1272/2008 (CLP Regulation) shall be prohibited. However, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by SCCS and found safe for use in cosmetic products. To these ends the Commission shall adopt the necessary measures in accordance with the regulatory procedure with scrutiny referred to in Article 32 paragraph 3 of the Cosmetics Regulation (European Commission, 2016a).

Paragraph 2 of Article 15 indicates that the use in cosmetic products of substances classified as CMR substances, of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 (CLP Regulation) shall be prohibited. However, it is also noted that such substances may be used in cosmetic products by way of exception where, subsequent to their classification as CMR substances of category 1A or 1B under Part 3 of Annex VI to the CLP Regulation, all of the following conditions are fulfilled (European Commission, 2016a):

- a) They comply with the food safety requirements as defined in Regulation (EC) No 178/2002 establishing the European Food Safety Authority and laying down procedures in matters of food safety;
- b) There are no suitable alternative substances available, as documented in an analysis of alternatives;

- c) The application is made for a particular use of the product category with a known exposure; and
- d) They have been evaluated and found safe by the SCCS for use in cosmetic products, in particular in view of exposure to these products and taking into consideration the overall exposure from other sources, taking particular account of vulnerable population groups.

Article 17 refers to traces of prohibited substances and indicates that the non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3.

Annex I outlines the requirements for the cosmetic product safety report, which should include the following as a minimum:

Part A – Cosmetic product safety information

1. **Quantitative and qualitative composition of the cosmetic product:** including chemical identify of the substances (including chemical name, INCI, CAS, EINECS/ELINCS, where possible) and their intended function. In the case of perfume and aromatic compositions, description of the name and code number of the composition and the identity of the supplier;
2. **Physical/chemical characteristics and stability of the cosmetic product:** the physical and chemical characteristics of the substances or mixtures, as well as the cosmetic product. The stability of the cosmetics product under reasonably foreseeable storage conditions;
3. **Microbiological quality:** of the substance or mixture and the cosmetic product;
4. **Impurities, traces, information about packaging material:** the purity of the substances and mixtures. In the case of traces of prohibited substances, evidence for their technical unavoidability. The relevant characteristics of packaging materials, in particular purity and stability;
5. **Normal and reasonably foreseeable use;**
6. **Exposure to the cosmetic product:** data on exposure to cosmetic products taking into consideration findings under Point 5 in relation to: 1) the site(s) of application, 2) the surface area(s) of application, 3) the amount of product applied, 4) the duration and frequency of use, 5) the normal and foreseeable exposure route(s), 6) The targeted (or exposed) population(s) – potential exposure of a specific population will also be taken into account;
7. **Exposure to the substances:** data on exposure to the substances contained in the cosmetic product for the relevant toxicological endpoints taking into account the information under point 6;
8. **Toxicological profile of the substances;**
9. **Undesirable effects and serious undesirable effects;**
10. **Information on the cosmetic product:** Other relevant information, e.g. existing studies from human volunteers or the duly confirmed and substantiated findings or risk assessments carried out in other relevant areas.

Part B – Cosmetic product safety assessment

11. **Assessment conclusion:** statement of the safety of the cosmetic product in relation to Article 3;
12. **Labelled warnings and instructions of use:** statement on the need to label any particular warnings and instructions of use in accordance with Article 19 paragraph 1 (d);
13. **Reasoning:** explanation of the scientific reasoning leading to the assessment conclusion set out under point 1 and the statement under point 2. There shall be inter alia a specific assessment for cosmetic products intended for use on children under the age of three for products exclusively for use in external intimate hygiene;
14. **Assessor's credentials and approval of part B:** Name and address of the safety assessor as well as proof of qualification and date of signature.

A1.2.2 Labelling requirements (relevant to toys)

The Cosmetics Regulation outlines specific labelling requirements for cosmetic products that will also apply to cosmetic toys. As indicated above, **Paragraph 2 of Article 15** of the Cosmetics Regulation prohibits the use of substances classified as CMR category 1A or 1B under Part 3 of the CLP Regulation unless a series of conditions are met. Paragraph 2 also indicates that specific labelling to avoid the misuse of the cosmetic product shall be provided in accordance with Article 3 of the Regulation, taking into account possible risks linked to the presence of hazardous substances and the routes of exposure (European Commission, 2016a).

Chapter VI of the Regulation refers to consumer information with **Article 19** outlining the labelling requirements. **Paragraph 1** indicates that without prejudice to other provisions in this article, cosmetic products shall only be made available on the market where the container and packaging of the products bear the following information in indelible, easily legible and visible lettering (European Commission, 2016a):

- a) The name or registered name and address of the responsible person. This information may be abbreviated in so far as the abbreviation makes it possible to identify that person and his address. If several addresses are indicated, the one where the responsible person makes readily available the product information file shall be highlighted. The country of origin shall be specified for imported cosmetic products;
- b) The nominal content at the time of packaging, given by weight or by volume, except in the case of packaging containing less than 5 grams or 5ml, free samples and single-application packs; for pre-packages normally sold as a number of items, for which details of weight or volume are not significant, the content need not be given provided the number of items appears on the packaging. The information need not be given if the number of items is easy to see from the outside or if the product is normally only sold individually;
- c) The date until which the cosmetic product, stored under appropriate conditions, will continue to fulfil its initial function and, in particular, will remain in conformity with Article 3 ('date of minimum durability'). The date itself or details of where it appears on the packaging shall be preceded by the symbol shown in point 3 of Annex VII or the words 'best used before end of'.

The date of minimum durability shall be clearly expressed and shall consist of either the month and year or the day, month and year, in that order. If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability. Indication of the date of minimum durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period of time after opening for which the product is safe and can be used without any harm to the consumer. This information shall be indicated, except where the concept of durability after opening is not relevant, by the symbol shown in point 2 of Annex VII followed by the period (in months and/or years);

- d) Particular precautions to be observed in use, and at least those listed in Annexes III to VI and any special precautionary information on cosmetic products for professional use;
- e) The batch number of manufacture of the reference for identifying the cosmetic product. Where this is impossible for practical reasons because the cosmetic products are too small, such information need appear only on the packaging;
- f) The function of the cosmetic product, unless it is clear from its presentation;
- g) A list of ingredients. This information may be indicated on the packaging alone and shall be preceded by the term 'ingredients'.

Paragraph 2 of Article 19 indicates that where it is impossible for practical reasons to label the information mentioned in points (d) and (g) of paragraph 1 (above) as provided, the following applies (European Commission, 2016a):

- The information shall be mentioned on an enclosed or attached leaflet, label, tape, tag or card; and
- Unless impracticable, this information shall be referred to by abbreviated information or the symbol given in point 1 of Annex VII, which must appear on the container or packaging for the information referred in point (d) of paragraph 1 and on packaging for the information referred in point (g) of paragraph 1.

Paragraph 3 indicates that in the case of soap, bath balls and other small products where it is impossible for practical reasons for the information referred to in point (g) of paragraph 1 to appear on a label, tag, tape or card or in an enclosed leaflet, this information shall appear on a notice in immediate proximity to the container in which the cosmetic product is exposed for sale (European Commission, 2016a).

Paragraph 4 of the Regulation notes that for cosmetic products that are not pre-packaged, are packaged at the point of sale at the purchaser's request, or are pre-packaged for immediate sale, Member States shall adopt detailed rules for indication of the information referred to in paragraph 1 (European Commission, 2016a).

Paragraph 5 indicates that the language of the information mentioned in points (b), (c), (d) and (f) of paragraph 1 and in paragraphs 2, 3 and 4 shall be determined by the law of the Member States in which the product is made available to the end user (European Commission, 2016a).

Paragraph 6 indicates that the information mentioned in point (g) of paragraph 1 shall be expressed by using the common ingredient name set out in the glossary provided for in Article 33. In the absence of a common ingredient name, a term as contained in a generally accepted nomenclature shall be used (European Commission, 2016a).

Annex III of the Cosmetics Regulation provides a list of substances which cosmetics products must not contain except when subject to specific restrictions. This also includes wording of conditions of use and warnings that should be printed on the product label (European Commission, 2016a).

Annex V of the Regulation provides a list of preservatives allowed in cosmetic products and includes wording of conditions of use and warnings that should be printed on the product label (European Commission, 2016a).

Annex VI contains a list of UV-filters allowed in cosmetic products and includes wording of conditions of use and warnings that should be printed on the product label (European Commission, 2016a).

Annex VII presents the symbols to be used on cosmetic product packaging/containers and includes the symbols for: 1) reference to enclosed or attached information; 2) period-after-opening; and 3) date of minimum durability (European Commission, 2016a).

A1.3 CLP Regulation (1272/2008/EC)

A1.3.1 Chemical requirements (relevant to toys)

Regulation (EC) No 1272/2008 (the CLP Regulation) seeks to ensure that EU workers and consumers are clearly informed of the hazards associated with chemicals through a system of classification and labelling. The aim is to ensure that the same hazards are described and labelled in the same way in all EU countries. The Regulation requires companies to classify, label and appropriately package their hazardous chemicals before placing them on the market (EUR-Lex, 2015)

Toys that are themselves substances or mixtures e.g. poster paints, finger paints, slimes, modelling compounds, experimental sets need to comply with the CLP Regulation (EC) No 1272/2008 related to classification, packaging and labelling (European Commission, 2016e).

Article 4 of the CLP Regulation outlines the general obligations to classify, label and package substances/mixtures and **paragraph 1** indicates that manufacturers, importers and downstream users shall classify substances and mixtures in accordance with **Title II** of the Regulation (relating to hazard classification) before placing them on the market (European Commission, 2016b).

According to **Annex I** of the CLP Regulation, the generic concentration limits of ingredients of a mixture classified as CMRs that trigger classification of the mixture are:

- 0.1% for carcinogens category 1A and 1B, germ cell mutagens category 1A and 1B;
- 1% for carcinogens category 2 and germ cell mutagens category 2;
- 0.3% for reproductive toxicants category 1A and 1B; and
- 3% for reproductive toxicants category 2.

These concentrations apply to solids and liquids (w/w units) as well as gases (v/v units). However, generic concentration limits only apply if no specific concentration limits are set in Annex VI to the CLP Regulation. If a specific limit is set therein, then it also applies for the purposes of the Toy Safety Directive.

A1.3.2 Labelling requirements (relevant to toys)

As noted above, toys that are themselves substances or mixtures need to comply with the labelling requirements outlined in the CLP Regulation. **Title III** of the CLP Regulation refers to **hazard communication in the form of labelling** with **Article 17** providing the general rules. **Paragraph 1** of Article 17 indicates that a substance or mixture classified as hazardous and contained in packaging shall bear a label including the following elements (European Commission, 2016b):

- The name, address and telephone number of the supplier(s);
- The nominal quantity of the substance or mixture in the package made available to the general public, unless this quantity is specified elsewhere on the package;
- Product identifiers as specified in Article 18;
- Where applicable, hazard pictograms in accordance with Article 19;
- Where applicable, signal words in accordance with Article 20;
- Where applicable, hazard statements in accordance with Article 21;
- Where applicable, the appropriate precautionary statements in accordance with Article 22; and
- Where applicable, a section for supplemental information in accordance with Article 25.

Paragraph 2 notes that the label shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. Suppliers may use more languages on their labels than those required by the Member States, provided that the same details appear in all languages used (European Commission, 2016b).

Article 18 of the CLP Regulation refers to **product identifiers** with **paragraph 1** indicating that the label shall include details permitting the identification of the substance or mixture (hereinafter referred to as 'product identifiers'). **Paragraph 2** notes that the product identifier for a substance shall consist of at least the following (European Commission, 2016b):

- If the substance is included in Part 3 of Annex VI, a name and an identification number as given therein;
- If the substance is not included in Part 3 of Annex VI, but appears in the classification and labelling inventory, a name and an identification number as given therein;
- If the substance is not included in Part 3 of Annex VI nor in the classification and labelling inventory, the number provided by the CAS (number), together with the name set out in the nomenclature provided by the IUPAC, or the CAS number together with another international chemical name(s); or
- If the CAS number is not available, the name set out in the IUPAC Nomenclature or another international chemical name(s).

Where the name in the IUPAC nomenclature exceeds 100 characters, one of the other names (usual name, trade name, abbreviation) referred to in section 2.1.2 of Annex VI to Regulation (EC) No 1907/2006 (REACH Regulation) may be used provided that the notification in accordance with Article 40 includes both the name set out in the IUPAC Nomenclature and the other name used (European Commission, 2016b).

Paragraph 3 of Article 18 indicates that the product identifier for a mixture shall consist of both the following (European Commission, 2016b):

- a) The trade name or the designation of the mixture; and

- b) The identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT) or aspiration hazard.

Where, in the case referred to in (b), that requirement leads to the provision of multiple chemical names, a maximum of four chemical names shall suffice, unless more than four names are needed to reflect the nature and the severity of the hazards (European Commission, 2016b).

The chemical names selected shall identify the substances primarily responsible for the major health hazards which have given rise to the classification and the choice of the corresponding hazard statements (European Commission, 2016b).

Article 19 refers to **hazard pictograms** and **paragraph 1** indicates that the label shall include the relevant hazard pictogram(s), intended to convey specific information on the hazard concerned. **Paragraph 2** notes that subject to Article 33, hazard pictograms shall fulfil the requirements laid down in section 1.2.1 of Annex I and in Annex V. **Paragraph 3** indicates that the hazard pictogram relevant for each specific classification is set out in the tables indicating the label elements required for each hazard class in Annex I (European Commission, 2016b).

Article 20 relates to **signal words** and **paragraph 1** indicates that the label shall include the relevant signal word in accordance with the classification of the hazardous substance or mixture. **Paragraph 2** indicates that the signal word relevant for each specific classification is set out in the tables indicating the label elements required for each hazard class in Parts 2 to 5 of Annex I. **Paragraph 3** notes that where the signal word 'Danger' is used on the label, the signal word 'Warning' shall not appear on the label (European Commission, 2016b).

Article 21 refers to **hazards statements** with **paragraph 1** indicating that the label shall include the relevant hazard statements in accordance with the classification of the hazardous substances or mixture. **Paragraph 2** notes that the hazard statements relevant for each classification are set out in the tables indicating the label elements required for each hazard class in Parts 2 to 5 of Annex I. **Paragraph 3** indicates that where a substance is included in Part 3 of Annex VI, the hazard statement relevant for each specific classification covered by the entry in that Part shall be used on the label, together with the hazard statements referred to in paragraph 2 for any other classification not covered by that entry. **Paragraph 4** notes that the hazard statements shall be worded in accordance with Annex III (European Commission, 2016b).

Article 22 relates to **precautionary statements** and **paragraph 1** indicates that the label is required to include the relevant precautionary statements. **Paragraph 2** notes that these precautionary statements shall be selected from those set out in the tables in Parts 2 to 5 of Annex I indicating the label elements for each hazard class. **Paragraph 3** indicates that the precautionary statements shall be selected in accordance with the criteria laid down in Part 1 of Annex IV taking into account the hazard statements and the intended or identified use or uses of the substance or the mixture. **Paragraph 4** notes that the precautionary statements shall be worded in accordance with Part 2 of Annex IV (European Commission, 2016b).

Article 25 refers to **supplemental information** on the label with **paragraph 1** indicating that statements shall be included in the section for supplemental information on the label where a substance or mixture classified as hazardous has the physical properties or health properties referred to in sections 1.1 and 1.2 of Annex II. The statements shall be worded in accordance with sections 1.1 and 1.2 of Annex II and Part 2 of Annex III. Where a substance is included in Part 3 of

Annex VI, any supplemental hazard statements given therein for the substance shall be included in the supplemental information on the label (European Commission, 2016b).

Article 30 relates to the **updating of information on labels** with **paragraph 1** indicating that the supplier shall ensure that the label is updated, without undue delay, following any change to the classification and labelling of that substance or mixture, where the new hazard is more severe or where new supplemental labelling elements are required under Article 25, taking into account the nature of the change as regards the protection of human health and the environment (European Commission, 2016b).

Article 31 outlines the **general rules for the application of labels** with **paragraph 1** indicating that labels are required to be firmly affixed to one or more surfaces of the packaging immediately containing the substance or mixture and shall be readable horizontally when the package is set down normally. **Paragraph 2** notes that the colour and presentation of any label shall be such that the hazard pictogram stands out clearly. **Paragraph 3** indicates that the label elements referred to in Article 17 paragraph 1 shall be clearly and indelibly marked. They shall stand out clearly from the background and be of such size and spacing as to be easily read. **Paragraph 4** notes that the shape, colour and size of the hazard pictogram as well as the dimension of the label shall be as set out in section 1.2.1 of Annex I. **Paragraph 5** notes that a label shall not be required when the label elements referred to in Article 17 paragraph 1 are shown clearly on the packaging itself. In such cases, the requirements of this Chapter applicable to a label shall be applied to the information shown on the packaging (European Commission, 2016b).

A1.4 RoHS Directive (2001/65/EU)

A1.4.1 Chemical requirements (relevant to toys)

As indicated in Section A1.1.1, **Recital 25** of the Toy Safety Directive notes that environmental concerns are addressed by horizontal environmental legislation applying to electrical and electronic toys, namely Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive) and Directive 2002/96/EC on waste electrical and electronic equipment (WEEE Directive) (European Parliament and the Council, 2014).

The RoHS Directive reinforces existing rules on the use of hazardous substances in electrical and electronic equipment to protect human health and ensure waste is recovered and disposed in an appropriate way to minimise the environmental impact. The legislation updates Directive 2002/95/EC, which restricts the use of certain hazardous substances in electrical and electronic equipment (EEE) by extending protection from dangerous chemicals (such as lead, mercury and cadmium) to more electrical appliances. The ban now applies to all EEE and to cables and spare parts and will be applied in phases for different products (EUR-Lex, 2014a).

The Directive requires manufacturers to ensure that any EEE they sell has been designed and produced in line with the requirements set out in the legislation. Importers are required to check that equipment has been approved as meeting the required standards and distributors must also ensure that the rules are adhered to (EUR-Lex, 2014a).

Article 2 of the RoHS Directive outlines the **scope** with **paragraph 1** indicating that the Directive shall, subject to paragraph 2, apply to EEE falling within the categories set out in Annex I. It should be noted that the categories listed in **Annex I** include ‘toys, leisure and sports equipment’ (European Commission, 2015b).

Paragraph 2 indicates that, without prejudice to Article 4 paragraphs 3 and 4, Member States shall provide that EEE that was outside the scope of Directive 2002/95/EC, but which would not comply with this Directive, may nevertheless continue to be made available on the market until 22 July 2019. **Paragraph 3** notes that the Directive shall apply without prejudice to the requirements of Union legislation on safety and health, and on chemicals, in particular Regulation (EC) No 1907/2006 (REACH Regulation), as well as the requirements of specific Union waste management legislation (European Commission, 2015b).

Article 4 of the Directive relates to prevention with **paragraph 1** indicating that Member States shall ensure that EE placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the substances listed in **Annex II** (European Commission, 2015b).

In the case of DEHP, BBP and DBP, **Annex II** indicates that the associated restriction shall not apply to toys that are already subject to the restriction of DEHP, BBP and DBP through entry 51 of Annex XVII to Regulation (EC) No 1907/2006 (the REACH Regulation) (European Commission, 2015b).

Annex III of the RoHS Directive outlines the applications that are exempted from the restriction in Article 4 paragraph 1. This includes the specific exemption and the scope and dates of applicability (European Commission, 2015b).

A1.4.2 Labelling requirements (relevant to toys)

Article 7 outlines the **obligations of manufacturers** and indicates that Member States shall ensure that (European Commission, 2015b):

- a) When placing EEE on the market, manufacturers ensure that it has been designed and manufactured in accordance with the requirements set out in Article 4;
- b) Manufacturers draw up the required technical documentation and carry out the internal production control procedure in line with module A of Annex II to Decision No 768/2008/EC (on a common framework for the marketing of products) or have it carried out;
- c) Where compliance of EEE with the applicable requirements has been demonstrated by the procedure referred to in point (b), manufacturers draw up an EU declaration of conformity and affix the CE marking on the finished product. Where other applicable Union legislation requires the application of a conformity assessment procedure which is at least as stringent, compliance with the requirements of Article 4 paragraph 1 of this Directive may be demonstrated within the content of that procedure. A single technical documentation may be drawn up;
- d) Manufacturers keep the technical documentation and the EU declaration of conformity for 10 years after the EEE has been placed on the market;
- e) Manufacturers ensure that procedures are in place for series production to remain in conformity. Changes in product design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of EEE is declared shall be adequately taken into account;
- f) Manufacturers keep a register of non-conforming EEE and product recalls, and keep distributors informed thereof;
- g) Manufacturers ensure that their EEE bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the EEE does not allow it, that the required information is provided on the packaging or in a document accompanying the EEE;
- h) Manufacturers indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its

packaging or in a document accompanying the EEE. The address must indicate a single point at which the manufacturer can be contacted. Where other applicable Union legislation contains provisions for the affixing of the manufacturer's name and address which are at least as stringent, those provisions shall apply;

- i) Manufacturers who consider or have reason to believe that EEE which they have placed on the market is not in conformity with this Directive immediately take the necessary corrective measures to bring that EEE into conformity, to withdraw or recall it, if appropriate, and immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken; and
- j) Manufacturers, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the EEE with this Directive, in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have placed on the market.

Article 9 of the RoHS Directive outlines the **obligations for importers** and indicates that Member States shall ensure that (European Commission, 2015b):

- a) Importers place only EEE that complies with this Directive on the Union market;
- b) Importers, before placing an EEE on the market, ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer, and that they further ensure that the manufacturer has drawn up the technical documentation, that the EEE bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in points (g) and (h) of Article 7;
- c) Where an importer considers or has reason to believe that an EEE is not in conformity with Article 4, that importer does not place the EEE on the market until it has been brought into conformity, and that that importer informs the manufacturer and the market surveillance authorities to that effect;
- d) Importers indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. Where other applicable Union legislation contains provisions for the affixing of the importer's name and address which are at least as stringent, those provisions shall apply;
- e) Importers, in order to ensure compliance with this Directive, keep a register of non-compliant EEE and EEE recalls, and keep distributors informed thereof;
- f) Importers who consider or have reason to believe that an EEE which they have placed on the market is not in conformity with this Directive immediately take the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, as appropriate, and immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;
- g) Importers keep, for 10 years following the placing on the market of the EEE, a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request; and
- h) Importers, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the EEE with this Directive in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have placed on the market.

Article 10 of the RoHS Directive outlines the **obligations for distributors** and indicates that Member States shall ensure that (European Commission, 2015b):

- a) When making an EEE available on the market, distributors act with due care in relation to the requirements applicable in particular by verifying that the EEE bears the CE marking, that it is accompanied by the required documents in a language which can be easily understood by consumers and other end-users in the Member State in which the EEE is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in points (g) and (h) of Article 7 and in point (d) of Article 9;
- b) Where a distributor considers or has reason to believe that an EEE which they have made available on the market is not in conformity with this Directive, that they make sure that the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, as appropriate, are taken and that they immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken; and
- c) Distributors, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the EEE with this Directive in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have made available on the market.

Article 15 of the Directive refers to the **rules and conditions for affixing the CE marking** with **paragraph 1** indicating that the CE marking shall be affixed visibly, legibly and indelibly to the finished EEE or to its data plate. Where that is not possible or not warranted on account of the nature of the EEE, it shall be affixed to the packaging and to the accompanying documents. Paragraph 2 notes that the CE marking shall be affixed before the EEE is placed on the market (European Commission, 2015b).

A1.5 WEEE Directive (2012/19/EU)

A1.5.1 Chemical requirements (relevant to toys)

As indicated in Section 1.5.1, **Recital 25** of the Toy Safety Directive notes that environmental concerns are addressed by horizontal environmental legislation applying to electrical and electronic toys, namely Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive) and Directive 2002/96/EC on waste electrical and electronic equipment (WEEE Directive) (European Parliament and the Council, 2014).

The WEEE Directive is designed to prevent electrical and electronic waste by requiring EU countries to ensure the equipment is recovered, reused or recycled. The original WEEE Directive came into force in 2003 and set a minimum national target for public waste collection of 4kg per inhabitant per year from private households for a wide range of electrical products. Special responsibilities were also placed on producers requiring them to make a financial contribution to cover the costs of collecting, treating and sustainably disposing of both non-household equipment and private electrical waste deposited at dedicated collection points (EUR-Lex, 2014b).

The amended legislation broadens the scope to include all electrical and electronic goods, apart from certain items such as stationary industrial machinery and military material. It also changes the original 4 kg collection target to a variable one from 2016 onwards, taking account of individual national economies. The new collection target is 45% of the average weight of products placed on the market in a given country in the three preceding years, with this increasing to 65% from 2019.

The amended legislation simplifies the reporting obligations for producers resulting in potential cost savings (EUR-Lex, 2014b).

Article 1 of the WEEE Directive outlines the **subject matter** and indicates that the Directive lays down measures to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste from electrical and electronic equipment (WEEE) and by reducing overall impacts of resource use and improving the efficiency of such use in accordance with Articles 1 and 4 of Directive 2008/98/EC (the Waste Framework Directive), thereby contributing to sustainable development (European Commission, 2012).

Article 2 refers to the scope of the Directive with **paragraph 1** indicating that it shall apply to electrical and electronic equipment as follows (European Commission, 2012):

- From 13 August 2012 to 14 August 2018 (transitional period), subject to paragraph 3, to EEE falling within the categories set out in Annex I. Annex II contains an indicative list of EEE which falls within the categories set out in Annex I; and
- From 15 August 2018, subject to paragraphs 3 and 4, to all EEE. All EEE shall be classified within the categories set out in Annex III. Annex IV contains a non-exhaustive list of EEE which falls within the categories set out in Annex III (open scope).

Paragraph 2 of Article 2 indicates that the Directive shall apply without prejudice to the requirements of Union legislation on safety and health, on chemicals, in particular the REACH Regulation, establishing a European Chemicals Agency, as well as of specific Union waste management or product design legislation (European Commission, 2012).

Annex I provides the categories of EEE covered by the Directive during the transitional period as provided for in Article 2, with category 7 referring to 'toys, leisure and sports equipment'. **Annex II** provides an indicative list of EEE that falls within the categories of Annex I and for 'toys, leisure and sports equipment' includes (European Commission, 2012):

- Electric trains or car racing sets;
- Hand-held video game consoles;
- Video games;
- Computers for biking, running, rowing etc.; and
- Coin slot machines.

Article 12 of the Directive refers to **financing in respect of WEEE from private households** with **paragraph 1** indicating that Member States are required to ensure that producers provide at least for the financing of the collection, treatment, recovery and environmentally sound disposal of WEEE from private households that has been deposited at collection facilities set up under Article 5 paragraph 2. **Paragraph 3** notes that for products placed on the market later than 13 August 2005, each producer shall be responsible for financing the operations referred to in paragraph 1 relating to the waste from his own products. The producer may choose to fulfil this obligation either individually or by joining a collective scheme (European Commission, 2012).

A1.5.2 Labelling requirements (relevant to toys)

Article 14 of the WEEE Directive refers to **information for users** and **paragraph 1** indicates that Member States may require producers to show purchasers at the time of sales of new products, the costs of collection, treatment and disposal in an environmentally sound way. The costs mentioned shall not exceed the best estimate of the actual costs incurred. **Paragraph 2** notes that Member

States shall ensure that users of EEE in private households are given necessary information about (European Commission, 2012):

- The requirement not to dispose of WEEE as unsorted municipal waste and to collect such WEEE separately;
- The return and collection systems available to them, encouraging the coordination of information on the available collection points irrespective of the producers or other operators which have set them up;
- Their role in contributing to re-use, recycling and other forms of recovery of WEEE;
- The potential effects on the environment and human health as a result of the presence of hazardous substances in EEE; and
- The meaning of the symbols shown in Annex IX.

Paragraph 3 indicates that Member States shall adopt appropriate measures so that consumers participate in the collection of WEEE and to encourage them to facilitate the process of re-use, treatment and recovery. **Paragraph 4** notes that, with a view to minimising the disposal of WEEE as unsorted municipal waste and to facilitating its separate collection, Member States are required to ensure that **producers appropriately mark** (preferably in accordance with the European standard EN 50419) **EEE placed on the market with the symbol shown in Annex IX** (illustrated in Figure A1-2). In exceptional cases, where this is necessary because of the size or the function of the product, the symbol shall be printed on the packaging, on the instructions for use and on the warranty of the EEE. Paragraph 5 indicates that Member States may require that some or all of the information referred to in paragraphs 2, 3 and 4 shall be provided by producers and/or distributors, e.g. in the instructions for use, at the point of sale and through public awareness campaigns (European Commission, 2012).



Figure A1-2: Symbol for the marking of EEE (it must be printed visibly, legibly and indelibly)

Article 15 of the WEEE Directive refers to **information for treatment facilities** with **paragraph 1** indicating that in order to facilitate the preparation for re-use and the correct and environmentally sound treatment of WEEE, including maintenance, upgrade, refurbishment and recycling, Member States shall take the necessary measures to ensure that producers provide information free of charge about preparation for re-use and treatment in respect of each type of new EEE placed for the first time on the Union market within one year after the equipment is placed on the market. This information shall identify, as far as it is needed by centres which prepare for re-use and treatment and recycling facilities in order to comply with the provisions of this Directive, **the different EEE components and materials, as well as the location of dangerous substances and mixtures in EEE**. It shall be made available to centres which prepare for re-use and treatment and recycling facilities by producers of EEE in the form of manuals or by means of electronic media (e.g. CD-ROM, online services) (European Commission, 2012).

Paragraph 2 of Article 15 indicates that in order to enable the date upon which the EEE was placed on the market to be determined unequivocally, **Member States are required to ensure that a mark on the EEE specifies that the latter was placed on the market after 13 August 2005** (preferably the European standard EN 50419 shall be applied for this purpose) (European Commission, 2012).

Case Study 9: Consumer comprehension of and relevance of safety information on product labels

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1 Introduction

1.1 Overview

This case study considers the hazard information that the CLP Regulation¹ introduced when implementing the Globally Harmonised System for classification and labelling (GHS), particularly as regards consumer understanding of hazard labelling, looking across a range of consumer product sectors (excluding toys which are covered in case study 8)². As and where relevant in this case study report, issues relating to worker and professional user understanding are discussed.

Pictograms³ were used under the Dangerous Substances Directive⁴/Dangerous Preparations Directive⁵ for labelling on consumer products as well as on SDS for worker communication purposes. Since June 2015, mixtures of substances have to be labelled according to the GHS/CLP system and products with the diamond shaped GHS/CLP pictograms are increasingly appearing on the shelves of retail outlets such as supermarkets and DIY stores, replacing those products with the old labelling and pictograms.

In addition to consumer understanding of pictograms, other labelling elements such as hazard statements and precautionary statements are also considered, as well as the contribution of various aspects of a label to consumer comprehension of safe use information. Consideration is also given to the potential for the use of more innovative approaches for the communication of hazard and safe use information to consumers, such as QR-codes or other digital solutions. In addition, the relevance of existing consumer communication requirements is considered.

This case study feeds into the analysis of the effectiveness of hazard communication in Section 7.3 of Task 2 of the study report.

¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

² This means that other labelling components such as H- and P- statements were not specifically investigated for this case study. However, they are included in the discussion of this topic.

³ The GHS pictograms used in CLP can be found in Annex 1, along with a description of their various meanings.

⁴ Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

⁵ Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

1.2 Objectives and approach

The objective of this case study report is to:

- analyse the available information on consumer understanding of hazard labelling;
- draw conclusions on the effectiveness of hazard communication to consumers; and
- consider the potential for the use of more innovative communication approaches.

The primary method for gathering information was desk-based research of studies into consumer comprehension of pictograms, including academic literature dealing with the perception of GHS pictograms in the EU and in other countries. In addition, the literature review considers other material and publications that aim to inform the consumer about the (new) CLP system. Grey literature and popular media outputs were also analysed for any content directed towards the understanding of the CLP pictograms by consumers. The results of this desk-based research are summarised in Section 2.

Stakeholders interviewed for this case study included Member States, ECHA, the European Commission (various DGs), industry and consumer and industry associations.

The responses received from the stakeholders interviewed are used to support analysis of the issues relating to consumer understanding and the relevance of safety information on product labels. The literature review and the stakeholder consultation highlighted several main themes under which the analysis is organised. These are: consumer awareness and understanding of hazard communication; over-labelling; multi-lingual labelling; safe use instructions; safe use icons; the use of technology to communicate hazards to consumers and suggestions for improvement of hazard communication. These themes are analysed in Section 3.

This case study also takes into account relevant evaluation questions for the Fitness Check as a whole. Due to the overlaps between the scope of this case study and that of Case Study 5 (on labelling requirements for the detergents sector more specifically), some information may be repeated or, to avoid repeating larger sections of text, reference may be made to Case Study 5.

The first major survey into consumer understanding of CLP pictograms was the Eurobarometer (2011) into consumer understanding of labels and the safe use of chemicals. This can be considered to provide a benchmark against which developments in consumer understanding can be measured or evaluated. As many or most consumer products are mixtures, and as CLP required mixtures to be labelled accordingly as of mid-2015, there is little recent research which could indicate the extent to which consumer understanding has changed since the first Eurobarometer survey. What research there is has been quite specific in scope and therefore not directly comparable. The next Eurobarometer Survey included a small number of questions on consumer understanding of CLP pictograms and labels, and the outcomes of this survey are pending. There is therefore a weakness in the available quantitative data. As a result, in addition to the desk research specified for this case study, analysis includes more subjective information from consultation responses to the study as a whole, as well as input from a number of detailed stakeholder interviews.

2 Literature Review

2.1 Defining pictograms and their purpose

Pictograms may be defined as “a stylised figurative drawing that is used to convey information of an analogical or figurative nature directly to indicate an object or to express an idea” (Tijus *C et al.*, n.d.) or simply as “a pictorial symbol for a word or phrase”⁶. They are a vehicle used to communicate certain information and can be found in many day-to-day situations, e.g. on road traffic signs, household products, pharmaceuticals, and even in computer software where pictograms are used to warn or guide the user.

On consumer products, pictograms range in scope from signs of danger to indications of methods of proper recycling and disposal. They seek to provide the end-user with information concerning safety, health, energy efficiency and/or environmental issues relating to the use or consumption of a product. The CLP pictograms seek to “help us to know that the chemicals we are using might cause harm to people or the environment”⁷.

2.2 Advantages and disadvantages of pictograms

Pictograms are one of the key tools to communicate hazard information to downstream users of chemicals. One particular advantage of pictograms over written messages or warnings is that they minimise the scope for misinterpretation; warnings can be instantaneously understood through the use of shapes and colours which are often subconsciously recognised as an indication of danger (e.g. the colour red) (Tijus *et al.*, n.d.). Pictograms can help to convey a message to those with visual or learning difficulties, and can be processed at a greater distance than textual information. They can also produce a more immediate mental picture and comprehension of the message (AISE, 2006). Other recognised advantages of pictograms include (DTI, n.d.):

- They can make warnings more noticeable or “attention grabbing”;
- They can serve as “instant reminders” of a hazard or an established message;
- They have the potential to be interpreted more accurately and more quickly than words;
- They can sometimes be recognised and recalled far better than words;
- They can improve the legibility of a warning; and
- They may be better when undertaking familiar or routine tasks.

However, pictograms also have the disadvantage that only very few are universally understood (DTI, n.d.) and, depending on their use, they may not be interpreted correctly by all groups of consumers and across all cultures (Tijus *et al.*, n.d.). It can also take many years for any pictogram to be widely recognised and understood (the longer a pictogram is in circulation the better known and more effective it will be) (DTI, n.d.). Other disadvantages of pictograms include (DTI, n.d.):

- The potential for critical confusion (interpreting the opposite or often undesired meaning) which can create an additional safety hazard;

⁶ Oxford Dictionaries (2016): Definition of ‘Pictograph’. Available at: <http://www.oxforddictionaries.com/definition/english/pictograph>

⁷ Health and Safety Executive (n.d.): Hazard pictograms. Available at: <http://www.hse.gov.uk/chemical-classification/labelling-packaging/hazard-symbols-hazard-pictograms.htm>

- Any advantages in noticeability will be affected by the size, positioning and clutter on the packaging; and
- The majority of studies seem to suggest that while pictograms may have some role in conveying safety information, they are not a guaranteed solution to improving the effectiveness of text only messages.

2.3 Designing pictograms

Different studies suggest key factors which ought to be taken into account when designing pictograms and labels for safe use communication. For instance, ECHA (2010) notes that hazard pictograms are more intuitively indicative of a hazard and hence have the largest effect on risk perception, regardless of country, gender, age or educational level. Other conclusions include:

- Product labels and product packaging should send consistent messages, e.g. avoid the combination of hazard symbols with (hidden) messages that activate positive feelings or feelings of innocence (e.g. nature, pictures of babies and mothers);
- Messages should focus on safe storage as well as specific safety and disposal measures, make use of intuitive behaviours and be consistent with the message of the hazard pictogram. For example, when a product package is red and/or black, users automatically tend to judge the product as more dangerous;
- Households differ in terms of their vulnerability (accessibility of products to children, etc.). Therefore, hazard communication is most effective if it systematically targets specific household categories (e.g. families with young children, people with disabilities, and the elderly); and
- Information on chemicals should be offered in the relevant context of use. This implies that information “builds up” in households over a longer period of time and needs to be available for consumers before or at the time of use of the product.

A recent study “Design and validation (in accordance with ISO rules) of graphical symbols conveying certain safety warning messages to be used for childcare articles”⁸ published by DG Justice and Consumers provides some valuable input into the complexities of graphic symbol design as well as methods for developing new symbols. The study considers research on existing standardised symbols that convey the same or similar meaning; the process of designing symbols for those messages⁹; and the cross-European validation process with consumers¹⁰. The study also developed new pictograms and applied the ISO rules to assess their validity. Some points made in the study are of relevance to this case study, as they relate to pictograms and to consumer understanding. These include:

- The aim of producing a graphical symbol is always that it should be comprehended without associated words and without specific education;
- Before designing a graphical symbol, it is necessary to ascertain that the new graphical symbol will not give rise to ambiguity of meaning, nor overlap with the symbols already

⁸ Consumers, Health, Agriculture and Food Executive Agency (2015): Design and validation (in accordance with ISO rules) of graphical symbols conveying certain safety warning messages to be used for child-care articles: final report. Available at:

<https://publications.europa.eu/en/publication-detail/-/publication/412f2e40-9d7a-11e5-8781-01aa75ed71a1/language-en>

⁹ Following ISO/IEC standards.

¹⁰ Following ISO standard specifications ISO 9186-1-2014, ISO 9186-2-2008, and ISO 9186-3-2014.

standardised. If a suitable symbol exists, it shall be used. In any field of application, an established graphical symbol should only be used to convey one message;

- The general criteria to produce the design solutions¹¹ include incorporating users/consumers in the design process, taking into consideration the whole user experience (user requirements) and altering the design solutions in response to user-centred evaluation and feedback; and
- It may be necessary to present a graphical symbol together with supplementary text explaining its meaning in the language of the intended users; and to inform people about the meaning of the graphical symbols by including its meaning in manuals, instructions or training.

2.4 Consumer understanding of CLP pictograms and labels

2.4.1 Understanding in the EU

As noted above, the effectiveness of pictograms not only requires consumers to understand what they mean, it also requires consumers to act upon that information. Several studies have shown that of those who notice a warning, only some will read it, and even less will take the recommended precautions (Friedman, 1988 in DTI, n.d.). A number of factors contribute towards the effectiveness of a warning message. These include users' perceptions of the risks associated with the product, users' familiarity with the product, and how much effort (and cost) is required to carry out the required behaviour (DTI, n.d.).

Consumers' understanding of labels and how this understanding affects their usage of chemicals was the research objective of a large European Eurobarometer study in 2011 where a sample of 26,574 European citizens (from the EU27) was surveyed (Eurobarometer, 2011). The survey assessed the communication of information to the general public on the safe use of substances and mixtures and the potential need for additional information on labels. The survey showed that there is a far greater understanding of some hazard pictograms than there is for others. The flammability symbol, for example, is almost universally understood (91% of European respondents correctly interpreted the meaning of this symbol. In Romania, where awareness was lowest, this symbol was correctly interpreted by 72% of respondents).

The results of the Eurobarometer 2011 study are analysed and presented in the ECHA report on communication on safe use of chemicals, which analyses in detail the results of the "Eurobarometer Survey Questionnaire on consumer perception of labels and chemicals" and the qualitative research "In-depth study of hazard perception of household chemical products" (ECHA, 2012)¹². This can be considered a baseline for assessing the extent of EU consumer understanding of CLP pictograms and safety information on labels. The ECHA report is a good reference point for this case study, firstly because it is very specific analysis of EU consumer understanding of CLP pictograms and also because it provides a baseline against which changes in levels of understanding can be measured. This is because the research was undertaken just after the introduction of CLP for consumer products and before the deadline for labelling mixtures (such as household detergents), and gives a comprehensive view of EU consumer perceptions at this very early phase of the use of CLP pictograms. The ECHA report's key findings include the following:

¹¹ According to ISO 9241-210: 6.4.

¹² ECHA (2012): Communication on the safe use of chemicals: Study on the Communication of Information to the General Public. Available at https://echa.europa.eu/documents/10162/13559/clp_study_en.pdf

1. Awareness-raising activities are needed to enhance the general public's understanding of the new CLP labels. All the feedback in the context of this study indicates that the CLP labels (pictograms) are scarcely understood by the general public: only a few pictograms are recognised for what they actually symbolise and misunderstandings are clearly evident;
2. Awareness-raising activities need to address national hazard perception patterns and should be targeted at the general public, including specific groups and taking national differences in perception into account. All stakeholders involved in such communication and awareness raising activities, both industry and Member States, should share best practice (including joint training activities);
3. Awareness-raising activities also need to play on the emotional drivers of risk-related behaviour such as the use and storage of household chemicals, giving due consideration to the fact that safety behaviours are influenced by an experience-related rather than an information-based hazard perception; and
4. A new analysis of the impact of the CLP pictograms on EU citizens' behaviour and understanding will be needed after 2015 – the date by which new labels must have replaced the old hazard pictograms on all mixtures.

The recently published “Design and Validation (in accordance with ISO rules) of graphical symbols conveying certain safety warning messages to be used for child-care articles”¹³ also considers some of the issues related to consumer understanding of pictograms.

The study, investigating the perception of the general population and also experts in the USA, provided some useful insights. While it appeared that both groups have an equal understanding of the labels, the key finding of this study seems to be that the presence of pictograms has led to improved response rates and also increased the risk perception of the individuals taking part in the survey. The study examined consumer comprehension of graphical symbols which are used to convey certain safety or warning messages used for child-care articles. The aim of producing a graphical symbol is always that it should be comprehended without associated words and without specific education. Nevertheless, a conclusion of the study is that if a graphical symbol is not well understood, it may be necessary to provide explanatory text in simple language alongside the symbol as well as using manuals, instructions or training to inform people about the meanings of the graphical symbols.

It is also important to note that the effectiveness of any pictogram cannot be reviewed in isolation from the effectiveness of warnings in general (DTI, n.d.).

However, it also cannot be assumed, for example, that because a warning is provided, that consumers will modify their behaviour accordingly (Ayres *et al.*, 1989, in DTI, n.d.).

Despite the focus of the research on consumer understanding of pictograms, the issues of consumer understanding of other labelling elements, i.e. hazard statements and precautionary statements cannot be excluded. As can be seen from the above, when taking these literature review points into

¹³ Consumers, Health, Agriculture and Food Executive Agency (2015): Design and validation (in accordance with ISO rules) of graphical symbols conveying certain safety warning messages to be used for child-care articles: final report. Available at: <https://publications.europa.eu/en/publication-detail/-/publication/412f2e40-9d7a-11e5-8781-01aa75ed71a1/language-en>.

consideration and applying them to other aspects of a CLP label such as H- and P- statements, the implication is that for CLP, pictograms should be sufficient in and of themselves. Consumers should be able to understand them without associated words or specific education. Evidence from the EU barometer study and ECHA report suggest that this is not the case. However, the DG Justice and Consumers study also points out that “if a graphical symbol is not well understood, it may be necessary to provide explanatory text in simple language alongside the symbol [such as H- and P-statements] as well as using manuals, instructions or training to inform people about the meanings of the graphical symbols”.

As no research subsequent to the ECHA report has suggested that consumers have in the interim developed a comprehensive understanding of CLP pictograms, it could be assumed that the H- and P- statements included on labels of consumer products are of added value, and form an important part of consumer communications. However, further research into this would be needed to be able to determine the validity of this assumption.

A very recent study into safety information on household products has been undertaken by AISE (in June 2016) and a brief overview is presented here. This study focuses on labels on consumer products, particularly household detergents. The objective of this study is to explore consumer attitudes to safety information on labels, to evaluate the extent to which consumers read labels and to examine consumer reactions when they are asked to look at labels in detail. The methodology employed was qualitative research with one-to-one interviews being held with 30 individual participants in June 2016, 10 in each of Belgium, Spain and Poland. Each in-depth interview was for 1 hour and 45 minutes¹⁴. Participants were selected to represent relevant consumer profiles (gender, age, singles/couples, with/without children). The research also tested consumer approaches to assessing back label information and, as it appeared this is not something participants do automatically, a “forced deep dive” into the contents of the back label was included in the approach. Early findings from the study include (AISE, 2016):

- Except for people with very young children and those with slight skin problems, “safety” is not a key purchasing criteria;
- Very few consumers read back labels, though the incidence increases for new products;
- Label design impacts the attention paid to back labels (clarity, colour, structure, no overloading);
- Consumers appear to depend on intuition regarding risk and safety of these products, and personal network experience, though pack design helps signal power, danger or safety; and
- CLP pictograms and texts do not help distinguish levels of hazard or safety: the three pictograms most likely to be found on detergent products were tested (exclamation mark, corrosion, dead tree/fish) and consumers could not distinguish relative risk indicated by these symbols, with the impression that all information is similar and all indicate similar levels of hazard. It seems therefore that CLP is not helping consumers to differentiate between levels of safety based on pictograms and the hazards they are intended to communicate.

¹⁴ Note: because it is qualitative research, this is a limited survey, and is not statistically significant. To that extent it can be considered similar to a case study as opposed (for example) to an open public consultation or Eurobarometer Survey, which would be more statistically representative.

2.4.2 Understanding of GHS pictograms in the USA

In 2013, a team of researchers from the USA published a report on a study they undertook to assess how well certain groups of people understood the hazard information provided through Safety Data Sheets (SDS) or labels, focusing in particular on the understanding of the GHS pictograms (Boelhouwer E *et al.*, 2013) which are used for industrial and professional products in the US.


For the survey undertaken as part of the study, the subjects were divided into three groups: 55 'naïve' users (Auburn University engineering undergraduate students), 21 'workers' and 52 'experts'. It should be mentioned that the description of naïve users relates to the precondition of not being familiar with the subject of chemical legislation and hazard communication.

For this survey, the participants were given a questionnaire which covered physical hazards, precautionary measures, potential health effects, preventative actions, and personal protective equipment (PPE) assessing the labels for 12 different chemicals whose name was replaced with a letter to avoid bias (Boelhouwer E *et al.*, 2013).

The researchers found that, on the whole, the participants responded correctly to the survey material, with little variation. Overall, 89% of naïve users, 91% of workers and 92% of experts responded correctly to the survey questions. It was noted that "the presence of precautionary pictograms led to improved response rates to the survey items and to an increase in perceived risk rating by the participants" (ibid). This finding has been confirmed in a consumer perception survey of the irritancy label in which the researchers found that, with the pictogram alone, misinterpretation is reduced, but that when using pictograms and text together, that the risk perception increases significantly (AISE, 2006).

Differences between the US and EU CLP approach to hazard communication

In the US, GHS building blocks have been adopted and introduced for workers¹⁵, but not for consumers. In the EU, CLP applies to both workers and consumers. Clearly, industrial and professional users are given safety training which is not available to consumers. This means that given the same set of CLP (or GHS data) information, workers can be expected to have a level of comprehension of pictograms and hazard statements and the associated risks and safe use information that is not available to consumers. Take the exclamation mark pictogram for example. It is a common consumer product pictogram and can have 9 different meanings, contributing inevitably to consumer confusion as to what is meant by the pictogram on the label.

CLP Pictogram	General meaning and symbol name	Meaning
	<i>Health hazard</i> And/or <i>Hazardous to the ozone layer</i> Symbol: Exclamation Mark	May cause respiratory irritation May cause drowsiness or dizziness May cause an allergic skin reaction Causes serious eye irritation Causes skin irritation Harmful if swallowed Harmful in contact with skin Harmful if inhaled Harms public health and the environment by destroying ozone in the upper atmosphere

¹⁵ See Task 1 of the study report for details.

The literature review highlights that pictograms have the advantage of minimising the scope for misinterpretation; however, having nine possible meanings associated with one pictogram as in the example above is not likely to have a positive impact on consumer comprehension. The ECHA report lists this as one of the two pictograms EU consumers found difficult to interpret, and notes that while it is clear that the consumer should pay attention, it is not clear what they should pay attention to. This symbol does not meet the criterion of being “comprehended without associated words and without specific education”¹⁶.

2.4.3 Understanding of GHS pictograms in Japan

As the GHS system was adopted before the CLP Regulation came into force, studies on the perceptions of GHS are more readily available. For example, one study has evaluated the recognition of presently used UN-GHS labels in Japan (Hara K *et al.*, 2007). The results of this study are of interest as the previously used system of classification and labelling differs significantly to the GHS system (which did not require the use of pictograms). This means that the unfamiliarity of the Japanese population with hazard pictograms for chemical substances or products containing chemicals offers some clear insights into consumer understanding of pictograms.

The recognition test of the pictograms was administered to a variety of people from different backgrounds (students, company workers, researchers and other individuals) who had attended seminars or lectures provided by the research team on chemical risk management or the UN-GHS system (Hara K *et al.*, 2007).

It is interesting to note that less than 60% of the questions were answered correctly on the meaning of the labels (without any further statements) with the GHS pictograms depicting gas under pressure, corrosive, health hazard and environmental hazards. The participants in this study also struggled to understand the label when only a single word was provided (Hara K *et al.*, 2007, p.265). Difficulties understanding the meaning or differentiating the meaning of various labels appeared with the flammable pictogram and the oxidising/flame over circle pictogram, while other participants had problems understanding the exact meaning of the skull and crossbones (short term or acute toxicity) and the health hazard pictogram (warning of long-term chronic toxicity) (Hara K *et al.*, 2007). The lack of understanding of certain symbols and the related meaning was confirmed by the AISE 2006 consumer perception survey which stated that “people have problems differentiating between terms such as ‘toxic’ and ‘very toxic’ or ‘harmful’ and ‘irritant’.

2.4.4 Understanding of GHS pictograms in Switzerland

In Switzerland, the introduction of the GHS system was aligned with the European implementation of CLP because despite not being a member of the European Union, Switzerland has close economic ties with the EU (the EU being Switzerland’s largest trading partner)¹⁷. In Switzerland, the orange

¹⁶ Consumers, Health, Agriculture and Food Executive Agency (2015): Design and validation (in accordance with ISO rules) of graphical symbols conveying certain safety warning messages to be used for child-care articles: final report. Available at:

<https://publications.europa.eu/en/publication-detail/-/publication/412f2e40-9d7a-11e5-8781-01aa75ed71a1/language-en>

¹⁷ European External Action Service (n.d.): EU relations with Switzerland. Available at: http://eeas.europa.eu/switzerland/index_en.htm

pictograms were introduced in 2005 replacing the so-called toxicity classes that were used to communicate the hazard that is associated with certain products or substances (BAG, 2009).

In this study, the general remarks on awareness and knowledge of hazard communication tools in the form of pictograms and phrases can be relevant to this assessment. The study is composed of three parts which are made up of a literature search and explorative conversations with experts, in-house research with behaviour observations and a representative online consultation.

When assessing the perception of the hazard pictograms, a division between passive perception of the consumer (the symbol had been noticed) and active perception (the information has been searched) was applied.

In the consumer perception survey on household products it emerged that “consumers read labels more when the product area is deemed to be more potentially risky” which was confirmed in the consumer perception survey undertaken by the International Association for Soaps, Detergents and Maintenance Products (BAG, 2009; AISE, 2006). The question on the recognition of symbols showed, through the in-house assessment, that symbols with the skull and the flame were recognised by almost all participants. The symbol ‘corrosive’ was recognised by half of the participants while the symbol ‘environment’ recognised by a quarter of the participants (BAG, 2009). The online consultation focusing on the difference of people’s perception revealed that younger people are more familiar with the symbols and that more men know the symbols for ‘corrosive’ and ‘environment’.

Another interesting aspect of this study was the question of design and layout referring to the position of pictograms on the product. The results of the literature search provided that labels attract attention if they are written in big, bold letters, colours, boundaries/contrasts, pictograms. The explorative conversations confirmed that users are more conditioned to pay attention to written communication and the in-house research showed that the bigger the symbol, the higher the likelihood that it will be noticed (BAG, 2009, p.14).

With regards to general interpretation/understanding of the hazard symbols, the literature search showed that symbols are better understood if they are not abstract and if the message is further specified through details. Through the explorative conversations it was discovered that the symbols poisonous (the skull and crossbones pictogram), flammable and corrosive are understood intuitively. The symbol for irritant (the St. Andrew’s cross pictogram which has been replaced with the exclamation mark) and the one for hazardous to health (also the St. Andrew’s cross) were not understood well. It has been noted that the fact that there are two meanings for this symbol adds to the confusion. This is relevant for the analysis of the GHS/CLP symbols because as was shown above, the exclamation mark refers to nine different health hazards.

The main result from the general interpretation/understanding of the hazard symbols has been summarised as “abstract symbols and descriptions are not as easily interpretable as concrete pictures” (BAG, 2009).

2.4.5 Understanding of GHS pictograms in the Netherlands

Although the following study was submitted as a Master’s thesis, the research objective of this study fits well with this assessment investigating the perception of warning symbols, in particular the CLP pictograms, on household chemicals. The research question of this thesis, which was commissioned by the Netherlands Food and Consumer Product Safety Authority (NVWA) [Nederlandse Voedsel- en Warenautoriteit], was as follows: “how do consumers respond to the risk and warning information on household chemicals, what role do message-, product-, personal- and situational factors play and

how can the label design make a positive contribution” [to the safe use of these products by the consumer]¹⁸?

The study first presents the GHS symbols and then moves on to an experimental study on the design aspects of warning labels of household chemicals in general. This study builds upon the results of a research project from Milieu Centraal and the communication and advice consultancy Schuttelaar & Partners which was commissioned by the NVWA to develop a consumer information strategy in 2008 (Van Bussel K, 2008).

One chapter of the theoretical section of this thesis addresses the message factor of the label form and how this can contribute to a warning effect. It provides some useful insights and confirms some of the points raised in the previous studies reviewed above. With regard to understanding, the author deduced (from academic literature) that design characteristics (such as font size, colour and the shape of the signal word) influence crucial variables, such as people’s understanding of warnings (Van Bussel K, 2008, p. 12). The chapter with the greatest relevance analyses the perception of the symbols themselves for which the author screened the relevant literature. At the time the Dutch research was undertaken, there had been only a few studies which focused on GHS. The author utilises four studies which had been undertaken on behalf of the United Nations Institute for Training and Research (UNITAR) in Africa (South Africa, Gambia and Zambia) and in Asia (Philippines and Thailand) (Van Bussel K, 2008).

With regards to the understanding of the symbols of the pictograms the author drew the following conclusions (Van Bussel K, 2008):

- The presence of symbols increases the consumer’s attention to a warning;
- Research into the comprehensibility of the symbols showed that they are not generally understood;
- The visibility of pictograms on the labels impacts the extent to which they are remembered, the extent to which the pictogram is perceived to represent the risk, the perception of the extent to which risk is communicated in an understandable fashion, as well as the communicative competence and capacity of the pictogram; and
- Symbols are key for the information on risk. Risk perception arises from: the understanding of the pictograms, the virtual meaning of the pictogram, the relationship between the pictogram and the meaning, and the relationship between the perceived risk and the danger [portrayed] in the pictogram.

Specifically related to the GHS/CLP symbols, the author concluded the following points which are similar to some degree to the previous studies mentioned in this case study (Van Bussel K, 2008):

- The toxic symbol and the flammable symbol are the symbols which are understood best;
- The oxidising symbol and the corrosive one are not well understood; and
- The new symbols “gas under pressure” and “serious health hazards” are not well understood.

¹⁸ Original in Dutch: Hoe gaan consumenten om met risico- & waarschuwinginformatie op huishoudchemicaliën, welke rol spelen boodschap-, product-, persoonlijke- en situationele factoren hierbij, en hoe kan labelontwerp daar een positieve bijdrage aan leveren?

2.5 Product-factors and location of purchase

This part of the desk research for this case study addresses people's perception of the product itself and the relationship to hazardous properties of the chemicals in that product. This is a factor that has been mentioned in many assessments of people's risk perception and relates to people's familiarity with a certain product. The Eurobarometer Survey (Eurobarometer, 2011) also investigated the question of whether people feel well informed or poorly informed about particular consumer products and whether they actually read the label when buying a product.

Regarding the first question, the respondents were asked how well informed they feel they are as regards the potential risks of everyday detergents such as washing powder or washing up liquid. Slightly more than half (53%) of the respondents stated that they feel moderately well-informed about the potential risks, while 34% responded that they feel well informed. Just 11% of respondents admitted that they feel poorly informed.

Respondents were asked whether they read the safety instructions of different consumer goods. They were asked about everyday products like washing powder or hand washing up liquid but also about more dangerous products such as drain cleaners or oven cleaners. The results of the survey (presented in Figure 2-1) show that, in most countries, about half the respondents read the instructions in full, while another large percentage of respondents read the label partially.

Regarding other cleaning products, such as drain cleaners and oven cleaners, half of the respondents claimed that they felt moderately informed about these kinds of products while 28% said that they are well informed and 12% admitted that they are poorly informed. For these types of products, it appears that the number of respondents who do read the label is better than for everyday cleaning products (as indicated in Figure 2-2) and, in some ways, corresponds to the consumers' perceptions of the hazards of the product.

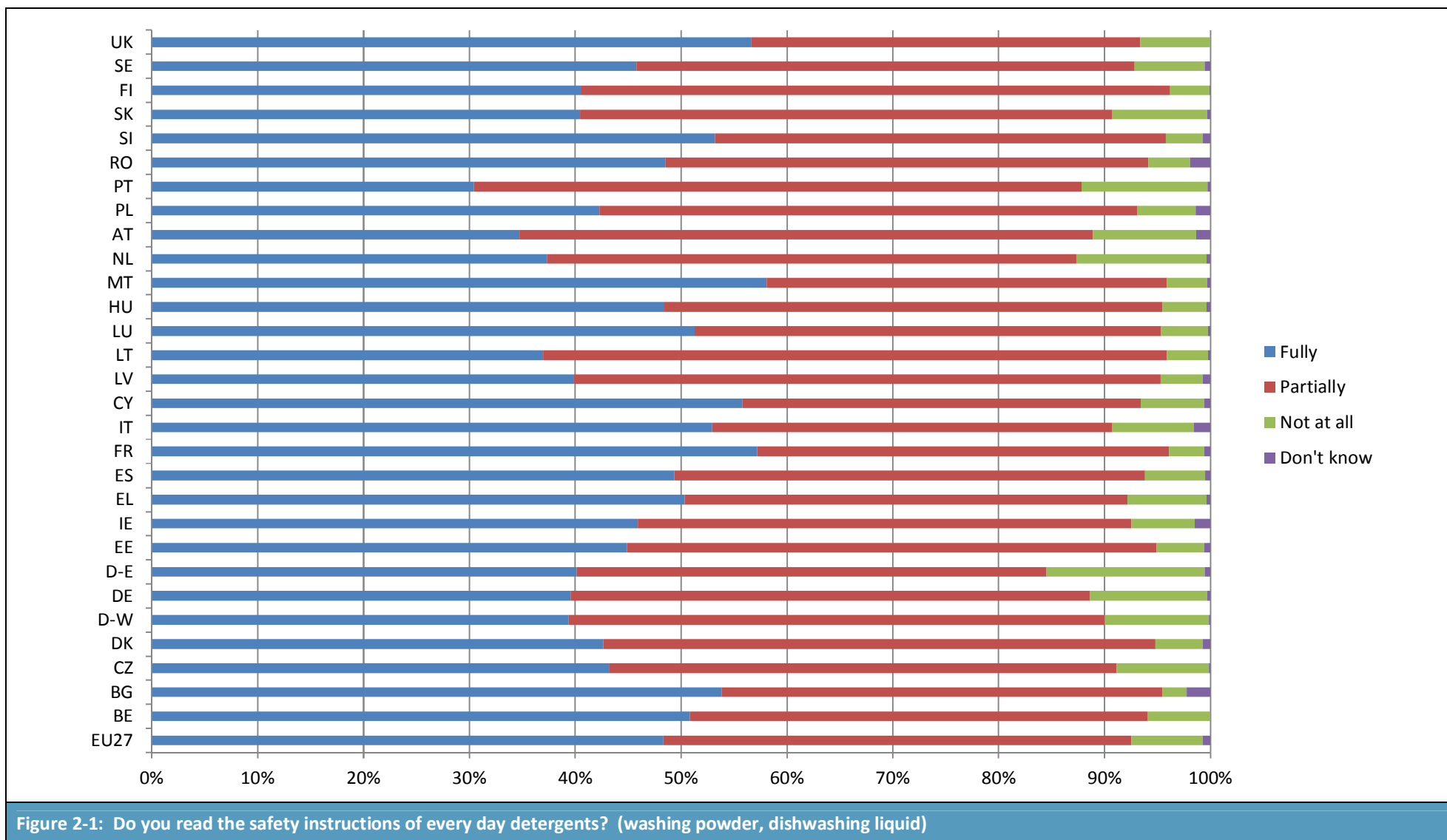




Figure 2-2: Do you read the safety instructions of other cleaning products? (oven cleaner, drain cleaner)

When looking at reports from poison centres, child consumption of a household cleaner or medicine is the most commonly reported accident (Deutsches Ärzteblatt, 2014). One reason which has been provided is that the design of the cleaners makes them look more like toys than something hazardous (e.g. because the containers are brightly coloured). In 2015, an experiment was undertaken in the Netherlands to investigate what a toddler chooses if offered a choice between a softly coloured toy and a brightly coloured household cleaner container. From this experiment, it emerged that 51% of the toddlers reached for the household cleaner rather than the toys¹⁹. The Netherlands safety foundation has also published an interactive website in which parents can undertake the same test virtually²⁰.

Another reason why accidental poisoning occurs is that people are familiar with the products they use safely regularly and therefore do not suspect that they could pose a danger. This low risk perception of every day/familiar products was confirmed in the AISE consumer perception survey, in the Swiss study and the Dutch Master's thesis. Most people keep their household cleaners under the sink or have the dish washing liquid next to the sink. Some household cleaners are used every day and also washing powder is used without thinking much about its hazardous properties. On the other hand, when the product is a less familiar product such as paint then consumers might pay more attention to the label. Recent research by CEPE indicated that 91% of DIY product consumers read the labels²¹, it has also been pointed out that because of the CLP labelling requirements, the label of a typical paint product contains more pictograms which in turn could discourage the consumer to purchase the product. This means that the same product could contain more pictograms alerting the consumer of a hazard while the formula of the product has not changed (CEPE, 2014).

This familiarity, and the corresponding lack of hazard awareness, has been investigated and it has been observed that the more familiar people are with the product, the less hazardous they perceive the product to be (Van Mussel, 2008). The consumer perception survey confirms this point finding that "long familiarity with the product category and/or brand and the experience of safe use" leads to a low risk perception of these products (AISE, 2006). Most consumers will read the label on a product that is new or perceived as being hazardous; labels on products that are familiar or which are not perceived as being hazardous are far less likely to be read. Indeed, Wogalter *et al.* (1986) found that perceived hazard level was the primary factor in determining whether or not a warning is likely to be read. This means that consumers are far more likely to read the label on the package of medicine than the label of the dish washing liquid (AISE, 2006).

These findings were confirmed in the Swiss study in which familiarity was a separate point that had been assessed. The question was similar to the Dutch Master's thesis, explained above, focusing on people's risk perception of a familiar product and the location from where it is bought. Information from literature review and explorative conversations confirmed that the better the consumer knows the product, the less the attention paid to the warning (advice or symbol) on the product (BAG, 2009). This has been explained as a psychological mechanism - over time, people become more familiar with certain actions and products and build up experience with them, people do not think

¹⁹ VeiligheidNL (2015): Helft jonge kinderen verkiest huishoudchemicaliën boven speelgoed [half of young children chose household chemicals over toys]. Available at:

<https://www.veiligheid.nl/organisatie/actueel/nieuws/jonge-kinderen-huishoudchemicalien>

²⁰ Gaaf of Gevaarlijk (n.d.): Gaaf of Gevaarlijk [Nice or nasty]. Available at: <http://www.gaafofgevaarlijk.nl/desktop.html>

²¹ Information obtained during stakeholder interview.

about routine actions. This lack of interest in reading labels has been deemed problematic when 'perceived familiar' products (e.g. from commercials or similar products) are used in the known way although they have to be applied differently (BAG, 2009). A survey undertaken for the Detergents Association found out that only 20% of consumers always check the safety symbols before purchase and that 36% never or rarely check the safety symbols before purchase which confirms the general findings on consumer awareness in other studies (AISE, 2006).

Another factor that contributes to the risk perception of a product is the location of the purchase. In Switzerland, as well as in many other countries, certain products which are especially dangerous (e.g. corrosive, toxic) cannot be bought in retail stores but can only be bought in specialised stores. However, there are still many other hazardous products which can be bought freely in a supermarket (e.g. drain cleaners). In the Eurobarometer Survey, 11% of respondents indicated that the type of shop where the product comes from is a factor that informs them about its possible hazards (Eurobarometer, 2011, p.25). Because of this distinction of location of purchase, consumers are more cautious with products which have been bought in specialised stores, perceive them as being more dangerous and handle them with greater care. This was confirmed in the Swiss study, in the explorative conversations, the in-house research as well as through the online consultation (BAG, 2009).

3 Key Themes

3.1 Overview

From the interviews with stakeholders, several themes have arisen relating to issues with consumer understanding of hazard communication. These include: discussion of consumer understanding of pictograms and hazard communication more widely; aspects of the current system which work well to communicate hazards; what information is essential for inclusion on a label; whether labels are clear; over-labelling; safe use icons; the potential role of technology in hazard communication and other ways to improve hazard communication to consumers. These themes are discussed in detail in this section, drawing on both input from stakeholders and desk research. Where possible, data from the various data collection exercises are also used.

3.2 Consumer awareness and understanding of pictograms

3.2.1 General understanding of pictograms

As described in section 2.4 above, the literature review indicates that understanding of CLP pictograms in the EU varies for the different pictograms. Only 11% recognised that the exclamation mark warns of possible skin irritation (Eurobarometer, 2011). However, the flammability symbol was almost universally understood (91% of European respondents correctly interpreted the meaning of this symbol. The lowest level of correct interpretation for this symbol (Romania) was still 72% (Eurobarometer, 2011).

During research for this case study, it was noted that consumer understanding of pictograms and labels seems to be increasing but that this may be due to greater efforts by NGOs and increased information in the media which have raised consumer awareness, rather than CLP. It was also noted that consumers are becoming increasingly more interested and aware of the chemicals used in everyday products they use.

Yet several stakeholders stated that the CLP pictograms and labelling requirements are not clear to consumers as they were not designed specifically for consumers and as such, their suitability for use on consumer products was questioned. (Across all stakeholder groups participating in this study, including Member States and industry, the majority of respondents viewed the effectiveness of CLP in communicating to consumers to be less than in communication to workers – see also Annex II on the results of the Open Public Consultation).

There is concern that, because pictograms were not designed exclusively with consumers in mind, their presence on consumer products is devalued and consumers do not pay attention to them. It was pointed out that poison centres are concerned by this “banalisation” of the CLP pictograms in terms of effective consumer hazard communication.

Table 3-1 details Member State responses to a series of questions regarding the effectiveness of labelling requirements under CLP and other legislation in terms of consumer understanding and communicating hazards and risks to consumers, workers and professional users. There are clear differences in opinion across Member States regarding the effectiveness of hazard communication, particularly to consumers. For instance, 9 out of 13 (or 69% of) Member States who responded either agree or strongly agree that the information requirements for labels are necessary and appropriate, yet only 6 out of 13 respondents (46%) agreed that consumers understand the CLP

pictograms information provided on labels. Nevertheless, 69% of Member States think that current labelling requirements are necessary and appropriate, with 60% against any reduction of labelling requirements to the most important information only.

Table 3-1: Member State perspectives on consumer comprehension of labelling information (Please indicate whether you agree or disagree with the following statements, with respect to labelling under the CLP and other legislation such as the Plant Protection Products Regulation, Detergents Regulation, Biocidal Products Regulation, Aerosols, etc.)					
Statements	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Consumers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals (n = 13)	0%	46%	23%	31%	0%
Consumers understand any additional voluntary industry icons that are included on products (e.g. cleaning products, plant protection products, biocides) (n = 12)	0%	8%	67%	25%	0%
Some of the CLP hazard pictograms are misrepresentative or misleading of the actual hazard (n = 13)	0%	69%	0%	31%	0%
The information currently required to be included on labels is necessary and appropriate (n = 13)	15%	54%	8%	23%	0%
A reduction in labelling requirements to provide only the most important hazard information on the label may be appropriate, if additional information is available as part of use instructions (n = 15)	0%	40%	0%	47%	13%
Consumers generally do not look beyond the label for hazard information and information on safe use (n = 14)	36%	43%	14%	7%	0%

3.2.2 Comprehension of particular pictograms

As described in Section 2.4.1 above, survey data from 2011 demonstrated that there are varying levels of understanding for the different pictograms. A particularly low level of understanding was identified for the exclamation mark, with only 11% recognising that it can warn of possible skin irritation (Eurobarometer, 2011, p. 11). This can be contrasted with the views of stakeholders.

Stakeholders identified particular pictograms that are believed to be confusing to consumers. These include: environment ('hazardous to the environment'), 'serious health hazard' and the exclamation mark ('health hazard and/or hazardous to the ozone layer'). Several stakeholders pointed out that the corrosive pictogram is not suitable for conveying hazard information about eye damage.

The corrosion symbol which means "causes severe skin burns" and which may be found on a hand washing up liquid is potentially confusing to the consumer as clearly the vast majority of users will not experience skin burns from using this product. Although the presence of this symbol on hand washing-up liquid may well be due to the issue of the potential over-classification of mixtures (due to the mixture classification rules or to concentration limits), its presence on a consumer product

which manifestly does not cause severe skin burns is not likely to aid consumer comprehension or confidence in pictograms and safety information on labels²². This can result in consumers ignoring the pictograms as the meaning is not clear and they do not provide safe use instructions that are appropriate and fit for purpose.

The ‘hazardous to the environment’ was considered to be confusing in terms of consumer comprehension, with stakeholders reporting that the actual hazard represented by this pictogram is not clear (some people think the product is hazardous for people). More importantly, it is difficult for consumers to understand why a biodegradable product is labelled as having chronic toxicity for the environment. Therefore, while consumers may intuitively understand the meaning of the environment pictogram²³, they may not understand its application or use on a label of a biodegradable product, for example.

Conversely, it has been suggested that it does not matter whether the consumer understands the pictogram or not, it is the presence of the pictogram that will signal to the consumer that they need to take precautions when using the product. The ECHA study reported that pictograms are perceived to indicate a hazard, but because the understanding of the meaning of the various pictograms is limited, it is the general features of CLP symbols rather than the specific meanings that are decisive to the perception of hazards.

3.3 Consumer understanding of label information other than pictograms and icons

3.3.1 Essential information versus over-labelling

It is important that consumers read the labels to ensure safe use. However, consumers may ignore labels with too much information. This is a concern for industry and some Member States as, under CLP the burden of text (such as multiple P-statements) combined with multiple languages can lead to information overload on labels. This is not optimal as it can result in diminished consumer attention to label information and therefore have a (potentially) detrimental impact on achieving the goals of safe use.

In principle, from a consumer perspective, the more information on the label, the less likely it is to be read, and repetition leads to confusion. Most stakeholders interviewed agree that the hazard information on labels on consumer products should be kept as simple and concise as possible as over-labelling can cause confusion.

In addition, it is widely suggested that the information included on consumer product labels and the language used for these ought to differ from that which is used for labels on chemical intermediates or professional products. Labelling for consumers does not need to be as technical as it is for those working in the chemicals supply chain.

Other stakeholders have recommended that there should be a maximum number of statements on the label. One stakeholder has suggested that it would be optimal to restrict consumer product

²² It should be noted that this does not mean that this pictogram (a metal rod plus hand) would not be comprehended on other products which are corrosive, such as drain cleaners).

²³ As established in the Eurobarometer Survey

labels to “a few pictograms, a warning symbol to say read the label and a QR code (or similar digital medium) for additional information in all languages”. The use of technology to avoid over-labelling was also supported by another stakeholder; this is discussed in Section 4. Another stakeholder recommends using colour on the label and having safety instructions listed in one sentence in the national language of the market in which the product is being placed. However, this would have negative consequences for producers who place products in multiple Member States.

The use of safe use instructions is widely recommended across stakeholders who believe this would be a more effective way to communicate hazards to consumers. Some stakeholders argue that safe use information, as provided on cosmetic products for example, is more effective than the hazard information provided on products labelled according to CLP. For example, the use of a cosmetic product is clearly known and safe use information for consumers is valuable because it is targeted to that specific use whereas hazard information is not. For consumer products where the end use is known, it can be better from a consumer communication perspective to provide targeted safe use information on the label rather than hazard information.

3.3.2 Issues relating to consumer understanding of label elements other than pictograms/icons

This sub-section provides an overview of information on consumer understanding of other aspects of labelling besides pictograms, as obtained from interviews with subject-matter experts for this case study. This information was provided mostly in response to specific evaluation questions which can be found in the Roadmap and which are relevant to this case study.

As has been noted in the literature:

- Consumers are more likely to read the labels of products they do not use regularly (such as paints or biocides, for example);
- A limited number of messages on a label works, as do simple instructions on how to use the product;
- There is a lack of consistency of consumer communication. Some of the warnings and pictograms may not be effective in communicating to users about what to do, as they focus on what not to do, for example: “do not dispose of ...”;
- There are issues around labelling consumer products under multiple legislations, such as CLP and the Detergents or Plant Protection Product Regulations (for garden pesticides for example) due to similar precautionary statements or double ingredient listing leading to duplication and redundancy;
- Safety information needs to be clear and consistent for detergent or biocidal products or any downstream legislation. Clarity and simplicity are key. Stakeholders noted that if all labelling were consistent with CLP, this would ensure a single common way of safe use messaging;
- If the use is known (which is the case with consumer products), it is better to provide targeted risk information rather than hazard information. On the other hand, where the end-use is not known, harmonised hazard information can be a good surrogate for risk information; and
- As regards the use of P-statements, CLP limits the label to including only the six most relevant statements; an issue arises in that different Member States have their own views on which are the most relevant P-statements, leading to different labels for the same product in different MSs and therefore to inconsistent consumer communication, which may impact on consumer understanding.

One best practice example on the labelling of consumer products comes from the UK where the competent authority regularly surveys human health related reports or enquiries involving consumer garden products. The UK competent authority extracted key information for these products which has to be included on the labels (e.g. information on when and how to use the products). In identifying key information, the authority took an average reading age of 12 into account and also found most people read the “how to use” part of the labels on these products. The UK authority then undertakes a regular Human Health Enquiry and Incident Survey²⁴ which surveys all authorised products and requires all authorisation holders “to provide the Chemicals Regulation Directorate of the Health and Safety Executive with details of all human health related reports or enquiries involving their products, which were received from users or any other source”, including emails, letters and phone calls, during the year under review. The reports on this survey in relation to consumer garden products indicate that labels on these products are effective in communication terms.

Another best practice example on non-pictogram text included on a label is found in the UK, where there used to be around 200 deaths a year from volatile substance abuse (VSA), with aerosols a potential contributing factor. The numbers have now dropped to around 50 a year. Under a voluntary initiative, industry uses the so-called SACKI statement (Solvent Abuse Can Kill Instantly) to warn consumers of the potential danger. This illustrates that carefully selected text can make a positive contribution to the safe use of products by consumers. There is less consensus that H- and P-statements designed originally for workers are also effective in terms of consumer communication, as there is no research on this aspect.

3.4 Inconsistency across legislation

Several stakeholders have noted that there are overlaps and inconsistencies across different sets of legislation which create unnecessary burdens and even hinder the effectiveness of hazard communication to consumers.

One example of overlap is between pesticides legislation and CLP: the equivalent statement for “keep out of reach of children” in pesticides is “keep products away from children and pets” and both statements are required on the label and in different areas; these are very similar statements. Another example of this kind of overlap across legislations is the labelling requirements according to CLP, which are repeated in the Aerosols Directive. This is considered unnecessary and may lead to inconsistencies.

Member States were asked whether they consider the labelling requirements under other legislation to be effective in terms of communicating hazard. The responses to this question are given in Table 3-2 below.

²⁴ Health and Safety Executive (2015): Human Health Enquiry and Incident Survey (HHEIS) and Resistance Reporting 2014. Available at: <http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/enforcement/hheis-survey-2014.htm>

Table 3-2: Member State perspectives on effectiveness of labelling requirements under other legislation (Question: In your opinion, are the labelling requirements under the different legislation effective at communicating hazards and risks to workers, professional users and consumers (i.e. are the labels sufficiently clear to consumers to ensure that hazards/risks are understood)?

Legislation	Ineffective	Neutral	Effective	Don't know
Regulation (EC) No 1223/2009 on cosmetic products (n = 13)	46%	8%	31%	15%
Regulation (EC) 648/2004 on detergents (n = 13)	15%	8%	61%	15%
Council Directive 75/324/EEC on aerosol dispensers (n = 9)	0%	0%	67%	33%

Only four out of 13 respondents (31%) believe the labelling requirements for the Cosmetics Regulation are effective, with six (46%) stating it is ineffective. Member States were generally more positive about the labelling requirements under the Detergents Regulation and the aerosols legislation.

As part of the remit for this case study, a number of stakeholders from different sectors were interviewed to give their views on consumer understanding of pictograms and labels. Detergents are discussed in more detail in case study 5. Some of the key points made for various sectors of the consumer market are detailed below.

3.4.1 Detergents

For detergents, the key outcome of classification of mixtures is the labelling of consumer products. However, consumer detergent products are also subject to (different) labelling requirements under the Detergents Regulation. The various requirements of labelling under CLP and the Detergents Regulation (DR) are considered to lead to complex labels, the inclusion of unnecessary or irrelevant information, provision of confusing data (some duplicate data such as ingredients and composition) or too much information for consumers and are not seen to be effective in communicating safe use or other essential information (the number of languages adds to the complexity). Due to lower thresholds under CLP than under the Dangerous Preparations Directive, known and trusted consumer products previously not labelled as hazardous may now have a hazardous label, causing further consumer confusion. While stakeholders perceive the value of harmonisation being a key aim, in practice in just about every country there are big or small differences in implementation which have to be taken into account. Part of the issue is that enforcement is local. So if an auditor in one country thinks something different than the auditor in another country, companies must comply and label their products accordingly, leading to different labels for the same product and therefore reducing harmonisation of communication to consumers²⁵.

3.4.2 Paints, inks and coatings

The paints inks and coating sector is highly involved in producing consumer products which must be labelled under CLP. Multiple languages are needed on packaging for low volume high value products such as artist's colours, where labelling is problematic due to package size; it might be preferable to confine information to pictograms and one or two H-statements, combined with a Q-R code and/or short URL for the rest of the information. The more text required, the smaller the text and the less

²⁵ For further details on detergents and examples to illustrate issue encountered, please see the Detergents case study.

likely it is that consumers will read it. Where labelling under multiple legislations e.g. biocides and CLP, sensible consumer communication should be the focus rather than just compliance.

There was a survey in 2015 of the DIY painting sector; about 91% are aware of safety instruction on labels. So these consumers do look at labels, possibly because these are not every-day use products and consumers therefore perceive a greater need to check on safe, and correct, use.

Classifications and labelling have changed under CLP. For example, in the case of printing inks, water-based ink is now labelled with a corrosive pictogram (due to a serious eye damage, H318 classification), despite the product's formulation not changing.

It was also noted that there are concerns for in-can preservation needed to protect water-based paints; 80 - 85% of decorative paints are water based, so they need preservatives, which means the Biocidal Products Regulation²⁶ is relevant to this sector. The biocide review program does not take account of the issue of in-can preservation in a holistic manner; it looks at individual substances case by case without considering the potential impact. There are no thresholds in the Biocidal Products Regulation for skin sensitisers. CLP requires warnings for skin sensitisation, but the Biocidal Products Regulation does not want skin sensitisers sold to consumers. This creates issues for water-based paints. It could lead to only professionals being allowed to do painting of houses, to the detriment of consumers. For the paints sector, the Biocidal Products Regulation is the main focus, rather than CLP.

3.4.3 Pesticides

Another sector that faces issues with labelling consumer products under various regulations is the garden products (e.g. pesticides) sector. The main labelling is under the Plant Protection Products Regulation²⁷, and the primary hazard classification system is CLP. Even if not classified under CLP, there are specific H phrases for pesticides which are compulsory. This is fine in principle though, as suggested by some stakeholders, these may not generally be understood by consumers. There can be an issue of the use of similar precautionary phrases being used between the pesticide guidance and CLP, leading to some duplication and redundancy. Generally the products would not have classification above Category 2 skin and/or eye irritant or Category 4 acute toxicity. Because the products themselves are safe, the focus on the labels is on safe use.

3.5 Raising the awareness of consumers on safe use of products

3.5.1 Technology and its potential role in hazard communication

The possibilities of using new technologies to complement labelling of consumer products are becoming increasingly apparent. In general, there is consensus amongst the stakeholders interviewed that new technologies offer a real opportunity to facilitate improved consumer communication, albeit with a number of provisos such as the continued obligation to include pictograms and safety and hazard information on labels. Examples of comments made include the

²⁶ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

²⁷ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

belief that websites and other such digital media would allow a different way of communicating with consumers. Additionally, one stakeholder said that the use of QR (Quick Response) codes would enable the functioning of the single market as it would provide an efficient communication system across all languages. Another suggested that consumers are probably ready for it but the regulators may not yet be.

However, it is not recommended that technology completely replaces the information on product labels: the use of technology is intended to perform an auxiliary function, providing additional information to those who want to know more. One stakeholder has said that certain information, such as ingredients and safety information, must still be on the label on the product and that consumers must not be obliged to look for this type of information themselves. Another stakeholder believes that the use of technology should enable a simplification of the label; they further state that it would not be beneficial if the current requirements for labelling remain with the additional obligation to provide a QR code.

The majority of Member State respondents considered that consumers would not look for safe use information if it is not on the packing, and a number agreed that innovative approaches should not be adopted until proven. It was also noted that the effectiveness of mobile phone or tablet apps (applications) to disseminate safety information to consumers should be readily assessable. In this respect, it was recognised that individuals learn and understand through different methods and that younger people are likely to be far more open and responsive to innovative use of latest technologies. The differences in demographics are, therefore, a factor which needs to be considered when considering the increased dependence on technology for hazard communication to consumers. As a result, one stakeholder commented that a campaign or strategy to encourage consumers to make use of these technologies ought to be developed alongside the technology, especially, as another stakeholder commented, consumers do not always check online for product information even if it is available and so this would need to be encouraged.

The general consensus amongst stakeholders is that new technology is welcome for hazard communication provided that it is at least as effective as the current measures, and that, until they prove to be widely available and standardly used by consumers, they must only be used in a complementary manner and not as a replacement to the current measures.

3.5.2 On-line purchasing

An EU trend which is relevant to current considerations on consumer comprehension of labels is the acceleration in digital purchasing. Consumers are increasingly buying products online (from within the EU and outside of it). This means that Member State-specific labelling requirements (e.g. the label language) may not effectively communicate hazards to consumers who do not live in the same Member State as the supplier of their online purchases of consumer products. This in turn suggests that greater consistency in interpretation of labelling requirements throughout the Member States would be needed to ensure consumers across all Member States are adequately informed of safe use and are able to comprehend the information on the labels of any product they purchase. It is likely therefore that innovative technologies will have an increasingly important role to play in the digital market for consumer products that carry a CLP label.

3.5.3 Voluntary safe use icons

The detergents sector is the most prominent proponent of the use of safe use icons, having a voluntary initiative for safe use icons to be used alongside CLP pictograms on detergents products. While some Member States and some SMEs commented that these voluntary icons are not

particularly clear, other stakeholders have commented that, when used, safe use icons are effective in communicating hazard to consumers. This finding was confirmed in the recent AISE survey (AISE 2016) which found that consumers are familiar with safe-use icons and that these are understood by consumers to relate to usage rather than hazard and/or risk.

The detergents sector safe use icons are illustrated in Figure 3-1 below.

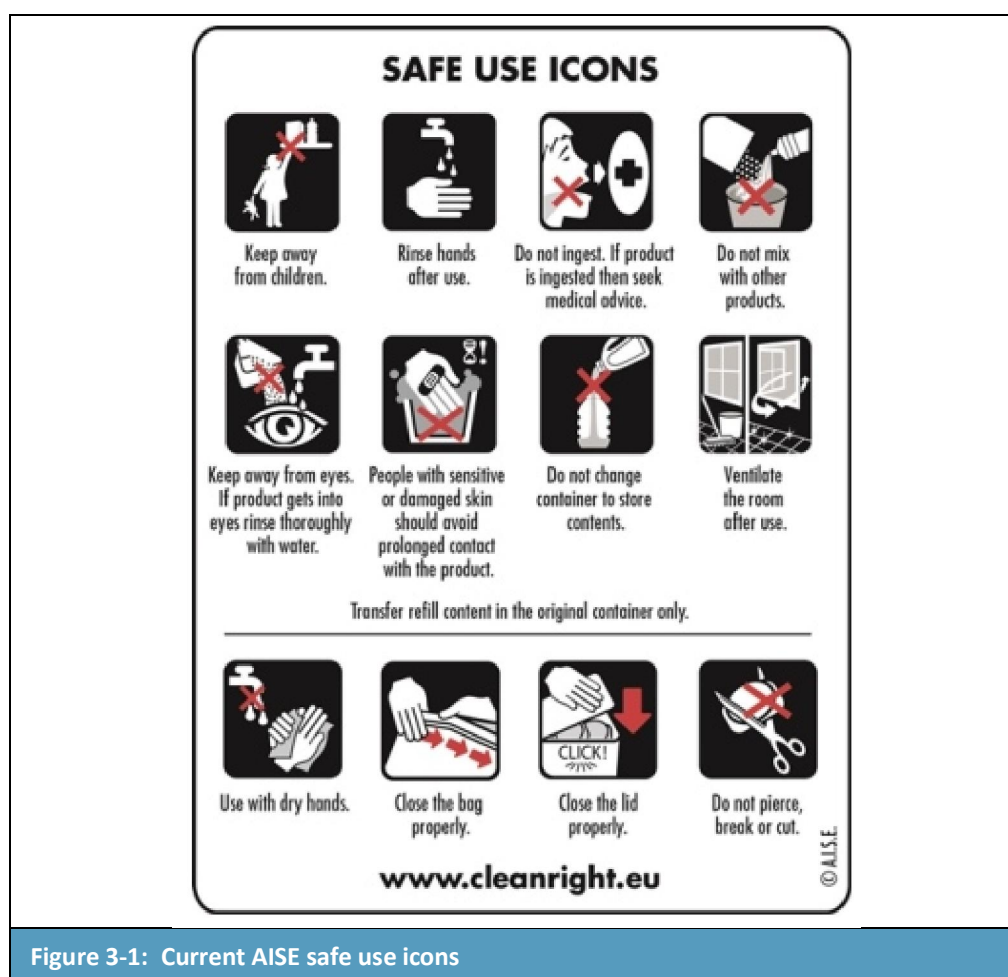










Figure 3-1: Current AISE safe use icons

AISE's original safe use icons were introduced in October 2005, and today are used on the majority of the detergent and maintenance products placed on the market by the industry in Europe. As part of their introduction, it was agreed to evaluate their "non-verbal effectiveness" after five years. In 2010 internet research was undertaken in five big European countries to assess the level of understanding of these icons without words. One hundred consumers in each country were shown each icon and asked to assess if they knew what it meant. The key results of this survey are summarised in Table 3-3.

Table 3-3: Consumer understanding of original AISE safe use icons

Level of understanding	Safe use icons
Extremely well understood >90% got it right or were close >80% got it exactly right	 
Well understood > 80% got it right or were close > 65% got it exactly right	   
Poorly understood ²⁸ <70% got it right or were close <40% got it exactly right	 

Not all stakeholders agree that safe use icons would be a better alternative to the CLP hazard pictograms. For instance, some Member States reported concerns about safe use icons, including that in some cases they felt that the icons were misleading and at first sight appeared to give the opposite warning to the CLP pictograms. Other issues were raised relating to the prospect of using safe use icons in addition to the current CLP pictograms and labelling requirements: if both systems of hazard communication are used, along with marketing information, there is a danger of overloading the label which may result in consumers ignoring or misunderstanding the information. There is also the danger that the safe use icons may divert attention away from the CLP pictograms as they are larger.

Encouraging the use of safe use icons may undermine the purpose of CLP: to harmonise hazard communication across sectors and Member States. This would not only lead to confusion for consumers but it could also cause problems for industry who may not understand their obligations in terms of pictograms. Furthermore, it may not be an efficient use of resources – it may be better to spend time and money on raising consumer awareness of the current set of CLP hazard pictograms, rather than encouraging the development and use of industry safe use icons.

3.5.4 Member State programmes to enhance consumer awareness

Educational campaigns aimed at consumers, explaining the meanings and significance of the pictograms and label information are of benefit to consumer comprehension. Member State activities to educate and raise awareness of consumers about labels and pictograms are varied and in some cases, creative and innovative. Research and input received for this study indicate that recent and/or relevant Member State activities include the following.

The Netherlands

In 2015, an experiment was undertaken in the Netherlands to investigate what a toddler chooses if offered a choice between a softly coloured toy and a brightly coloured household cleaner container. In the experiment, the children's eye movements were tracked to identify what they were focusing on. In the accompanying video, the reason for the children's choice can be seen very clearly when looking at the products and how brightly coloured they are. From this experiment, it emerged that 51% of the toddlers reached for the household cleaner rather than the toy. The Netherlands safety

²⁸ These have been subsequently redesigned to improve consumer comprehension.

foundation has also published an interactive website in which parents can undertake the same test virtually.

The Netherlands Food and Consumer Product Safety Authority (NVWA) ran a label lottery in 2013 with the aim of increasing consumers' awareness and understanding of the safety information provided by labels on consumer products.

Denmark

A consumer awareness raising campaign was carried out in 2015 to assess consumers understanding of the CLP hazard labelling and their behaviour with regard to checking hazard information with focus on household products. The results are only available in Danish. The overall figures were:

- 82% of the consumers knew that household products can be hazardous to human health and the environment;
- 63% claimed to know how to find out whether a product is hazardous;
- 57% of the consumers often/frequently/always check the hazard labelling of household products;
- 6% were aware about the transition to a new labelling system (CLP); and
- 28% knew that the new pictograms consist of a white square with red frame and black symbol.

The United Kingdom

The UK's Department for Business, Innovation and Skills (BIS) (Toys and Cosmetics) undertook research in 1997 which resulted in the DTI report 'The role of pictograms in the conveying of consumer safety information'. Although published in 1997, this report still has valid observations and conclusions where it was stated that 'there are problems with the use of safety warnings in general; there is still discussion even on the methods used to assess the effectiveness of any type of safety warning. Warnings do not replace the need to educate consumers generally through other forms of safety publicity.'

The Health and Safety Laboratory, which is part of HSE, has recently conducted research in to the communication of hazards through the supply chain in the cleaning sector and this is awaiting publication.

Also available is a report on the methodology for applying pictograms particularly in respect of the most vulnerable group children. Although not specifically related to chemicals, it does address many physical and thermal hazards but more importantly how consumers recognise the meaning of pictograms.

Hungary

As reported in the ECHA newsletter of February 2014, there are board games, colouring books, stories and cards – all to teach children about hazard symbols and chemical safety in general. A programme developed by local chemical safety inspectors in Hungary has become extremely successful, involving 3 500 children, their parents and 200 teachers over recent years.

Findings from consultation

In the targeted data collection exercise, Member States were asked whether they ran educational programmes for consumer understanding of pictograms and labels. The results are given in Table 3-4 below:

Table 3-4: Member States responses to question about programmes they oversee aimed to raise consumer awareness of CLP hazard pictograms and labelling		
Statement	Number of responses	
	Yes	No
We provide educational programmes (n = 11)	6	5
We are developing educational programmes (n = 11)	7	4
Another organisation provides or is developing educational programmes (n = 11)	8	3

It can be seen that numerous Member States or agencies from Member States are providing or developing educational programmes for consumers as regards their understanding of pictograms and labels, in line with the recommendations of the ECHA report.

ECHA also runs an interactive website which provides training on CLP pictograms²⁹. This type of material is a useful and effective method to raise consumer awareness of the CLP pictograms which are placed on many of the household products they may use. Arguably, the tool could be more effective if more consumers are made aware of its presence; there are many routes through which this could be achieved, particularly to school children and in workplaces.

Other efforts to raise awareness

The OECD Global Awareness-raising Campaign on Laundry Detergent Capsules (16 to 23 March 2015) aims to inform of the risks posed by a product that is present in growing number of households worldwide: laundry detergent capsules (or packets). These products can be attractive to children and can pose serious dangers if not handled and stored safely. This worldwide campaign involves 26 consumer product safety authorities from 5 continents: European Commission (project leader), Australia, Bosnia and Herzegovina, Canada, Chile, Cyprus, Czech Republic, Estonia, Finland, France, Hungary, Iceland, Ireland, Italy, Japan, Korea, Latvia, Luxembourg, Malta, Mexico, Peru, Portugal, Singapore, Spain, United Kingdom, United States.

The campaign aims to inform consumers, especially parents, to safely use and store laundry detergent capsules, keeping them away from children; businesses are asked to follow/share safety related best practices as well as to help raise awareness on the safe use of laundry capsules. An example of the artwork used in the campaign is depicted in Figure 3-2 overleaf.

²⁹ See ECHA (<https://echa.europa.eu/clp-quiz>).



Figure 3-2: Example of artwork used in OECD Global Awareness-raising Campaign 2015

Source: http://ec.europa.eu/justice/newsroom/consumer-marketing/events/150316_en.htm

3.6 Other issues

Many comments from industry stakeholders interviewed referred to inconsistencies in Member State interpretations of what is required on labels for consumer products which can, in some cases, lead to the same product having different labels and different pictograms. This can lead to consumer confusion.

It was also noted that further research is needed into multilingual labels where the people using the product do not understand the language on the product they use, so, for example, foreign workers in France do not understand the French safe use instructions.

4 Conclusions

The CLP Regulation requires industry to inform users about the potential hazards of chemicals through labelling. The labels consist of a set of harmonised elements that are determined by CLP, e.g. hazard pictograms or hazard statements. These are mandatory for all labels of hazardous chemicals that are placed on the market in the EU³⁰, and it is important that consumers read and understand this information to ensure safe use.

The 2011 Eurobarometer Survey and the subsequent 2012 ECHA report³¹ could be used as a benchmark for assessing consumer comprehension of CLP pictograms and safe use information on labels. Since the 2011 survey, no published research has indicated that consumer comprehension has changed, neither that it has improved nor that it has declined. . Additional targeted research, such as a repeat of the Eurobarometer Survey, would need to be undertaken to be able to determine what changes have occurred since 2011. Indeed, the 2012 ECHA report on consumer understanding recommended that it would be appropriate to re-visit the level of understanding of European citizens at a later date, when consumers' experience and acquaintance with the pictograms have developed.

During the course of research for this case study, several issues relating to the system of consumer communication via pictograms were identified. Firstly, Eurobarometer and stakeholder consultation results demonstrate that the level of recognition and understanding varies between the different CLP pictograms. Secondly, research data and stakeholder consultation suggest that few consumers read the CLP label, in particular for products that they are familiar with. Large-scale surveys are needed to confirm this. Thirdly, while hazard labelling may direct the attention of consumers to the existence of a hazard or to certain dangers, it is considered to be less effective in communicating actionable safe use advice for consumers than for workers who are trained to understand labels. Labels carrying information which does not match consumer experience may contribute to consumers ignoring labels. In turn, such label fatigue can lead to carelessness when consumers handle products that need special care.

Stakeholders noted that the multiple regulations dealing with labelling can lead to overcrowded labels, or "label overload" (a key issue identified), and potentially add to consumer confusion. Consumer comprehension of label information is important for promoting the safe use of products.

Technology, such as websites and digital media, allow a different and potentially supplementary approach to consumer communication. In general, there was consensus amongst the stakeholders interviewed that new technologies offer a real opportunity to facilitate improved consumer communication, though they should not be seen as a replacement for labelling on products.

Stakeholders interviewed for this case study noted that some aspects of labelling under CLP work quite well. For example, pictograms work well for professionals and, more generally, labels (in addition to SDSs and SUMIs) work well for professionals.

³⁰ Eurobarometer (2011): Consumer understanding of labels and the safe use of chemicals. Available at: http://ec.europa.eu/public_opinion/archives/ebs/ebs_360_en.pdf

³¹ ECHA (2012): Communication on the safe use of chemicals: Study on the Communication of Information to the General Public. Available at: https://echa.europa.eu/documents/10162/13559/clp_study_en.pdf

For consumers, for products they do not use regularly (such as paints or biocides for example), research indicates that they are more likely to read the labels. Also, it is widely suggested that a limited number of messages on a label are effective, as are simple instructions on how to use the product. However, more generally, the research finds that stakeholders from all stakeholder groups consider CLP pictograms and labelling requirements not optimal as regards consumer communication, with the key issues being consumer comprehension of pictograms and over-labelling. Some stakeholders noted that the CLP pictograms were not designed with consumers in mind and that neither were the labelling provisions for consumer products.

As described in this case study, various Member States have undertaken awareness-raising activities. While there is no data to measure the exact impact of these activities on consumers, awareness-raising is considered as an important activity to ensure the effectiveness of CLP labels.

5 References

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Annex 1 Pictograms and their Meanings





Pictograms used on consumer products labelled under CLP

In order to provide a clear starting point for the analysis of information gathered as part of the research for this case study, Table A1-1 details the CLP pictograms, together with their common names and their meanings.

Table A1-1: CLP Pictograms, symbol names and meanings ³²		
CLP Pictograms	General meaning and symbol name	Meanings
	<i>Health hazard</i> And/or <i>Hazardous to the ozone layer</i> Symbol: Exclamation Mark	May cause respiratory irritation May cause drowsiness or dizziness May cause an allergic skin reaction Causes serious eye irritation Causes skin irritation Harmful if swallowed Harmful in contact with skin Harmful if inhaled Harms public health and the environment by destroying ozone in the upper atmosphere
	<i>Corrosive</i> Symbol: Corrosion	May be corrosive to metals Causes severe skin burns and eye damage
	<i>Hazardous to the environment</i> Symbol: Environment	Very toxic to aquatic life with long lasting effects Toxic to aquatic life with long lasting effects
	<i>Flammable</i> Symbol: Flame	Extremely flammable gas Flammable gas Extremely flammable aerosol Flammable aerosol Highly flammable liquid and vapour Flammable liquid and vapour Flammable solid
	<i>Oxidising</i> Symbol: Flame over circle	May cause or intensify fire; oxidiser May cause fire or explosion; strong oxidiser

³² ECHA (n.d.): CLP Pictograms, available at <https://echa.europa.eu/chemicals-in-our-life/clp-pictograms>

Table A1-1: CLP Pictograms, symbol names and meanings³²

CLP Pictograms	General meaning and symbol name	Meanings
	<i>Explosive</i> Symbol: Exploding bomb	Unstable explosive Explosive; mass explosion hazard Explosive; severe projection hazard Explosive; fire, blast or projection hazard May mass explode in fire
	<i>Acute toxicity</i> Symbol: Skulls and Crossbones	Fatal if swallowed Fatal in contact with skin Fatal if inhaled Toxic if swallowed Toxic in contact with skin Toxic if inhaled
	<i>Serious health hazard</i> Symbol: Health hazard	May be fatal if swallowed and enters airways Causes damage to organs May cause damage to organs May damage fertility or the unborn child Suspected of damaging fertility or the unborn child May cause cancer Suspected of causing cancer May cause genetic defects Suspected of causing genetic defects May cause allergy or asthma symptoms or breathing difficulties if inhaled
	<i>Gas under pressure</i> Symbol: Gas cylinder	Contains gas under pressure; may explode if heated Contains refrigerated gas; may cause cryogenic burns or injury

Case Study 10: Linkages between CLP and OSH Legislation

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1. Introduction

1.1 Background and Overview

1.1.1 Case study focus

Several pieces of EU occupational safety and health legislation draw on CLP classifications of substances and mixtures to trigger various risk assessment and other requirements in the workplace. These include:

- the Chemical Agents Directive (CAD)¹;
- the Carcinogens and Mutagens Directive (CMD)²;
- the Asbestos Directive³;
- the Pregnant Workers Directive⁴;
- the Young Workers Directive⁵; and
- the Safety Signs and Signals Directive⁶.

As a result, changes in classification, and in particular the agreement of new harmonised classifications under CLP, will trigger automatic requirements under the above OSH legislation. These requirements will include employers undertaking an assessment of the workplace risks associated with the exposure of workers to chemicals. For example under the CMD, a new CLP classification for carcinogenicity and/or mutagenicity will trigger the need for employers to work through the hierarchy of elimination or minimisation of risk, preferably by substitution (which is mandatory if there is a technically feasible alternative), controls of exposure via containment, or other measures to reduce exposure to levels as low as is technically possible. Formaldehyde is an example of a substance that has recently been newly classified and thus for which employers must carry out a workplace risk assessment.

In principle, and in relation to new harmonised classifications, employer's obligations with respect to their OSH obligations will commence following the transition time set out in the relevant Adaptation to Technical Progress, which adds the substance to Annex VI of the CLP.

This case study examines the appropriateness of this transition period and its implications in terms of worker health and safety, as well as costs to employers. This is done by specifically discussing

¹ The Chemical Agents Directive (CAD) 98/24/EC Protection of the health and safety of workers from the risks related to chemical agents at work.

² The Carcinogens and Mutagens Directive (CMD) 2004/37/EC on the protection of workers from the risks from the risks related to exposure to carcinogens and mutagens at work.

³ The Asbestos Directive 2009/148/EC on the protection of workers from the risks related to exposure to asbestos at work.

⁴ The Pregnant Workers Directive 92 / 85 / EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding.

⁵ The Young Workers Directive 94/33/EC on the protection of young people at work.

⁶ The Safety Signs and Signals Directive 92/58/EEC on the minimum requirements for the provision of safety and/or health signs at work.

how CLP impacts OSH responsibilities, wider OSH responsibilities will not be covered as they are almost always qualified by risk assessment.

It is of note that not all chemical agents relevant to workplace risks fall within the scope of CLP. In particular, employers have obligations in relation to two types of chemical agent under the CAD and CMD which fall outside the scope of the CLP's requirements:

1. Under the CAD and CMD, there are requirements for risk management of substances that are outside the scope of CLP, e.g. for risk management of process-generated substances (such as diesel fumes or hardwood dust) that are not placed on the market;
2. In addition, OSH legislation applies to substances that are explicitly exempted from CLP, such as certain mineral fibres, but which fall under the scope of the CAD and CMD.

Formaldehyde may also occur in the workplace as a process-generated substance, and risk management measures to address exposures in these cases would also be required.

1.1.2 Who is affected by the issue?

This issue will impact a wide range of stakeholders. A primary focus is workers handling the relevant substances, as the aim of both CLP and the EU OSH legislation are to provide hazard information and subsequent risk control, in order to minimise the potential effects on worker health. However, the impact will be felt across a much wider range of stakeholders. Employers are clearly affected by changes to risk management (possibly due to reformulation) of relevant substances in their workplaces. Chemical suppliers are also affected by significant changes to the classification of substances, where this impacts the way in which OSH legislation will then control that substance, with the potential for some uses of the substance to be phased out. Regulators also require a thorough appreciation of how linkages between the different legislation work and the downstream impacts of changes that are made to substance classifications.

1.1.3 Methodology

Originally this case study was to primarily be formulated around stakeholder consultation (targeted interviews and written input) and examination of the situation relevant to a specific chemical agent. However, the consultants had difficulty in gaining the participation of Member State authorities and industry. Interviews were carried out with BaUA, the Swedish Chemicals Work Agency, the European Trade Unions Institute and an academic institute.

In order to fully understand the differences between the legislation it was decided to use formaldehyde as the case study chemical. Formaldehyde has been given a harmonised classification as a category 1B carcinogen under the CLP, and also has a draft SCOEL recommendation for an OEL (which would be expected to become a binding OEL in the future, assuming that an EU-wide OEL is adopted within the framework of the CMD). Although formaldehyde may be intentionally used in a range of processes, it may also be a process generated chemical agent and hence require that measures be adopted in such cases under the CAD and the CMD. This latter aspect is not considered in detail.

The work on formaldehyde does not consider issues arising in relation to cosmetics; nor does it include consideration of possible overlaps in relation to animal feed, pesticides or biocides.

2. Overview of Key OSH Legislation

As noted above, several pieces of EU OSH legislation make reference to hazardous chemical substances and mixtures, with a non-exhaustive list mentioned in Section 1.1.

These directives use the CLP Regulation to define hazardous substances and mixtures; however, additional items also have the potential to fall into the scope of the relevant directives. An assessment has therefore been carried out to establish how key OSH directives define what is hazardous to workers. OSH Directives apply more broadly than chemical 'substances and mixtures' as defined in CLP.

2.1 Chemical Agents Directive (CAD)

The following fall within scope of the CAD:

- Any chemical element or compound, on its own or admixed, as it occurs in the natural state or as produced, used or released, including release as waste, by any work activity, whether or not it is produced intentionally or placed on the market; in other words, the scope includes process-generated agents;
- Any chemical agent which meets the criteria for classification as hazardous within any physical and/or health hazard classes laid down in Regulation (EC) No 1272/2008 of the European Parliament and of the Council (19), whether or not that chemical agent is classified under that Regulation; and
- Any chemical agent which, whilst not meeting the criteria for classification as hazardous in accordance with CLP, because of its physico-chemical, chemical or toxicological properties and the way it is used, or is present in the workplace, presents a risk to the safety and health of workers, including any chemical agent that is assigned an occupational exposure limit value under the CMD.

While CLP applies 'per-chemical substance or mixture', CAD does not apply 'per-chemical agent' but 'per-activity' and '-workplace, where multiple and dynamic chemical (and other) hazards may be present.

2.2 Carcinogens and Mutagens Directive (CMD)

This Directive applies to potential worker exposure to carcinogens and mutagens, which are defined as follows.

Carcinogen:

- (i) *"a substance or mixture which meets the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No 1272/2008".*
- (ii) *"a substance, mixture or process referred to in Annex I to this Directive as well as a substance or mixture released by a process referred to in that Annex".*

Mutagen:

"A substance or mixture which meets the criteria for classification as a category 1A or 1B germ cell mutagen set out in Annex I to Regulation (EC) No 1272/2008".

From the above definitions it is clear that carcinogens and mutagens may fall into the scope of CMD although they are not regulated under CLP, if they are included in Annex I to the Regulation. On the whole, the listed items are very specific to areas of industry and, therefore, relatively easy for employers to track.

2.3 Pregnant Workers Directive

This Directive specifies a number of conditions and agents that pregnant or breastfeeding mothers should not be exposed to. This includes substances and mixtures which meet the criteria for classification under CLP for carcinogenicity, mutagenicity and reproductive toxicity, including for effects on or via lactation, and for specific target organ toxicity after single exposure. It also includes chemical agents in Annex I to Directive 2004/37/EC of the European Parliament and of the Council, chemical agents of known and dangerous percutaneous absorption, and carbon monoxide.

There are parallels between the scope of the chemical agents that will be within the scope of this Directive due to its alignment with the CAD, but not within the scope of the CLP.

2.4 Young Workers Directive

Again the Directive gives a number of agents and conditions that young workers should not be exposed to. In relation to chemical agents to which young workers should not be exposed, this includes substances and mixtures which meet the criteria for classification under CLP in a range of physicochemical and health hazard classes and hazard categories. The Directive refers to chemical agents that will be in the scope of CLP but also those that are outside of its scope, in line with the CAD and CMD. There is also an extended list of the types of hazardous materials defined in the CLP that should not be used by young workers.

2.5 Employer obligations

EU OSH legislation sets out obligations on the employer with the aim of protecting workers that may be exposed to chemical agents. For example, under the CAD, the employer has a number of duties including but not limited to the following:

1. They must ensure that a risk assessment has been carried out, taking into account factors such as the hazardous properties of the chemical agent(s), the level, type and duration of exposure, and any occupational exposure limits or biological limit values that have been assigned. This risk assessment must be kept up to date and take account of any significant changes in circumstances;
2. Employers must take preventive measures to eliminate the risk, or reduce it to an acceptable level. Selection of preventative measures should follow the hierarchy of control, with a preference for eliminating the risk by changing the process or product so that the chemical agent is no longer required. If elimination is not possible, substitution of the chemical agent for another less hazardous one should be considered; and if this is not possible, control measures should be put in place. Control measures include, in order of priority:
 - a. Use of appropriate work processes and engineering controls, such as enclosure of the process, to avoid or minimise release of the chemical agent;

- b. Use of collective protection measures at the source of the risk, such as adequate ventilation, and appropriate organisational measures, such as minimising the number of workers exposed, and the duration of exposure; and
 - c. Use of individual protection measures, i.e. personal protective equipment.
- 3. Employers must regularly monitor levels of hazardous chemical agents against any relevant occupational exposure limits. If exposure limits are found to be exceeded, the employer must take immediate measures to rectify this. For materials with binding biological limit values, health surveillance must be carried out and up-to-date individual health and exposure records must be kept.

Furthermore, chemical agents that fall within the scope of the CMD have an additional, more stringent set of requirements, again largely aimed at the employer:

- 1. The employer must assess and manage the risk of exposure to carcinogens and mutagens as defined in the Directive. This process must be kept up to date and take account of any changes that may affect exposure. The details of this process must be available to the authorities on request; and
- 2. If technically possible, the employer must prevent exposure to carcinogens and mutagens by replacing such materials with less hazardous ones. If it is not technically possible to substitute the materials, they should be used within a closed system. If a closed system is not technically possible, the employer must reduce exposure to as low a level as is technically possible.

Annex III of the CMD also contains occupational exposure limits for specific carcinogens and mutagens which must not be exceeded.

Amongst other requirements, when provided for by a Member State, employers must be able to provide on request details of how they are using carcinogens or mutagens to the enforcement authority. This includes details of the activities in which they are being used, the reasons for their use, the quantities used, the number of workers exposed, what preventative measures are in place, what protective equipment is used, the nature and degree of exposure, and conclusions on whether the carcinogens or mutagens could be replaced with less hazardous materials.

3. Stakeholder Consultation

A number of stakeholders were contacted and participated in a survey on 'Linkages and overlaps between OSH and CLP legislation'. Responses were received from the BAuA the German Federal Institute for Occupational Safety and Health, the UK's Cranfield University, the ETUC, the Estonian Health Board and the Cypriot department of Department of Labour Inspection, Ministry of Labour, Welfare and Social Insurance. The UK's Health and Safety Authority and the Swedish Work Environment Authority were unable to provide a case study specific response in the time provided and, instead, their response to the main targeted consultation has been used.

The main points arising from these responses are summarised below.

- 1) CLP classifications are important to the proper functioning of OSH legislation, particularly for the proper functioning of the Chemical Agents Directive, the Carcinogens and Mutagens Directive and the Pregnant Workers Directive. Respondents hold conflicting views on the degree to which employers are considered to have a high level of understanding of the classification and labelling information that they receive. Some believe that employers have a high understanding of the information, while others rate this as low.
- 2) However, risk assessment is a key component of OSH legislation and, whilst classification is the starting point for such an assessment, ultimately more information is needed to assess a risk so the hazard information that comes from CLP is not the only consideration. Some respondents believe that these are conducted to a high standard, while others believe that insufficient consideration is often given to exposure information specific to the employer's own workplace.
- 3) Hazards posed by chemical agents that are not classified under CLP are considered by most employers in their Chemical Agents Directive risk assessment, although views on the adequacy of this aspect of the risk assessments vary across the respondents. All agree that it is much less likely that toxicological data and hazards arising from combination effects of workplace chemicals are considered by most employers. The risk assessment required under the Chemical Agents Directive should cover all applicable risks if conducted correctly, although specific risks may also be covered by other legislation such as the Biocidal Products Directive. Problems should only arise if information is missing or the regulatory requirements have been applied incorrectly.
- 4) Employers may be relatively slow to update their risk assessments to take account of changes in classification, e.g. as a result of a new harmonised classification. In some cases, although information may be communicated by manufacturers through an updated SDS and labels in good time, there may not be sufficient time for employers to make all of the changes they are required to within the transition periods; in other words, risk assessments may not be reviewed quickly enough to enable more sophisticated strategies for responding to changes in risk to be put in place. Thus, the transition time for introduction of, and complying with, a new Harmonised Classification, is too short, especially for SMEs and for manufacturers and suppliers who may need to reformulate their products.
- 5) One respondent noted that the scientific and political debate surrounding what types of materials fall into the scope of Chemical Agents Directive and Carcinogens and Mutagens Directive is causing regulatory incoherence. In this respect, the issue is more one of inconsistencies between Chemical Agents Directive and Carcinogens and Mutagens Directive

rather than the difference between CLP and Chemical Agents Directive or Carcinogens and Mutagens Directive.

- 6) There are inconsistencies and overlaps between OSH legislation and the work undertaken by ECHA's Risk Assessment Committee when agreeing Harmonised Classifications under CLP, resulting in a need for better agreement between SCOEL and ECHA; however, a working group is in place to reduce differences and align the methodologies being used. In this respect, it was noted that there is a need for the responsible bodies to explain clearly the reasoning behind their decisions. As different scopes could lead to different results, it is important that the methodologies used to make decisions are clear.
- 7) Respondents have varying views on the extent to which CLP and OSH legislation have played a role in reducing workplace chemical accidents, with some believing it has and others arguing that such reductions are driven mainly by financial drivers or a sense of corporate social responsibility; views in general are positive with regard to the effects of hazard communication for workers from CLP, although OSH legislation was rated as having a more positive impact. In this respect, one respondent noted that greater reinforcement of requirements was needed at a national level, in order to increase the benefits associated between CLP and OSH legislation.
- 8) The extension of the scope of the CAD and CMD scope beyond CLP, for example to process-generated substances, is considered by all respondents as necessary and as not creating legislative incoherence.

4. Formaldehyde Case Study

4.1 Introduction

Formaldehyde (EC number: 200-001-8, CAS number: 50-00-0 and EC Index Number: 605-001-00-5) is a naturally occurring colourless gas found in the environment. It was chosen for this case study as it provides a good example of how OSH legislation is impacted by a change in the harmonised classification of a substance under CLP.

Although much of the case study focuses on its intentional use, it is of note that formaldehyde may also occur in the workplace as a process-generated substance. It forms naturally from the degradation of airborne hydrocarbons and the combustion of hydrocarbons from both natural, such as forest fires, and manmade processes, such as vehicle exhausts.

4.2 Uses of formaldehyde

Formaldehyde is a major industrial chemical, with annual global production of over 40 million tonnes (at 37% concentration). According to Formacare (the formaldehyde sector group of the European Chemical Industry Council (Cefic) representing key European producers of formaldehyde, aminoplast glues and polyols) the European Union is the second largest producer of formaldehyde after Asia, producing over 3.6 million tonnes of formaldehyde each year which accounts for about 30% of global production. Annual sales of formaldehyde-based chemicals in the EU are roughly €9.5 billion a year and 22 of the 27 EU Member States manufacture formaldehyde. Germany is the largest formaldehyde producer in the EU, followed by Italy, Spain, the Netherlands, Sweden and the UK (see Table 3-1).

Table 3-1: EU Formaldehyde Production & Capacity		
Country	Production 2010 (tonnes)	Capacity (tonnes/year)
Germany	1,716,000	2,145,000
Netherlands	760,000	950,000
Italy	736,000	919,000
Spain	660,000	825,000
Sweden	432,000	540,000
United Kingdom	372,000	465,000
Portugal	244,000	305,000
Belgium	232,000	290,000
Austria	140,000	175,000
Finland	128,000	160,000
Denmark	92,000	115,000
Lithuania	86,000	107,000
Ireland	64,000	80,000
Hungary	48,000	60,000
France	44,000	54,000
Bulgaria	24,000	30,000
Source: Merchant Research and Consulting (2012)		

Formaldehyde has a number of uses and applications including:

- Formaldehyde based glues and resins – used in wood-based panels (WBPs) for construction and manufacture of furniture, as well as cars and planes;
- As a chemical intermediate for the production of a wide range of industrial chemicals, such as 1,4 butanediol and 4,4'-methylenediphenyl diisocyanate;
- Vaccines – due to the antibacterial properties of formaldehyde;
- Biocidal products – formaldehyde has antibacterial and preservative properties, and is often used in disinfectants; and
- Paints and coatings – formaldehyde is often used as a preservative, and in the production of other chemicals (it is used as an intermediate) for example in the production of polyurethanes.

Formaldehyde is widely used in the construction, automotive, aircraft, healthcare and clothing industries.

Formaldehyde resins (urea formaldehyde resins, phenol formaldehyde resins and melamine formaldehyde resins) and adhesives are also used in the manufacture of wood based panels. These panels are made from wood in many forms (including chippings, strips, sawdust, particles, veneers, strands, fibres and recycled wood waste) which are bonded with formaldehyde based resins and glues to form panels. WBPs contain formaldehyde in two forms, one which is held within the polymer chain and free formaldehyde. The amount of formaldehyde that is emitted is dependent on a number of factors, primarily the type of board and whether it is coated. This case study focuses on just one application (WBP), although there are many applications that will be affected. The same level of complexity exists for the other applications and uses of formaldehyde.

Since 2004, there have been two types of WBP European Standard EN 13986; E1 and E2 for use in construction. These are judged on how much measurable formaldehyde they emit over time, a property that is affected by their constituents and physical form. The most common emission class in Europe is E1, and boards that meet this standard are less likely to have any irritant or inflammatory properties affecting the olfactory mucous membranes. The second emission class, E2, releases more formaldehyde compared with E1 boards and, whilst they are legally permitted in most countries in Europe, they are widely recommended for use only in outdoor applications for consumer protection.

Alternatives

There are a number of possible alternative adhesives for use in WBP and these can be grouped into:

- Alternative formaldehyde-based adhesives (e.g. MF, MUF, PF, PRF-based resins, etc.);
- Isocyanate-based adhesives (e.g. p-MDI and emulsion polymer isocyanates);
- Polyurethane-based adhesives;
- Epoxy-based adhesives;
- Polyvinyl and ethylene vinyl acetate adhesives; and
- Bio-based adhesives (e.g. protein glues, lignin, tannins, etc.).

A recent study carried out by TNO Triskelion et al. (2013) into risk management options for formaldehydes found that there is no alternative which is generally suitable for use across all grades of WBP. Furthermore, the alternatives currently available also result in a different set of risks, leading to potential trade-offs of risk. There are also cost and availability issues with many of the alternatives considered. The independent study was commissioned by Formacare and the European Panel Federation (EPF) in March 2012 after a joint action by France and the Netherlands, adding

formaldehyde to the Community Rolling Action Plan (CoRAP) for substance evaluation under the REACH Regulation.

The study concluded: *“Overall, taking into account the information on alternatives, it is clear that the most appropriate RMO must focus on the key concern which is releases of formaldehyde from WBP, rather than on focusing solely on switching away from formaldehyde-based resins as a family. The analysis of alternatives indicates that there are other formaldehyde-based resins (PF, MF, MUF, RF, and PRF) which release little to no formaldehyde from the cured product and, as such, can be considered as substitutes for high-emitting UF resins. The use of these resins effectively reduce, if not eliminate (to background levels), releases of formaldehyde from WBP and avoid adverse effects on the health of consumers.”*

However, the same study found that a number of these substitutions would contain little free formaldehyde, and therefore would be safer for the end consumer but would likely increase the formaldehyde within the working environment. This was not only due to the formaldehyde required in the formation of the substitutes, but also due to the higher or longer curing and hardening temperatures.

Technical Feasibility

TNO Triskelion et al. (2013) found there were three key aspects which determined whether substitution was technically feasible in WBP:

- Existing plants, equipment and production processes, for instance, the plant size, structure and location, production permits, relevant equipment, etc.;
- Technical selection criteria for the WBP manufacturer (e.g. physico-chemical properties, press times, curing times, hydrolysis resistance, hardening temperature, etc.), taking into account, the range of WBP, for instance, the feasibility of a given alternative substance to all seven grades of particleboard; and
- Downstream user, client or market requirements, for instance, in relation to the ability to meet regulatory pressures, safety requirements, product guarantees, lifetime and recycling requirements and appearance requirements in furniture (e.g. adhesive colour).

Whilst this is specifically for WBPs, these are the requirements that must be assessed and addressed when any substance comes under the scope of the CMD. Indeed, in the case of WBPs, it was reported that they run highly integrated production processes that may not be easily switched over to alternative resins or production methods. This was determined particularly as some plants create their own resins on site and would therefore require alternative storage and transport arrangements to accommodate the substitution. Consequently, substitution to alternative formaldehyde based resins could result in significant economic and time costs.

The majority of plants use urea formaldehyde resin systems due to their technical properties, low cost, and due to the fact that they can produce the widest range of WBPs. Some of the alternatives such as p-MDI and phenolic formaldehyde resins could give rise to other regulatory concerns. For example, if the plant altered its process to produce phenol-formaldehyde resins, which have minimal free formaldehyde, then they would have to store large amounts of phenol on site. This could bring it into the scope of the Seveso Directive and not only affect the location of the quantities of substances stored but even the plant location. Furthermore, as phenol is toxic and mutagenic, it is not a good substitute; in order to avoid regrettable substitutions, it is important that less harmful chemicals and processes are introduced.

4.3 Hazard properties of formaldehyde

4.3.1 Carcinogenic and mutagenic properties of formaldehyde

Formaldehyde is an extremely strong cross-linking agent and it is this, coupled with its electrophilic carbonyl, which gives rise to its potential genotoxicity and carcinogenicity. This electrophilic carbonyl can bind with the nucleophilic sites of macromolecules such as proteins and DNA to form irreversible cross-links. Formaldehyde reacts rapidly with skin at the point of exposure causing localised cell destruction. These effects are dependent on the exposure concentration rather than a cumulative dose.

Formaldehyde is an endogenous compound and so these DNA adducts are a naturally occurring, endogenous process. However, the background incidence of nasopharyngeal tumours is very low in humans despite the prolificacy of these adducts. Over 2ppm, the number of exogenously caused DNA adducts becomes greater than the number of endogenous adducts. It is at this point that cell proliferation can begin to increase, leading to tumours. Formaldehyde is very water soluble and as such the reaction with formaldehyde normally occurs at the point of exposure, namely the mucous layer of the upper respiratory tract for inhalation, or the gastrointestinal tract for ingestion. These carcinogenic effects are observed at doses that are high enough to cause chronic irritation. Formaldehyde has exhibited mutagenic properties both in vivo and in vitro; however, these effects are limited to those cells that have come into direct contact with the chemical. This is supported by evidence of a lack of systemic effects from formaldehyde, for example, inhalation of formaldehyde does not lead to any increase in formaldehyde blood concentration.

The majority of evidence of carcinogenic and mutagenic effects is in animal data, rather than humans. Human data from case-control studies has shown a link between occupational formaldehyde exposure and cancer of the nasopharynx and leukaemia. A less clear, but positive effect, has been observed for sinonasal cancer. In human data there has been no recorded increases in reported nasal cancer rates for formaldehyde at the following mean exposure levels: 1.25 mg/m³ and with peak exposures below 5 mg/m³.

4.3.2 Reproductive toxicity

There is no evidence to suggest that formaldehyde is a reproductive toxin. This is likely to be in part due to formaldehyde being an endogenic compound, with carcinogenic effects largely only seen from exogenic exposures over a threshold concentration, at the point of exposure.

4.3.3 IARC classification

In 2006, the IARC (International Agency for Research on Cancer) upgraded their classification on the carcinogenicity of formaldehyde to class 1 stating that there is “sufficient evidence of nasopharyngeal cancer in humans, strong but not sufficient evidence of leukaemia in humans, and limited evidence of sinonasal cancer in humans.” A class 1A carcinogenicity rating was suggested to ECHA by the French competent authority, but a classification of 1B was adopted as there was deemed insufficient human data to assign a class 1 classification.

4.4 Harmonised classification of formaldehyde

The original harmonised classification for formaldehyde under CLP (from the 1st Adaptation to Technical Progress (ATP) – which transferred the classifications from 30th and 31st ATP of DSD) is summarised in Table 3-2.

Table 3-2: Original harmonised classification of formaldehyde		
Hazard and category	Hazard statement	Specific concentration limits
Carc. 2	H351 - Suspected of causing cancer	Skin Corr. 1B; H314: C ≥ 25% STOT SE 3; H335: C ≥ 5% Skin Sens. 1; H317: C ≥ 0,2%
Acute Tox. 3 *	H331 - Toxic if inhaled	
Acute Tox. 3 *	H311 - Toxic in contact with skin	
Acute Tox. 3 *	H301 - Toxic if swallowed	
Skin Corr. 1B	H314 - Causes severe skin burns and eye damage	Eye Irrit. 2; H319: 5% ≤ C < 25% Skin Irrit. 2; H315: 5% ≤ C < 25%
Skin Sens. 1	H317 - May cause an allergic skin reaction	

Following the changes in classification by various international groups including IARC from Group 2A (probably carcinogenic to humans) to Group 1 (carcinogenic to humans); a proposal was submitted to ECHA by the French competent authority to change the harmonised (Annex VI) classification. A class 1A carcinogenicity rating was suggested by the French competent authority, but a classification of 1B was adopted as there was deemed insufficient human data to assign a class 1 classification.

This decision was implemented through the 6th ATP to the CLP Regulation, published in the Official Journal of the European Union on 6th June 2014. The change was adopted and the deadline for the transition period was extended to 1st January 2016. After 1st January 2016, the new classification and labelling rules had to be applied to substances containing 0.1% free formaldehyde or above. The updated classification increased the carcinogenicity hazard category from 2 to 1B and also introduced the additional hazard of mutagenicity at category 2.

The updated Annex VI classification is outlined in Table 3-3.

Table 3-3: Updated Annex VI classification of formaldehyde		
Hazard and category	Hazard statement	Specific concentration limits
Carc. 1B	H351 – May cause cancer	Skin Corr. 1B; H314: C ≥ 25% STOT SE 3; H335: C ≥ 5% Skin Sens. 1; H317: C ≥ 0,2%
Muta. 2	H341 - Suspected of causing genetic defects	
Acute Tox. 3 *	H331 - Toxic if inhaled	
Acute Tox. 3 *	H311 - Toxic in contact with skin	
Acute Tox. 3 *	H301 - Toxic if swallowed	Eye Irrit. 2; H319: 5% ≤ C < 25% Skin Irrit. 2; H315: 5% ≤ C < 25%
Skin Corr. 1B	H314 - Causes severe skin burns and eye damage	
Skin Sens. 1	H317 - May cause an allergic skin reaction	

This updated classification resulted in formaldehyde being subject to control under the Carcinogens and Mutagens Directive (CMD), e.g. OSH risk management – including substitution, risk assessment and management, application of the hierarchy of controls and application of any existing Member State OELs; this is in addition to the CAD provisions which already applied and continue to apply. Industry is therefore now required to implement various RMMs (risk management measures) and these will act to further control the releases of/exposure to formaldehyde in the workplace.

4.5 OSH related impacts of the harmonised classification

4.5.1 OSH requirements triggered by classification

The most significant impact of the updated classification is that the change in classification brings formaldehyde within scope of the CMD, and the associated additional measures that must now be taken in workplaces where formaldehyde is encountered, whether used intentionally or as a process generated substance:

- Substitution – the CMD upgrades the substitution legal requirement from 'by preference' to mandatory 'where possible'; due to its category 1B carcinogen classification, formaldehyde should be replaced in a process by a non-carcinogenic or non-mutagenic substance;
- Introduction of a closed system – where it is not possible to substitute formaldehyde the processes where it is used should be altered to closed systems;
- Where a closed system is not possible other steps must be taken to reduce exposure to as low a level as is technically possible.

This is in addition to the general control measures for carcinogens and mutagens mentioned in the CMD text quoted above and of course the requirements of other relevant Directives.

4.5.2 SCOEL recommendations for a binding OEL

On 17 November 2016, the Scientific Committee for Occupational Exposure Limits (SCOEL) published the draft Occupational Exposure Limit (OEL) recommendation on formaldehyde. A consultation period was open until 17 February 2016. SCOEL recommends an 8-hour TWA of 0.3 ppm (0.369 mg/m³) and a STEL of 0.6 ppm (0.738 mg/m³). This proposed limit is 0.1 ppm below that set out in the REACH dossier, and would require an update to the associated chemical safety report and exposure scenarios.

There is currently variation in the OELs implemented across the Member States. If this OEL becomes binding within the framework of the CMD, at the values quoted above, then it would lower the OEL in a number of Member States. For those Member States that have a lower OEL, as the CMD is a Directive, they have the opportunity to retain their lower OEL at levels below the binding value when it is implemented at a national level.

SCOEL has determined that an exposure level of over 1 ppm is needed for the external formaldehyde carcinogenic processes to be greater than those that are endogenic. A 0.3 ppm TWA (8hr) is therefore determined to be highly protective as it is 3.3x lower than the 1 ppm needed for the external formaldehyde carcinogenic processes to be greater than those that are endogenic.

Furthermore, the SCOEL recommendation determined that '[a]s a result of the exclusively local effects of formaldehyde, a "skin" notation is not required. Formaldehyde is a well-known contact allergen to the skin. Against the background of a widespread use, respiratory sensitisation has been reported only in single cases and therefore the designation as respiratory sensitizer is not warranted.'

4.5.3 Cost implications of the recommended OEL

The TNO Triskelion report states that for a proposed OEL of 0.3ppm, ~70% of the '*plants producing formaldehyde indicated that they will have one-off costs, with only one of the plants stating it needs no improvements. All plants categorised as 'formaldehyde and resin manufacture' have indicated one-off costs. Approximately half of the plants categorised as 'resin manufacture' (10 of 21) do not yet require improvements at 0.3 ppm, while 16 of 21 plants need improvements with one-off costs at 0.2 ppm and a respondent for one plant indicated that at this level the plant would need to close*'.

Estimated one-off costs for an OEL reduction for formaldehyde resin manufacturing plants to 0.3ppm from the TNO Triskelion study are presented in Table 3-5.

Table 3-5: Estimated one-off costs for an OEL reduction for formaldehyde resin manufacturing plants to 0.3ppm

Subgroup ^{a)}	One-off costs for keeping an OEL of 0.3 ppm		
	Per plant reporting costs (range)	Average over plants reporting costs	Average over all responses
Formaldehyde production	€75,000 – €9,420,000	€2,075,000	€1,482,143
Formaldehyde and resin production	€100,000 – €1,580,000	€566,772	€566,772
Resin production ^{b)}	€175,000 – €9,500,000	€1,753,454	€964,400
Total Formaldehyde and resin manufacturers ^{c)}	€50,000 – €1,580,000	€1,329,537	€944,671
Aggregate Estimates			
Minimum estimate	€35,897,500		
Average estimate	€55,735,592		
High estimate	€63,817,778		
Source: TNO Triskelion RPA report			

As part of the work, TNO also determined workplace exposure limits for different industries with various risk management levels. It was determined that LEV and enhanced general ventilation, and in some cases RPE with a protection factor of ten, was sufficient to keep exposure below the SCOEL proposed harmonised OEL. Notable exceptions to this are PROC 1, 2, 5, 6, 14, 25, 8b, 10, and 15. All but one of these use formaldehyde, or release formaldehyde as a process generated agent, at temperatures of 60°C.

4.6 Impacts on the formaldehyde supply chain

4.6.1 Self versus harmonised classifications

When a harmonised classification is added to Annex VI of CLP, it must be used and the appropriate measures adopted under the relevant OSH legislation. In contrast, there is no obligation to use a self-classification from a supplier if employers do not agree that it is sound and appropriate. A brief look at the C&L inventory shows a wide variation in self-classifications for formaldehyde. As of November 2016, there are 73 aggregated notifications. The variations include the associated text with the STOT SE3 classification, others have self-classified as an eye irritant, others eye damage 1, while others have omitted these entirely. However, the carcinogen classification of a minimum of category 2 is a constant due to the previous harmonised classification. The self-classifications are overwhelming carcinogen 2, as there are barriers for manufacturers and supplier to self-classify at a higher category than the market norm. It is therefore possible that if a downstream user did not agree with the self-classification provided to him in lieu of a harmonised classification determined by ECHA, that there would potentially be a gap in the protection of workers.

4.6.2 Impacts of the time allowed for transition

The complex nature of the formaldehyde supply chain has been highlighted using the example of WBP. There are numerous products manufactured from just this one usage of formaldehyde. Each of these product types will have a unique manufacturing process that is designed around the properties of the raw materials used. There are also many other uses of formaldehyde in the manufacture of a range of final products. This includes the manufacture of resins for a wide variety of other downstream uses; use as an intermediate in the manufacture of chemicals to be used in the paint and coatings industries, as well as for biocidal control and use as a preservative.

Given the above, a very significant range of production processes will be in place throughout Europe that utilise formaldehyde. These processes will have been developed around the properties of all raw materials used in the process e.g. viscosity, density, volatility, hazard profile; and the reaction pathway that will be followed, e.g. need for heating and pressure control. Therefore, the substitution of one of the raw materials in the product process has the potential to create a significant re-design of a number of production processes.

A range of factors will have to be considered in this re-design process including:

- Level of integration of existing systems;
- Changes to the number/capacity of storage tanks;
- Compatibility of storage tanks, pipework, pumps etc. with any new raw materials;
- Changes to the time required for the reaction process to complete; and
- Shelf-life of any intermediate reactants.

The evaluation work required to determine how feasible changes to a manufacturing process are, is therefore considerable, even just for one process. Again, where the full number of processes for a substance such as formaldehyde is involved, the volume of preparatory work may be considerable, involving the design of new plant equipment; safety studies of new reaction processes; purchasing of new equipment; and plant shutdown of manufacturing process to allow for new construction.

The manufacturing process evaluation and re-design can only occur once research and development activities have been completed to establish suitable substances that could replace formaldehyde in the required applications. This research and development activity will also have to consider multiple issues:

- Cost implications;
- Product performance;
- Durability of the final product;
- Compatibility with materials the final product will be used with; and
- Impact on hazards of the final product.

This research and development effort has the potential to take significant amounts of time. This will be a particular issue where the life-time of the product is long, as durability tests will have to be run to ensure that there are no issues following the substitution of formaldehyde from the final product. For example, extensive research has been conducted to replace formaldehyde based resins used in WBP with polymeric diphenylmethane diisocyanate (p-MDI) materials.

As discussed earlier, alternatives may carry their own risks and regulatory requirements that would need to be explored and fulfilled. For example, to produce a water-durable WBP a phenol-formaldehyde resin substitution process may be chosen as an alternative as it has a reduced formaldehyde emission profile. This could lead to large quantities of phenol held on site bringing the

site within the Seveso Directive. This could have significant ramifications for the plant, say if it was located near a population centre, and as such limits its options for alternatives. It is of note that the majority of alternatives investigated by TNO Triskelion et al. (2013) still use formaldehyde, with formaldehyde free resins either resulting in drastic changes to processes or not being technically capable of replacing those that use formaldehyde.

Thus, when considering just one manufacturing use for formaldehyde, it can be seen that the 18 month phase-in for a classification change that results in a substance that was in the scope of the CAD, being within the scope of both the CAD *and the* CMD, leaves limited time for a full evaluation of the control measures recommended at the top of the CMD hierarchy. Users of formaldehyde would have had a restricted time line for evaluation of the most effective control measures available (i.e. to prevent exposure), with this potentially leading to measures lower down the hierarchy being selected as they can be implemented within the required time frame.

Thus, whilst the intention of the CMD is that other control measures should be considered before personal protective equipment is used to minimise exposure to carcinogens, the time lines involved in adapting to CLP classification changes have the potential of driving manufacturers towards concluding that PPE is the most appropriate measure. Whilst PPE does provide protection against exposure, there are known limitations to its effectiveness, including:

- Workers require training to ensure that the equipment is worn correctly;
- An effective maintenance programme should be in place to ensure that the equipment continues to provide protection;
- The equipment will need to be replaced at regular intervals; and
- The equipment may be uncomfortable for the workers to wear.

It is logical that SMEs will be more adversely affected by the limited time allowed for adoption of measures than larger enterprises, in part due to the administrative burden of the above, but also being at a research and development disadvantage compared to larger, more established enterprises. It is, therefore, likely that some SMEs would find it harder to adjust within the 18 month transition period.

It is of note that mandatory substitution, where technically feasible, does not necessarily align with the risk assessed approach taken with the CAD. If exposure levels are below an OEL value, which itself is below the DNEL, then it is reasonable to suggest that substitution should not be needed in terms of protecting employee's health and safety. Otherwise, the OEL is only applicable in industries where substitution of formaldehyde is not technically feasible, or where formaldehyde is process-generated and not in a closed system.

For example, the draft SCOEL recommendation for formaldehyde notes that whilst formaldehyde '*is a well-known contact allergen to the skin. Against the background of a widespread use, respiratory sensitisation has been reported only in single cases and therefore the designation as respiratory sensitiser is not warranted.*' This shows an inherent risk-based approach, as opposed to the hazard-based approach that exists in the linkage between CLP and CMD.

However, with carcinogens, the route of exposure and the mechanism of action are not taken into account in the classification. It may not, therefore, be appropriate to implement all of the respiratory control measures and substitute a substance that is only carcinogenic upon ingestion. In this scenario these measures would offer no greater worker protection but would result in significant industry costs.

5. Evaluation

A range of OSH legislation uses CLP as a tool to determine what chemical substances and mixtures should fall within the scope of the specific OSH legislation. There has been a transition process from OSH legislation referencing the Dangerous Substances Directive/Dangerous Preparations Directive classifications to the CLP classifications. As CLP was designed to include the UN GHS building blocks that were most closely aligned to the Dangerous Substances Directive/Dangerous Preparations Directive classifications, the process to update the OSH legislation was relatively straightforward and easily understandable for employers. For example, there is a straight forward mapping of carcinogen classifications under the Dangerous Substances Directive system to carcinogen classifications under CLP. OSH requirements on employers to re-evaluate risk assessments for products and processes to ensure continued compliance following re-classification under CLP would therefore not have presented a major change to assessments under the previous classification legislation. As a result, an effective chemical hazard classification system, which can be used under OSH legislation for risk assessment purposes, has been maintained through the introduction of the CLP Regulation.

The formaldehyde case study highlights that there are cases where a change in classification leads to a change as to which OSH legislation will apply to a substance. It also highlights how the changes to the harmonised classification of a substance may affect the measures that must be taken by employers to maintain compliance with the OSH legislation. In addition, it highlights that although OSH legislation may also apply to process generated chemical agents which are not placed on the market and thus do not fall under CLP, this does not lead to significant incoherence.

In particular, the case study illustrates the significant changes that may be required to product formulations and manufacturing processes when a substance falls newly into the scope of the Carcinogens and Mutagens Directive due to a harmonised classification under CLP. The timings of the phase-in for such changes to be realised may present problems for manufacturers in implementing the most effective and efficient measures for achieving compliance with the OSH legislation. It has been argued by stakeholders from both industry and some Member States that a longer transition period may help increase the overall effectiveness and efficiency of the legislative framework, by giving industry more time to identify substitutes rather than to adopt measures lower down the hierarchy within the Carcinogens and Mutagens Directive; in particular, this may be of value for SMEs who are likely to face greater challenges in terms of research and development. On the other hand, extending the transition period would delay the protection of workers.

Although the case study focuses on the issues related to the intentional use of formaldehyde in the wood based panel industry, similar issues will have arisen for those workplaces where exposures to formaldehyde may arise from it being present as a process-generated chemical agent. In addition, similar issues could reasonably be expected to arise from the re-classification of other substances. It should also be noted that whilst the implementation time for complying with a new harmonised classification under CLP is 18 months from the date when an ATP is issued, there will be information available, e.g. through the ECHA website that the classification change is being considered well in advance of this. This information will almost certainly be visible to major users and suppliers of the substance, who will therefore be in a position to start preparatory work. However, employers whose general operations do not bring them into frequent contact with CLP are unlikely to be tracking the substance evaluation and harmonised classification processes.

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Case Study 11: Risk Management Measures Triggered by Classification for CMR under CLP

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1 Introduction

1.1 The issue

Carcinogenic, mutagenic and reprotoxic substances are often grouped together, as such substances may exhibit all three of these properties. Such substances are chronically toxic; having long term effects on human health and may have the possibility of causing death. The harmonised classification of a substance as a carcinogen, mutagen or reprotoxin (CMR) 1A, 1B or 2 under CLP triggers risk management measures in other EU legislation. The types of risk management measures that may be triggered by a CMR classification range from a ban on the use of the substance in a product, which occurs in five of the six pieces of legislation identified below, to reduction of exposure through changes in technical procedures. The key pieces of legislation identified as being affected by a CMR classification are¹:

- The Biocidal Products Regulation²;
- The Cosmetic Products Regulation³;
- The Plant Protection Products Regulation⁴;
- The Toy Safety Directive⁵;
- The Regulation on Plastic Materials and Articles intended to come into contact with food⁶;
- The Carcinogens and Mutagens Directive⁷; and
- Prior Informed Consent Regulation⁸.

The focus of some of the above pieces of legislation is on the protection of consumers (Biocidal Products Regulation, Plant Protection Products Regulation, Cosmetic Products Regulation, Toy Safety Directive, food contact materials) or workers' health (Carcinogens and Mutagens Directive, Biocidal Products Regulation and Plant Protection Products Regulation), while in other cases it is the

¹ This list is not exhaustive. CMR substances are potential candidates for Authorisation or Restriction under the REACH Regulation (EC 1907/2006). REACH is not included in this case study as it is not included in the scope of this study. In addition, CMR substances are restricted for use under the Tobacco Directive (Directive 2014/40/EU on manufacture, presentation and sale of tobacco).

² Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

³ Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

⁴ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

⁵ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.

⁶ Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

⁷ Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC).

⁸ Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

environment (Biocidal Products Regulation, Plant Protection Products Regulation and Prior Informed Consent Regulation) and exposures to the public via the environment. This case study is concerned with assessing the differences in risk management that are triggered in downstream EU legislation following a substance gaining a harmonised classification as a CMR under CLP. The focus is on CMRs rather than other health hazards, as there are far fewer linkages to other types of health hazard classifications between CLP and downstream legislation. There are other vertical linkages, however, such as those between the Toy Safety Directive, CLP and Cosmetic Products Regulation where there are not only risk management measures for CMRs, but for allergenic substances and certain metals as well.

1.2 Case study aim

This case study seeks to examine the risk management measures triggered across the downstream legislation mentioned above by a CMR classification and their differences. It considers both harmonised classifications for which risk management is employed in the majority of professional and consumer legislation, and self-classified and harmonised classifications for which risk management is employed in OSH legislation. Key questions to be addressed relate to the extent of consistency, or lack thereof, in the approaches taken when implementing a risk management measure and whether this is appropriate:

- Should all legislation trigger risk management measures automatically by using generic risk considerations (e.g. hazard-based risk management of CMRs in consumer products)?
- Should a specific risk-based approach involving further assessment be applied on a case-by-case basis in order to ascertain the appropriate risk management option, or should it apply as a matter of principle in all cases?
- What types of costs do the different approaches to risk management measures trigger? If there are differences in the types of costs triggered by under the legislation, are these differences justified and on what grounds are they justified?

Although CMRs are subject to risk management under all of the above legislation, exemptions and derogations for their use may apply. These exemptions may allow for industry to continue using a CMR substance in its products, with the possibilities depending on the legislation. In this respect, it is important to examine whether there are differences in effectiveness (as an indicator of benefits) and associated efficiency (as an indicator of costs) appear appropriate given differences in the objectives of the various legislation.

The case study therefore reviews the requirements under the different legislation in terms of risk management and the potential for derogations or exemptions. It also considers effectiveness and efficiency issues by considering a series of case study substances and information on costs available from the literature. The case studies relate to N, N-Methylenebis(morpholine) (MBM), gallium arsenide, formaldehyde (also linked to Case study 10), tris(2-chlorethyl)phosphate (TCEP), lead (also linked to Case Study 2) and nickel.

1.3 Methodology

The information required for this case study was gathered through desk based research and consultation with industry associations and other stakeholders. Stakeholders consulted for the case study include:

- European Chemicals Agency (ECHA), European Food Safety Agency (EFSA), the Biocidal products Committee (BPC), the Scientific Committee on Consumer Safety (SCCS);

- The Commission services and the relevant Member State Committees;
- The European Consumer Organisation (BEUC), Health and Environment Alliance (HEAL), Pesticide Action Network (PAN), Women's Environment Network (WEN), European Trade Union Institute (ETUI), and other relevant non-governmental organisations; and
- Cefic, (European Association of Chemical Distributors (FECC), Eurometaux, Formacare, Cosmetics Europe, European Crop Protection Association, and CEEMET (European Employers Association representing Metals, Engineering and Technology based industry)).

The links between CMR classification under CLP and the resulting risk management measures can be derived from an analysis of the legislation but also from a review of the work and implementing measures of the different competent authorities via desk research (e.g. EFSA and ECHA websites).

Stakeholder consultation was also undertaken to establish what, if any, are the issues surrounding CMR classification and the resulting risk management procedures from the perspective of industry and consumer and environmental associations. This was carried out through targeted questionnaires, telephone interviews and face-to-face meetings.

It should be noted that it is not possible for the consultant to provide detailed cost-benefit analyses for the case study substances due to a lack of information. Instead, the focus has been on looking at the types of costs that classification could trigger and those identified by stakeholders or in the literature. No estimates of benefits can be provided due to a number of factors. CMR substances tend to exhibit long latency periods and it can be very difficult to pinpoint the causative factor. Even when a decrease in the incidence of cancer has been observed, it may not be possible to attribute this to one piece of legislation.

2 Legislative Context

2.1 Overview

Each of the pieces of legislation mentioned above has legal provisions regarding the risk management measures triggered by a CMR classification. Risk management measures may be hazard-based or risk-based, as outlined in Table 2-1 overleaf which builds on the more generic concepts presented in the Task 3 report. These pieces of legislation, with the exception of the Carcinogens and Mutagens Directive and Food Contact Materials Regulation, prohibit the use of CMRs but contain derogations or exemptions from this prohibition under certain circumstances. The criteria for exemption vary between legislation. In order for CMRs to be approved for use, many of the regulatory acts require an opinion approving the derogation or exemption from a scientific committee. The analysis focuses on three possibilities for how the CLP classification leads to a risk management measure (RMM), as detailed in the ToR:

- Possibility 1: The risk management measure is triggered automatically;
- Possibility 2: The risk management measure can only be triggered after further assessment;
- Possibility 3: The risk management measure is subject to further implementation steps (for instance, as defined and implemented by operators).

Further details for each piece of legislation are provided below.

2.1.1 Regulation (EC) No 1223/2009 on cosmetic products

The Cosmetic Products Regulation 1223/2009 seeks to address the protection of human health through making cosmetic products sold in the EU safer. Under Article 15 of the Regulation, CMR substances classified as category 1A, 1B or 2 under Part 3 of Annex VI of CLP are prohibited for use in cosmetic products. There are exemptions for this if all the following conditions can be met.

CMR category 1A or 1B

These substances are prohibited under Article 15(2) except where:

- a) They comply with the food safety requirements as defined in Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;
- b) There are no suitable alternative substances available, as documented in the analysis of alternatives;
- c) The application is made for a particular use of the product category with a known exposure; and
- d) They have been evaluated and found safe by the SCCS for use in cosmetic products. This must take into account exposure to these products, overall exposure from other sources and vulnerable population groups.

Risk management measures include specific labelling in order to avoid misuse of the product in accordance with Article 3 of the Cosmetic Products Regulation, taking into account the presence of hazardous substances and the routes of exposure.

In the event of these exceptions, the Commission shall adopt the necessary measures in accordance with Article 32(3) of Cosmetic Products Regulation (Committee procedure).

Table 2-1: Risk management procedures under the different legislation				
EU act	Possibility 1: automatic	Possibility 1.5: automatic with derogation or exemption	Possibility 2: Further assessment	Possibility 3: Further implementation measures
Consumer products				
Regulation (EC) No 1223/2009 on cosmetic products	CMR substances classified as category 1A, 1B or 2 under Part 3 of Annex VI of CLP are prohibited for use in cosmetic products	An exception is possible if SCCS ⁹ finds the substance safe for use (and regarding cat.1A and 1B if certain conditions are fulfilled)		
Directive 2009/48/EC on the safety of toys	Without prejudice to the restrictions referred to in the second paragraph of point 1, substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys	Derogation: Substances and mixtures classified as CMR category 1A and 1B and category 2 under CLP may be used in toys if they are contained in individual concentrations equal to or smaller than the relevant concentrations established by CLP, if they are inaccessible to children in any form, including inhalation, when the toy is used, if the use of the substance has been permitted. Double derogation: Neither the prohibition on use of CMRs in toys, nor the derogation allowing to use CMRs under the above conditions apply to materials complying with specific limit values set out in Appendix C		
Commission Regulation (EU) No	Based on Article 14, substances not listed in the Union list can be			

⁹ Scientific Committee on Consumer Safety (SCCS).

Table 2-1: Risk management procedures under the different legislation				
EU act	Possibility 1: automatic	Possibility 1.5: automatic with derogation or exemption	Possibility 2: Further assessment	Possibility 3: Further implementation measures
10/2011 on plastic materials and articles intended to come into contact with food	used in plastic layers that are not in direct contact with food and are separated from the food by a functional barrier, with the exception of CMRs. There is no potential for derogation or exemption from these provisions for CMRs			
Professional products – PPP and biocidal products are not only professional products but they are sold to consumers as well				
Regulation (EC) No 1107/2009 on plant protection products	An active substance shall only be approved if ... it is not or has not to be classified, in accordance with the provisions of the CLP Regulation as a carcinogen, mutagen or reprotoxin category 1A or 1B	RMM will also depend on a further assessment notably of the negligible nature of the exposure of humans, under realistic proposed conditions of use of the PPP for C1B and for R1B and for Endocrine disruptors		
Regulation (EU) No 528/2012 biocidal products	Any active substance that has been classified under CLP as a CMR category 1A or 1B substance is prohibited for use in biocidal products.	Exemptions apply if certain conditions can be met	Classification as CMR 1A or 1B under CLP may also trigger further assessment steps in order to determine whether the conditions for derogation to exclusion set in Art. 5(2) are met and whether risk assessment criteria are met	
Health & safety of workers				
Directive 2004/37/EC carcinogens or mutagens at work ¹⁰				- Employer must determine and assess risks of exposure to carcinogens and mutagens

¹⁰ Reproductive toxins (R) are not covered by the Carcinogens and Mutagens Directive.

Table 2-1: Risk management procedures under the different legislation				
EU act	Possibility 1: automatic	Possibility 1.5: automatic with derogation or exemption	Possibility 2: Further assessment	Possibility 3: Further implementation measures
				(Article 3) - Employer substitution requirement for less hazardous substances - In case replacement is not feasible employer must ensure the use of a close system - If a closed system is not feasible, set prevention and reduction of exposure measures
Environmental Protection				
Regulation (EU) No. 649/2012 concerning the export and import of hazardous chemicals (recast)	For chemicals listed in Part 3 of Annex I, that are classified as CMR, the explicit consent requirement cannot be waived in case the intended use declared in the export notification and confirmed in writing by the importer is not a category for which the chemical was listed in Part 2 or 3 of Annex I, and there is evidence from official sources that the chemical has in the last five years been used in or imported into the importing Party or other country concerned			

CMR category 2

These substances are prohibited under Article 15(1) except where the substance has been evaluated by the SCCS and found safe for use in cosmetic products. In the event of these exemptions, the Commission shall adopt the necessary measures in accordance with Article 32(3) of Cosmetic Products Regulation (Committee procedure).

Authorisation procedure¹¹

In order to get approval for use of a CMR category 1A, 1B or 2 substance in cosmetic products, the SCCS must formulate an opinion on the safety of their use. The Commission or Secretariat submits a draft request to the SCCS for such an opinion, with this request including the terms of reference (which must be a scientific risk assessment), Community interest, scientific background and the proposed deadline for the formulation of the opinion. The Scientific Committee then establishes a Working Group to review and evaluate the scientific evidence, in order to form its draft opinion.

At this point there may be a call for information from stakeholders in order to obtain any further relevant scientific information. The draft opinion is passed from the Working Group to the Committee who decides whether or not to accept the opinion based on what the Working Group has been able to establish. A pre-consultation opinion may be formed for public consultation in order to gather comments, suggestions, extra scientific information and to identify issues which need to be further developed. This public consultation is not based on policy or risk management matters, solely the collection of additional scientific information. Socio-economic considerations are not taken into account in this process. Revision of an opinion that has been closed will not be considered for 3 years.

The Commission is also required to send a mandate to the SCCS to re-evaluate CMR substances which have been granted authorisation for use in cosmetic products as soon as safety concerns arise, and at least 5 years after their inclusion in Annexes III to VI of the Cosmetic Products Regulation, and at least every subsequent 5 years.

Stakeholder and public participation

The Committee or the Commission may organise technical or public scientific hearings with stakeholders to obtain additional technical or scientific information, comments, suggestions, explanations and/or contributions on the scientific basis of the opinion. A technical hearing would occur during the drafting process, whereas a public hearing occurs during the public consultation after the draft opinion has been written.

Timelines

For CMR category 1A or 1B substances, the Commission has 15 months from the inclusion of the substance in Annex VI of CLP to amend the annexes of the Cosmetic Products Regulation in line with the regulatory procedure with scrutiny referred to in Article 32(3) of the Cosmetic Products Regulation. This appears to be a relatively short period for all of the activities required.

¹¹ European Commission (2013): Rules of Procedure: The Scientific Committees on Consumer Safety (SCCS), Health and Environmental Risks (SCHER), Emerging and Newly Identified Health Risks (SCENIHR). Available at: http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_2013_en.pdf

2.1.2 Toy Safety Directive 2009/48/EC

The Toy Safety Directive is intended to provide a common standard for the safety of toys sold within the European Economic Area, with a view to ensuring the health and safety of children.

Article 10 provides that Member States must ensure that toys which do not comply with the essential requirements under Annex II cannot be placed on the market. Point 3 of Part 3 of Annex II states that: *“Substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys”*.

A derogation may be given if one or more of the conditions outlined in Table 2-2 are met.

Table 2-2: Derogation criteria for CMR substances		
Derogation	CMR category 1A and 1B	CMR category 2
These substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances	✓	✓
These substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2)	✓	✓
A decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A	<ul style="list-style-type: none">• The use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure;• There are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives; and• The substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006 [REACH Regulation].	<ul style="list-style-type: none">• The use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure; and• The substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006 [REACH Regulation].

The Commission is also required to send a **mandate to the relevant Scientific Committee to re-evaluate those substances or mixtures as soon as safety concerns arise and at the latest every five years** from the date that a decision in accordance with Article 46(3) was taken.

Article 46(3) states that:

“The Commission may decide upon the use in toys of substances or mixtures that are classified as carcinogenic, mutagenic or toxic for reproduction of the categories laid down in section 5 of

Appendix B to Annex II and have been evaluated by the relevant Scientific Committee, and may amend Appendix A to Annex II accordingly. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 47(2)”.

As of 01/06/2015, substances and mixtures are classified under the rules of the CLP Regulation.

Safety requirements

The essential safety requirements under Article 10 have been criticised as they are general requirements based on standards. Members of the Toy Safety Expert Group have indicated that specific concentration limits for substances in toys (not simply the Specific Concentration Limit (SCL) outlined in the CLP Regulation) should be established for the more problematic chemicals, such as CMRs. Points 4 and 5, and the corresponding Sections 3 and 4 in Appendix B, could be improved by combining the provisions so that CMRs are covered by one paragraph, making the rules clearer. As these three classifications have the same provisions under the Toy Safety Directive, it makes little sense to have these provisions laid out over separate points.

Specific limit values have not been established for all substances considered to be of concern for toys under the Toy Safety Directive (as have been set out for TCEP, TCPP, TDCP and Bisphenol A). As such, the provision in the Toy Safety Directive for CMRs is that they should not exceed the limit value laid down by CLP. These are outlined in Table 2-2. The lack of established limit values can pose a problem for duty holders in establishing the concentration of a substance that is permitted or the migration limits that are acceptable. Stakeholders say that this poses issues in the conformity assessment and subsequent enforcement. One stakeholder has stated that “whilst such generic provisions are, of course, necessary they should not be regarded as a substitute for stipulating precise chemical requirements so that the application of the generic safety requirement becomes the very exception rather than a main route to ensure the chemical safety of toys”.

Table 2-3: Limit values laid down in CLP			
Ingredient classified as	Generic concentration limit		
	Category 1A	Category 1B	Category 2
Carcinogen	≥0.1%	≥0.1%	≥1%
Mutagen	≥0.1%	≥0.1%	≥1%
Reprotoxin	≥0.3%	≥0.3%	≥3%

Point 13 of Part III of Annex II provides a list of substances and associated migration limits that should not be exceeded for toys or toy components. These limit values do not apply to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin when used as specified in the first subparagraph of Article 10(2). This list of substances contains both classified CMR substances, such as cadmium, mercury and nickel, and substances that are not directly classified as CMRs but have compounds which are classified as CMRs, (chromium III, chromium VI, lead, strontium).

One substance (nickel) has been permitted under Appendix A of Annex II in accordance with point 6 of Part 3 to Annex II¹². It is classified as a category 2 CMR but is permitted for use in: 1) toys and toy

¹² Point 6 of Part II of Annex II of the Toy Safety Directive reads “Points 3, 4 and 5 shall not apply to nickel in stainless steel”.

components made of stainless steel, and 2) toy components which are intended to conduct an electric current.

The Toy Safety Directive has special provisions for toys for children under 36 months or for toys intended to be put in the mouth. Appendix C of Annex II provides specific limit values for chemicals used in toys intended for such uses and users, adopted in accordance with Article 46(2). Table 2-3 provides details of the limit values for the chemical substances listed in Appendix C.

Table 2-4: Substances with specific limit values listed in Appendix C of Annex II of the Toy Safety Directive in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth		
Substance	CAS No	Limit value
TCEP	115-96-8	5 mg/kg (content limit)
TCP	13674-84-5	5 mg/kg (content limit)
TDCP	13674-87-8	5 mg/kg (content limit)
Bisphenol A	80-05-7	0.1 mg/l (migration limit in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005)
Note: this refers to Appendix C of Annex II as of 30 June 2014		

Although this is considered to be a strength of the Directive, stakeholders (including Member States) believe that the comitology of Article 46 should apply to all toys irrespective of the intended age of the user. One stakeholder has suggested that this is not appropriate as it does not address the risks from dermal exposure and it also does not address the risks to children above the age of 36 months. As children are a vulnerable population, stakeholders believe that rules for chemicals in toys should be explicitly laid down so as to avoid any ambiguity and confusion.

Stakeholders have identified three types of toy that they have been aware of failing to meet the requirements for CMRs in toys. These toys were EVA foam toys, wooden puzzles (formaldehyde) and plastic balls (DIBP). They were manufactured outside of the EU, but the wooden puzzles containing formaldehyde had been identified as also being manufactured in the EU.

Scientific and Member State Committee Procedures

The Scientific Committee on Health and Environmental Risks (SCHER) and/ or the SCCS must provide their opinion on the use of CMRs in toys following the same rules of procedure as the SCCS (details above). Under Article 46(3) the formal decision on the authorisation of CMRs in toys is taken by the Commission after they have been evaluated by the relevant scientific committee. These measures are adopted in accordance with the regulatory procedure with scrutiny referred to in Article 47(2).

These scientific committees do not authorise substances but only provide scientific opinion. The formal decision is taken by the Commission under Article 46(3) of the Toy Directive:

'The Commission may decide upon the use in toys of substances or mixtures that are classified as carcinogenic, mutagenic or toxic for reproduction of the categories laid down in Section 5 of Appendix B to Annex II and have been evaluated by the relevant Scientific Committee, and may amend Appendix A to Annex II accordingly. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 47(2).'

Article 47(2) is the Committee procedure which involves Member States' representatives. The procedure is set under Regulation (EU) 182/2011 repealing Decision 1999/468 and more specifically Articles 5 and 10.

Clarity of legal text

In order to get a clearer view of the issues related to CMR use in toys, a targeted consultation with the Toy Safety Expert Group was carried out. One of the issues identified concerned the clarity of the legal text. Respondents from the Expert Group indicated that requirements are not clear for two reasons; lack of direction for limit values when they are laid out under other legislation; and the use of wide terminology such as "have reason to believe". An example given was limit values for benzene which are established under REACH and not stated under the Toy Safety Directive. It can be difficult for economic operators to know what the established rules are when they are not explicitly laid out or no direction is given to the appropriate legislative instruments. This lack of clarity on the rules for CMRs in toys could lead to manufacturers making mistakes as to what they can and cannot use, and at what concentration. In order to combat this, it has been suggested that there should be a list of restricted chemicals, as there is in the Cosmetic Products Regulation. This would be a first point of contact for economic operators looking to ensure that there is compliance with the chemical safety rules of the Toy Safety Directive. At present there is a list of restricted allergenic fragrances and a list of migration limits for toys and components of toys in Annex II. Appendix A holds the list of CMR substances and their permitted uses, but experts believe that clarity would be improved if a list of prohibited substances was added to the Annexes.

The wording of some of the aspects of the Toy Safety Directive is considered to be ambiguous and this does not help manufacturers meet the requirements for CMRs in toys. One stakeholder has highlighted the lack of clarity in Annex II, Part III where it states as a general requirement "that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures". Another issue lies with the ban on substances that are "classified as CMRs in accordance with CLP". Stakeholders are not clear as to whether this means those with a harmonised classification or those which are self-classified as well.

Automatic ban on CMRs in toys

The split of stakeholder opinion is fairly even regarding whether the automatic ban of the use of CMRs laid down in Annex II, Part III of the Toy Safety Directive is appropriate for ensuring adequate protection of children's health. Of those who responded to this question, 56% said that it was appropriate for both Category 1 and Category 2 CMRs. One stakeholder believes that this generic ban should be maintained as a first tier of protection in addition to a second tier which establishes specific limits for individual CMRs. Although risk assessment may be warranted, case-by-case assessment of substances of concern is costly and time consuming. This being said, one stakeholder stated that some CMRs are not a risk to children and so an automatic ban on their use would be unnecessary. At present, of the Member States who responded to their questionnaire, 2 respondents said they agreed with the current approach to risk management, whilst 1 disagreed (2 neutral and 3 didn't know).

Opinions from stakeholders within the Expert Group on Toy Safety on derogations for CMR use in Annex II, Part III are shown in Table 2-4. The derogation which is most heavily criticised by stakeholders is point 4(a) of Annex II, Point III. SCHER has issued an opinion that these limits do not ensure the safety of children as the generic concentration limits are not based on risk assessment and are not derived by considering children. The majority of stakeholders (a mix of industry, NGOs and Member States) are of the opinion that these generic concentration limit values are too high and should at least be reduced to 0.01%; a minority were of the view that the current limit is

acceptable or they held no opinion on the matter. NGOO and industry stakeholders indicated that non-threshold CMRs should not be permitted for use at all. Stakeholders also indicated that for organic CMRs in Toys, the Directive should be based on the opinion of SCHER. One Member State also pointed out that, in some cases, concentrations of CMRs below the classification limit can pose a risk.

There is also an issue with the term “inaccessible”. It has been suggested by stakeholders that the standard EN 71-1 is related to mechanical safety and does not address exposure pathways such as inhalation. See the box overleaf which provides further details on the nickel derogation.

Table 2-5: Stakeholder opinions on derogations for CMR use (n=9)

Point	Derogation criteria	Yes	No	Don't Know
4(a)	Concentrations equal to or smaller than those established in CLP	33%	67%	
4(b)	Where the substance or mixture is inaccessible to children in any form	89%	11%	
4(c)	Where a decision has been undertaken in accordance with Article 46(3) to permit use of the substance or mixture	89%	11%	
6	Nickel in stainless steel	78%	11%	11%
7	Materials complying with specific limits in Appendix C or covered by the provisions for food contact materials	56%	44%	

The case of nickel in toys

Nickel is used in toys in model railway tracks, wire plugs, connectors, and electrical contacts in model locomotives and cars. It is classified as a carcinogen category 2 under Regulation (EC) No 1272/2008. As a result of this, it is subject to the automatic ban on the use of CMRs in toys. Nickel is the only CMR to have been authorised for use under Appendix A of the Toy Safety Directive, with it currently being allowed for use in toys and toy components made of stainless steel and in toy components which are intended to conduct an electric current. In order to obtain the derogation under point 5, Part 3, Annex II, Nickel must not have been banned for use in consumer products under REACH, and an opinion on safe use had to be sought by an appropriate committee. There is no ban on consumer use of nickel in toys, but it is restricted to a release of 0.5 µg/cm²/week in a standardised release assay. In 2012, in order to obtain a derogation for the use of nickel in components which conduct electricity, The Commission requested an opinion from SCHER as per point 5, Part 3, Annex II. The two opinions sought and the SCHER response is given below.

1. *“Is there sufficient scientific information available to evaluate the risk to children's health from the presence of metallic nickel in materials allowing the correct electrical function of toys?”*

Ni only causes tumours in the respiratory tract after inhalation exposures to Ni-containing dusts and fumes, but not after oral intake as demonstrated by several studies summarised in the EU RAR. **Inhalation of Ni in the form of fumes or dusts released from toys is extremely unlikely in non-occupational setting** (e.g. for children) due to the very low vapour pressure of Ni. Toys need to be subjected to abrasive or thermal treatment of the Ni-containing parts using very specific equipment and high temperatures before Ni is likely to be produced in a form in which it could be inhaled. Malfunction of electric motors is not considered as a source of metal fumes in the occupational setting (EU RAR) and malfunction of the small electric motors in model cars and railway locomotives is thus not expected to release inhalable Ni under reasonably foreseeable conditions. **Therefore, the classification of Ni as a CMR, which is based on effects after inhalation of Ni-containing dusts and fumes, has no relevance for risk assessment of the oral or dermal exposures to Ni expected from handling of toys.**

2. *On the basis of the available scientific information, is it possible to conclude that the presence of metallic nickel in materials allowing the correct electrical function of toys would not pose a risk to the health of children? If so, please specify the specific use of metallic nickel where no risk on health is expected.*

Since inhalation of Ni from toys is extremely unlikely from toys, **a tumour risk due to Ni exposure when handling toys is not present**. Intake of Ni by oral or skin contact with Ni-containing parts of toys is also expected to be very limited due to the restrictions on Ni-release applicable to metal-containing parts in toys, the limited accessibility of the metal-containing parts, and the small surface area of the Ni-containing parts in the Ni application considered here. The EU RAR concluded large margins of safety for all oral Ni exposures including Ni exposures from food contact materials (3 µg/kg bw/d) and did not consider dermal exposures to Ni from coins (which release more Ni under standard conditions as compared to toys) as a health risk. SCHER therefore concludes that the use of Ni in parts of toys allowing the correct electric function of toys will result in a very low potential for exposure to Ni by oral and dermal intake. Thus, health risks are not expected¹³.

In forming these opinions, the Commission expressly asked that SCHER take into account the “particularity of the consumer, who is under 14 years old and the various possible exposure scenarios”¹⁴. Although some stakeholders may hold the view that vulnerable populations are not given enough consideration in the assessment process, this particular opinion shows that, depending on the questions to be asked, the population of concern and their characteristics may play a vital role in the final opinion. This could be considered to be a positive aspect of the risk management process for CMRs.

2.1.3 Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food

This Regulation sets out requirements for the manufacture and marketing of plastic materials and articles intended to come into contact with foods in order to reduce the risk to human health from the transfer of toxic substances from the plastic. Recital 27 states that “Substances that are mutagenic, carcinogenic or toxic to reproduction should not be used in food contact materials or articles without previous authorisation”. The constituents of plastic layers which are separated from the food by a functional barrier and are not listed in the Union list (authorised substances) or provisional list must not be classified as a CMR¹⁵.

CMR substances can be added to the Union list if they have been approved by EFSA following a risk assessment. Any substance in the Union list must comply with the specifications and restrictions of the Regulation. Specific migration limits for substances on the Union list are set by EFSA¹⁶, and examples of CMRs present on the Union list are: formaldehyde; acetaldehyde; 2,6-toluene diisocyanate; and 1,4-dihydroxybenzene.

Authorisation procedure

The CA will then forward the application to EFSA who check the validity of the application. EFSA has six months to provide an opinion on a valid application. Additional time can be added if more

¹³ Scientific Committee on Health and Environmental Risks (2012): Assessment of the Health Risks from the Use of Metallic Nickel (CAS No 7440-02-0) in Toys. Available at: http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_163.pdf

¹⁴ Scientific Committee on Health and Environmental Risks (2012): Assessment of the Health Risks from the Use of Metallic Nickel (CAS No 7440-02-0) in Toys. Available at: http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_163.pdf

¹⁵ Article 13 (4) and Article 14 (3). Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

¹⁶ European Commission Health and Consumer Directorate-General (2014): Union guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. Available at: http://ec.europa.eu/food/safety/docs/cs_food-contact-materials_plastic-guidance_201110_en.pdf

information is required to form the opinion. Following the opinion from EFSA, the Commission will make a decision on the authorisation of the substance. If authorisation is granted, then the 'Plastic Materials' Regulation shall be amended and the substance will be added to the Union list. If the proposal is agreed then it shall be published in the EU Official Journal. This process can take up to nine months from receipt of the EFSA opinion. The application for authorisation and any supplementary information from applicants, excluding that of a confidential nature, is made available to the public.

2.1.4 Regulation (EC) No 1107/2009 on plant protection products

Plant Protection Products (PPPs) are pesticides that protect crops or desirable/useful plants. PPPs are predominantly used in the agricultural sector, but are also used in forestry, horticulture, amenity areas and in domestic gardens (European Commission, 2015a).

Use of plant protection products must be safe for both human health and the environment. Before an active substance can be used within a PPP in the EU, it must be approved by the European Commission. The PPP must also be authorised for use by the Member States concerned before being placed on the market. Substances undergo an intensive evaluation and peer-review exercise by Member States and the European Food Safety Authority before a decision can be made on approval. PPPs may also contain other components including safeners and synergists.

CLH process for plant protection products

Article 36 (2) of the CLP Regulation establishing harmonised classifications applies to substances that are used as active ingredients in plant protection products and biocidal products. Substances that are regulated under the Plant Protection Products Regulation are normally subject to harmonised classification and labelling (CLH) for all hazardous properties¹⁷, while industrial chemicals may only be subject to harmonised classification and labelling for a subset of properties, such as CMR properties, or when justified.

Proposals for a substance used in plant protection products which are seeking harmonised classification must be submitted to ECHA and the Risk Assessment Committee (RAC) through an Member State competent authority. Unlike the case for substances used for other applications (e.g. industrial chemicals), proposals cannot be submitted by manufacturers, importers or downstream users for a CLH under the Plant Protection Products Regulation¹⁸. The RAC must deliver an opinion on a harmonised classification within 18 months of an application, with industry input restricted to one public consultation (and potential attendance at the RAC meetings where the proposal is being discussed). EFSA and ECHA are currently looking at ways to align their respective processes such that a CLH opinion can be concluded during the evaluation timeline for authorisation of an active substance¹⁹.

¹⁷ ECHA (2015): Introductory Guidance on the CLP Regulation. European Chemicals Agency. Available at: http://echa.europa.eu/documents/10162/13562/clp_introductory_en.pdf

¹⁸ ECPA (2015): Classification and labelling of Plant Protection Products. European Crop Protection Association. Available at: <http://www.ecpa.eu/information-page/regulatory-affairs/classification-and-labelling>

¹⁹ ECPA (2015): Classification and labelling of Plant Protection Products. European Crop Protection Association. Available at: <http://www.ecpa.eu/information-page/regulatory-affairs/classification-and-labelling>

Plant protection product active substance approval

There are two parts to the approval of plant protection products in the EU: 1) the active substance(s) must be approved at EU level; and 2) the formulated product must be authorised at Member State level.

All active substances must be evaluated by experts in an Member State competent authority, who act as the Rapporteur Member State (RMS), with the recommendations of the RMS then peer reviewed by EFSA. It can then be considered for approval by the European Commission after a favourable opinion of the Standing Committee on Plant, Animals, Food and Feed (PAFF). If a substance is approved at the EU level, the producers will apply to have formulated product registered at Member State level. The stages of the EU approval process are:

1. Submission of test results and studies to a RMS by the entity seeking approval;
2. Member State prepares a Draft Assessment Report. This must be submitted to the EFSA within 12 months of receiving the dossier of results;
3. Draft Assessment Report is independently reviewed by EFSA;
4. The results of EFSA's expert meetings are sent to the Commission:
 - a. When making the Draft Assessment Report available to the public, EFSA must allow a 60 day period for submission of written comments;
 - b. EFSA must adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of the Plant Protection Products Regulation within 120 days of the end of the submission period for written comments. An extension of 30 days can be applied if consultation is necessary;
5. In accordance with Article 13 of the Plant Protection Products Regulation, the Commission must present a Review Report and a draft Regulation to PAFF committee within six months of receiving their conclusion. This Review Report and draft Regulation must take into account the Draft Assessment Report of the RMS and the conclusions of EFSA;
6. Final approval of the active substance is decided by the Commission ; and
7. The approval is adopted by the Commission and published in the EU Official Journal.

This whole process can take between 2.5 to 3.5 years from the date of admissibility of the application to the publication of a Regulation approving the substance.

Plant protection product authorisation

As noted above, before a plant protection product can be placed on the market it must also be authorised for use by the Member States concerned. After considering specific local variations in climate, cropping patterns and diet, a Member State can grant a full authorisation of the product, an authorisation restricted to certain crops, or reject the authorisation. The data requirements for plant protection product approval by Member States, and the criteria by which the EU and Member States evaluate these products are harmonised at EU level.

Article 31 (2) states that:

“Authorisation shall set out the requirements relating to the placing on the market and use of the plant protection product. Those requirements shall as a minimum include the conditions of use

necessary to comply with the conditions and requirements provided for in the Regulation approving the active substances, safeners and synergists”.

Authorisation should include a classification of the plant protection product. Member States may provide that the authorisation holders shall classify or update the product label without undue delay following any change to the classification and labelling of the plant protection product in accordance with the CLP Regulation. Where classifications or product labels are changed, the Member State competent authority must be informed immediately.

Article 31 specifies that the authorisation granted by the competent authority shall include a classification. As a result, this is currently interpreted, in some cases, that **Member States should decide on the classification when granting the authorisation**. ECPA and individual industry stakeholders believe, however, that the CLP Regulation should take precedence over the PPP Regulation with respect to classification and labelling. They argue that the manufacturer or supplier therefore should be responsible for the classification of a plant protection product; some, but not all, of the CAs dealing with PPPs appear not to agree that the responsibility for classification and labelling should lie with the manufacturer or supplier. This has led to a lack of coherence between Member States in that some are requesting almost a re-submission of data with the new classification and others are happy to let companies reclassify and re-label without recourse to the authorisation and simply refer to the Safety Data Sheet (SDS)²⁰.

Articles 28-39 of the Plant Protection Products Regulation outline the requirements, contents and procedures for authorisation of plant protection products. Applications for authorisation by Member States are evaluated on a zonal basis. In some cases, the EU is considered as a single zone and a Member State may authorise the product for use in the entire EU.

The basic procedure for authorisation is as follows:

1. An application is made to the EU country/countries where the plant protection product is intended to be placed on the market via the Plant Protection Products Application Management System (PPPAMS). A zonal Rapporteur Member State (zRMS) is selected for each zone where the plant protection product is to be authorised (some uses are assessed by a single Member State on behalf of all zones);
2. zRMS carries out an assessment of the application;
3. Other Member States in the same zone comment on the zRMS's evaluation;
4. zRMS makes a decision on whether to grant or refuse an authorisation;
5. Other Member States make a decision on whether to grant or refuse an authorisation; and
6. If an authorisation is issued and later the applicant wishes to place the same product on the market in another Member State(s), an application is made for 'mutual recognition' of the product in the concerned Member State.

CMRs in active substances, safeners and synergists in plant protection products

Article 4 (1) of the Plant Protection Products Regulation states that:

²⁰ ECPA (2015): Classification and labelling of Plant Protection Products. European Crop Protection Association. Available at: <http://www.ecpa.eu/information-page/regulatory-affairs/classification-and-labelling>

“an active substance shall be approved in accordance with Annex II if it may be expected, in light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3”.

There are certain requirements for substances in plant protection products once they have been classified as a CMR. Annex II of the Plant Protection Products Regulation outlines the procedure and criteria for the approval of active substances, safeners and synergists pursuant to chapter 2 of the Plant Protection Products Regulation; these are set out in Table 2-5 below.

As can be seen from the table, in general, CMR substances are not to be used in plant protection products, but exemptions apply where “the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005 (on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC)”²¹.

Persistent, Bioaccumulative and Toxic Substances

Persistent, Bioaccumulative and Toxic substances (PBTs) are also not permitted for use in active substances, safeners or synergists. Paragraph 3.7.2.3 states that:

- *“an active substance, safener or synergist fulfils the toxicity criterion where:*
 - *the substance is classified as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2) pursuant to [the CLP Regulation]; or*
 - *there is other evidence of chronic toxicity, as identified by the classification STOT RE 1 or STOT RE 2 pursuant to [the CLP Regulation]”.*

²¹ Paragraph 3.6.3, Annex II to Regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

Table 2-6: Requirements for approval of substances classified as CMR in Plant Protection Products

Property	Annex II	Legislative text
Carcinogen	Paragraph 3.6.3	<i>an active substance, safener or synergist shall only be approved if, on the basis of assessment of carcinogenicity testing carried out in accordance with the data requirements for active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of [the CLP Regulation], as carcinogen category 1A or 1B unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005 (on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC)</i>
Mutagen	Paragraph 3.6.2	<i>an active substance, safener or synergist shall only be approved if, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of [the CLP Regulation], as mutagen 1A or 1B</i>
Reprotoxin	Paragraph 3.6.4	<i>an active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of [the CLP Regulation], as toxic for reproduction category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005 (on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC)</i>
<i>Outlined in Annex II of Regulation (EC) NO. 1107/2009 concerning the placing on the market of plant protection products.</i>		

2.1.5 Biocidal Products Regulation (EC) No 528/2012

Biocidal products are used to suppress pests and/ or protect materials but their properties can pose significant risks to humans, animals and the environment. The Biocidal Products Regulation harmonises the EU rules concerning the sale and use of biocidal products, whilst ensuring high levels of protection of human and animal health and the environment.

Approval procedure for active substances

For an active substance to be approved for use in a biocidal product it must be assessed by an evaluating Member State competent authority (eCA), who then pass their evaluation, in the form of a Competent Authority Report (CAR), to ECHA's Biocidal Products Committee (BPC). The BPC

prepares an opinion, within 270 days of receipt of the eCA evaluation, on whether or not the active substance should be approved for use.

A RAC opinion on the harmonised classification and labelling must be available at the time of submission of the CAR where CMR-based exclusion criteria are met. As a result, a CLH dossier must have been submitted by the time of the CAR submission. In the case of substitution criteria related to CMR properties, it is highly preferable that the RAC opinion on harmonised C&L is available at the time of CAR submission.

The BPC prepares opinions for:

- Applications for approval and renewal of approval of active substances;
- Review of approval of active substances;
- Applications for inclusion in Annex I of active substances meeting the conditions laid down in Article 28 and review of the inclusion of such substances in Annex I;
- Identification of active substances which are candidates for substitution;
- Applications for Union authorisation of biocidal products and for renewal, cancellation and amendments of Union authorisations, except where the applications are for administrative changes;
- Scientific and technical matters concerning mutual recognition in accordance with Article 38;
- At the request of the Commission or of the Member States, the BPC is responsible for preparing opinions on any questions that may arise from the operation of the Biocidal Products Regulation relating to risks to human or animal health or the environment, or to technical guidance.

Biocidal Product Authorisation

When a biocidal product is intended to be sold on the European market, it must gain a Union authorisation. The eCA finalises the draft assessment report (DAR) and the conclusions of its evaluation. The evaluation consists of a Product Assessment Report (PAR), which contains the conclusions of the evaluation and the draft Summary of Product Characteristics (SPC). The DAR is sent back to the applicant, who has 30 days to submit written comments. The evaluating competent authority (eCA) must submit its evaluation to ECHA after 365 days.

The Secretariat performs an accordance check for each PAR and draft SPC to verify that they are in the correct format and they are complete. There is also a check to see whether a comparative assessment has been performed when an active substance in the biocidal product is a candidate for substitution. An accordance check verifies whether there is a justification included in the specifications of a biocidal product family in line with the definition in Article 3(1)(s). The 180 day timeline for a BPC opinion through peer review assessment begins on a predefined date, following the PAR and draft SPC submission and the accordance check. If an accordance check is failed then the PAR and/or draft SPC is returned to the eCA for revision and is to be resubmitted during the next submission window.

The Commission, assisted by the Standing Committee for Biocidal Products, takes the opinion of the BPC into consideration and decides on the Union authorisation. The Standing Committee for Biocidal Products consists of representatives of the EU Member States²².

²² European Chemicals Agency (ECHA) (2013) Union Authorisation applications: working procedure for the Biocidal Products Committee (BPC).

Companies who wish to sell their product in one Member State must apply for authorisation in that country. The Member State concerned evaluates the application and decides on authorisation within 365 days. Mutual recognition allows for companies to extend their national product authorisation to other markets. Application for mutual recognition can be done in sequence or in parallel. Mutual recognition in sequence requires companies to first get authorisation by one Member State and then ask another to recognise it. Mutual recognition in parallel requires a company to submit an application for authorisation in one Member State (the reference Member State) and simultaneously ask other countries to recognise the authorisation as soon as it is granted. This process takes approximately five months from validation of the application by the eCA. If Member States do not agree to mutual recognition, the case is referred to a coordination group (composed of representatives of the Member States and the Commission), which has 60 days to seek agreement. It is now also possible to gain a National authorisation based on a Union authorisation²³.

Stakeholder and public participation

Meetings of the BPC are open to advisors, invited experts and observers. An advisor accompanies members of the Committee to provide scientific, technical or regulatory advice. Invited experts are those who are invited by ECHA, after a proposal by a Member State, to participate due to their expertise in a relevant scientific or technical field. Observers can include:

- The Executive Director and his representatives of the European Commission;
- Nominated representatives of accredited stakeholder organisations (ASO) - upon the request of ECHA Management Board, they may contribute their scientific or technical expertise;
- An applicant; and
- Representatives of third countries and international organisations (upon request of ECHA Management Board).

ASOs and applicants may be refused admittance on a case-by-case basis for reasons of confidential business information. Applicants may participate in discussions at the meetings, but they will not have access to the documents of the BPC, apart from in exceptional circumstances. They may be called upon by the BPC to submit additional information after they have submitted their application in order for clarification before an opinion can be developed and adopted.

Timelines

The BPC opinion on approval of an active substance must be submitted to the Commission 270 days after the receipt of the conclusions of the eCA. The BPC opinion for biocidal products must be submitted to the Commission 180 days after the receipt of the evaluation. Figures 2-4 and 2-5 displays the BPC process for active substance approval, and Figure 2-6 displays the BPC process for biocidal product approval.

²³ Biocidal Stakeholders Day 2016.

Requirements for CMR

Under Article 5(1), any active substance that has been classified under CLP as a CMR category 1A or 1B substance is prohibited for use in biocidal products. Exemptions apply if the active substance can be shown to meet one of the following conditions²⁴:

- A. The risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment;
- B. It is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment;
- C. Not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance; or

In order to meet with the conditions laid down in Article 5 (2), the availability of suitable and sufficient alternative substances or technologies must be taken into consideration. The use of a biocidal product which has met these conditions is subject to risk-mitigation measures in order to ensure that exposure to humans, animals and the environment is minimised. The use of a biocidal product containing active substances approved in accordance with Article 5 (2) is restricted to Member States in which at least one of the conditions is met.

The presence of a CMR prevents authorisation of a biocidal product intended for use but the general product under Article 19(4)(b).

2.1.6 Carcinogens and Mutagens Directive 2004/37/EC

The aim of this Directive is to protect workers against health and safety risks from exposure to carcinogens and/or mutagens at work. The Directive requires eliminating or reducing to a minimum the risks arising from the occupational exposure to carcinogenic or mutagenic substances and mixtures. It establishes a hierarchy for the risk management of exposures to carcinogens, based on both preventive and protective measures, including placing an obligation on employers to substitute these chemicals by less or non-hazardous substances, mixtures or processes, as far as technically possible. This obligation for substitution away from the use of carcinogens and/or mutagens has the highest priority. If substitution is not technically feasible, other measure to prevent exposure, such as working in a closed system or reducing the number of workers potentially exposed, have to be put in place by the employer.

Whether a substance or mixture falls under the scope of the Carcinogens and Mutagens Directive is primarily based on its classification as a carcinogen and/or mutagen (category 1A or 1B) according to the criteria established under the CLP Regulation²⁵. However, process-generated substances (PGS)

²⁴ Article 5(2) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

²⁵ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures. Available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1396363361882&uri=CELEX:02008R1272-20110419>

that are classified or recognised by other international bodies (e.g. the International Agency for Research on Cancer - IARC) also fall under the scope of the Carcinogens and Mutagens Directive, where these are included in Annex I to the Directive. This Annex covers substances, mixtures or processes (or substances /mixtures released by a process referred to in that Annex) which are not yet classified according to the CLP Regulation as carcinogens or mutagens, but are for example recognised by other international bodies (like as substances, mixtures or processes of equal concern²⁶).

There is also an obligation on employers to ensure that the limit values set out in Annex III to the Directive are not exceeded. Limit values are time-weighted upper thresholds for the concentration of hazardous substances in the air for a reference period of time and within the breathing zone of a worker. These are referred to as occupational exposure limit values, or OELs, which are established by the Commission taking into account Recommendations or Opinions of the Scientific Committee on Occupational Exposure Limits (SCOEL). Commission (COM) proposals for OELs also take into account the scientific-technical feasibility of monitoring exposure including the availability of suitable measurement techniques.

Under the current OSH legal framework, two types of occupational exposure limit values (OELs) are established:

- Indicative Limit Values (IOELVs); and
- Binding Limit Values (BOELVs).

IOELVs can be established under the Chemical Agents Directive (94/24/EC²⁷), based on SCOEL recommendations for health-based limit values that describe a threshold below which adverse effects to human health are unlikely to occur. BOELVs can be proposed under the Chemical Agents Directive and the Carcinogens and Mutagens Directive, and are established for the majority of the carcinogenic or mutagenic substances for which health-based limit values cannot be derived (as there is no threshold for effect). As it is not possible to derive an occupational exposure concentration below which carcinogenic or mutagenic effects will not occur for these substances, the OEL becomes binding in order to ensure a minimum level of exposure. Furthermore, as COM proposals for BOELVs also take into account technical feasibility factors, even where the occupational exposure of workers is equal or at the BOELV, additional protective and preventive measures need to be in place to ensure protection of workers' health.

For EU IOELVs, Member States are only obliged to establish a national OEL by taking the EU IOELV into account; national OELVs can be lower (more protective) or higher (less protective) than the EU IOELV, provided that a Member State can justify the deviation to the Commission. For EU BOELVs, Member States must establish a corresponding national limit value, from which they can only deviate to a lower more protective but not to higher value. It should be noted that:

²⁶ 1. Manufacture of auramine. / 2. Work involving exposure to polycyclic aromatic hydrocarbons present in coal soot, coal tar or coal pitch. / 3. Work involving exposure to dusts, fumes and sprays produced during the roasting and electro-refining of cupro-nickel mattes. /4. Strong acid process in the manufacture of isopropyl alcohol. / 5. Work involving exposure to hardwood dusts.

²⁷ Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work as amended. Available at: <http://eur-lex.europa.eu/legal-content/AUTO/?uri=CELEX:31998L0024&qid=1399304939016&rid=2>

- Since the Carcinogens and Mutagens Directive was first adopted in 1990, BOELVs have been set under the Carcinogens and Mutagens Directive for three substances (benzene, vinyl chloride monomer and hardwood dusts); and
- Under the Chemical Agents Directive, one BOELV has been set (for inorganic lead and its compounds) and 123 IOELVs have been adopted since 1991.

The obligation on employers with respect to keeping exposures to carcinogens and mutagens as low as possible applies regardless of the existence of a limit value.

2.1.7 Regulation (EU) No. 649/2012 concerning the export and import of hazardous chemicals (Prior informed Consent)

Article 14 of the Prior Informed Consent Regulation requires that chemicals listed in Parts 2 or 3 of Annex I are subject to export notification and explicit consent of the country of destination prior to the export of these chemicals. Article 14(7) contains two exemptions to the explicit consent requirement. Chemicals listed in Part 2 or 3 of Annex I may be exported without explicit consent if no evidence from official sources of final regulatory action to ban or severely restrict the use of the chemical taken by the importing Party or other country exists and if, after reasonable efforts, no response to a request for explicit consent pursuant to point a)²⁸ of Article 14(6) has been received within 60 days and where one of the following conditions are met:

- a) There is evidence from official sources in the importing Party or other country that the chemical is licensed, registered or authorised; or
- b) The intended use declared in the export notification and confirmed in writing by the natural or legal person importing the chemical into a Party or other country, is not in a category for which the chemical is listed in Part 2 or 3 of Annex I, and there is evidence from official sources that the chemical has in the last 5 years been used in or imported into the importing Party or other country concerned.

The chemicals listed in Part 2 or 3 are substance or mixtures containing such substances in a concentration that triggers labelling obligations under Regulation (EC) No. 1272/2008 irrespective of the presence of any other substances. However, for chemicals listed in Part 3 of Annex I, an export based on the fulfilment of point b) is not allowed if, among others, they are classified as a CMR category 1A or 1B under the CLP Regulation. The granting of export under these conditions is carried out by the exporter's Member State, in consultation with the Commission assisted by the Agency, with decisions made on a case-by-case basis.

²⁸ Article 14(6). Substances listed in Part 2 or 3 of Annex I or mixtures containing such substances in a concentration that triggers labelling obligations under Regulation (EC) No. 1272/2008 irrespective of the presence of any other substances shall, regardless of their intended use in the importing Party or other country, not be exported unless either of the following conditions is fulfilled: (a) explicit consent to import has been sought and received by the exporter through the designated national authority of the exporter's Member State in consultation with the Commission assisted by the Agency, and the designated national authority of the importing Party or an appropriate authority in an importing other country.

3 Substance Specific Examples

3.1 Introduction

This section considers substance specific case study examples of substances of the types of impacts that may result due to the risk management approach under the various pieces of legislation examined in this case study. It provides the background to issue surrounding these substances, including a summary of impacts, but does not perform any analysis. This comes under the subsequent sections. In addition, as none of the examples relate to a plant protection product, more general discussion is provided below.

3.2 N,N-Methylenebismorpholine

N,N-Methylenebismorpholine (MBM) is a formaldehyde releaser and is found in biocidal products used as bactericides for the preservation of fuels (PT 6) which are prone to bacterial decay, and for use in metal-working fluids.

For example, MBM is intended to be incorporated by industrial users into fuels during the formulation process, which is carried out automatically in a closed system²⁹. The final concentration of the active substance is in the range of 0.01% and 0.1%, which results in a maximum of 0.016% total releasable formaldehyde in the fuel. The biocidal activity of the active substance is due to the interaction of the released formaldehyde with protein, DNA and RNA. MBM is classified under Regulation (EC) No 1272/2008 as a carcinogen category 1B and a mutagen category 2 due to the released formaldehyde having these classifications. As the assessment report was submitted before the entry into application of the Biocidal Products Regulation (1st September 2013), it could be approved, but Member States can later only authorise biocidal products for use if it is considered that they could meet one of the criteria under Article 5(2).

Austria was the evaluating Competent Authority for the approval of MBM and submitted the assessment report and conclusion of its evaluations to the Commission in July 2013. The BPC opinion was adopted in October 2014. For this purpose a common dossier was developed for formaldehyde, which was agreed at a Biocidal Technical meeting³⁰. This dossier formed the basis for the hazard assessment for formaldehyde and all formaldehyde releasers. It was possible to use a formaldehyde core dossier for MBM as the toxicological profile of MBM and the respective hydrolysis study data provide sufficient evidence to read-across the local effects data from formaldehyde to MBM³¹. From the evaluation of the assessment report and eCA evaluation, the BPC

²⁹ Biocidal Products Committee (2014): Opinion on the application for approval of the active substance: N, N-Methylenebismorpholine. Product Type 6. Available at: <http://echa.europa.eu/documents/10162/82ee743e-b7df-4453-a03b-32f51afd2164>

³⁰ Biocidal Products Committee (2014): Opinion on the application for approval of the active substance: N, N-Methylenebismorpholine. Product Type 6. Available at: <http://echa.europa.eu/documents/10162/82ee743e-b7df-4453-a03b-32f51afd2164>

³¹ Acceptable exposure concentration (AEC) and acceptable exposure level (AEL) estimates were based on threshold assumptions in line with the formaldehyde core dossier.

proposed that MBM **should be approved** and be included in the Union list of approved active substances³².

This approval was subject to specific conditions:

1. Specification: minimum purity of the active substance evaluated: 92.1% w/w;
2. Relevant impurity: max. 0.005% w/w (=50ppm) formaldehyde;
3. MBM is considered a candidate for substitution in accordance with Article 10(1)(a) of Regulation (EU) No. 528/2012;
4. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance;
5. Mixing and loading of MBM to formulation vessels shall be automated, unless at product authorisation excluding potential exposure to skin, eye and respiratory tract to MBM can be demonstrated by other means; and
6. When a treated article has been treated with or intentionally incorporates MBM releasing formaldehyde, and where necessary due to the possibility of skin contact as well as the release of formaldehyde under normal conditions of use, the person responsible for placing the treated article on the market shall ensure that the label provides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

With respect to the carcinogenic properties of MBM releasing formaldehyde and the use in treated articles of biocidal products containing MBM, the following options are proposed by the BPC to be considered in the decision making process under Article 9(1) of Regulation (EU) No 528/2012:

- i. Restricting the use to the representative use in fuels;
- ii. Including a condition: “where a treated article has been treated with or intentionally incorporates MBM, and where necessary due to the possibility of exposure as well as the release of formaldehyde under conditions of use, the person responsible for placing the treated article on the market shall ensure that the label provides information on the carcinogenicity, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012”;
- iii. At product authorisation special attention shall be paid to the carcinogenic properties of MBM releasing formaldehyde; and
- iv. For biocidal products containing MBM intended to be used for the treatment of, or the incorporation in articles, the application for authorisation should show that all these treated articles are safe for use. In this respect, the assessment of a reference article (leading article) should allow to conclude that all other treated articles with a comparable treatment and similar use are also without unacceptable risk.

Table 3-1 sets out the impacts of the requirements placed on the authorisation of MBM under the Biocidal Products Directive and the potential impacts of a refused authorisation under the Biocidal Products Regulation, should this be the outcome of the re-approval process.

³² Approval is for 5 years (2017 to 2022).

Table 3-1: Impacts of risk management trigger sectors with respect to MBM					
Legislation	Stakeholder	Negative impacts	Comments	Positive impacts	Comments
Biocidal Products Directive	Industry	Need to ensure systems for loading and unloading MBM are automated Labelling costs	Costs of any equipment changes to ensure closed systems	Reduction in exposures for workers and in potential number of worker disease cases	No evidence of carcinogenic potential for MBM; ban based on the carcinogenicity of formaldehyde (see also below)
	Users	Potential impacts of additional risk management measures under Chemical Agents Directive/ Carcinogens and Mutagens Directive as part of handling		Potential reduction in exposures for workers and in potential number of worker disease cases	
	Society	None identified		Unlikely – possible reduction in health care related cost if reductions in disease cases occur	
Non-approval under Biocidal Products Regulation	Industry	Potential future ban on MBM would result in reformulation and substitution for use in fuels	Product withdrawal may also occur due to lack of drop-in replacement	Reduction in exposures for workers and in potential number of worker disease cases	
	Users	Potential future ban could result in more frequent replacement of stored fuels or fluids impacted by bacterial decay Potential future ban could result in the reduction of biocidal product options for use in fuels and of up to 60% for use in metal working fluids	On-going replacement costs which could be significant or which would result in the need to modify storage and maintenance practices. Change in product options may impact on processing equipment, other materials and wastes	Potential reduction in exposures for workers and in potential number of worker disease cases	
	Society	Uncertain – depends on sectoral effects		Uncertain – depends on alternative and number of disease cases	

3.3 Gallium arsenide

Gallium arsenide (GaAs) is a semiconductor and can be found in wireless applications such as smartphones, photonic applications, solar applications and telecommunications. It is used extensively in digital circuits and its research and development was initially funded by the US Department of Defence to compete against silicon³³. From 1990 to 2015, total revenues for GaAs grew from around US \$250 million globally to a figure approaching US \$7 billion globally, with this growth linked to the evolution of smartphones and increasing data traffic.

GaAs is not naturally occurring and is manufactured from the raw materials gallium and arsenic. It has a harmonised classification for carcinogenicity Category 1B, and therefore is subject to requirements under the Carcinogens and Mutagens Directive. The Carcinogens and Mutagens Directive lays down a stringent set of requirements with respect to carcinogens and mutagens for employers:

1. The employer must assess and manage the risk of exposure to carcinogens and mutagens as defined in the regulation. This process must be kept up to date and take account of any changes that may affect exposure. The details of this process must be available to the authorities on request.
2. If technically possible, the employer must prevent exposure to carcinogens and mutagens by replacing such materials with less hazardous ones. If it is not technically possible to substitute the materials, they should be used within a closed system. If a closed system is not technically possible, the employer must reduce exposure to as low level as is technically possible.

Given the classification for GaAs, then substitution should be the first step to be implemented, if possible. However, a 2013 report by ICF International noted that substitution of GaAs is difficult to achieve, as existing alternatives are not suitable at the current stage of development. GaN could be an alternative but there is a vast price difference with the cost per unit being €3000, whereas for GaAs it is around €60 per unit³⁴. In addition, there is currently no manufacturer able to supply the quantities of GaN that would be needed to replace GaAs. Gallium arsenide is produced in some instances in a closed system, but, according to the REACH registration dossier, the possibility of exposure arises through use in batch and other process (synthesis), treatment of articles by dipping and pouring, and transfer of substance or preparation into small containers³⁵. However, industry stakeholders have indicated that there are currently no issues regarding exposures within EU workplaces, with industry having taken appropriate measures in line with the Carcinogens and Mutagens Directive. Given the size of the EU market that exists for GaAs based semi-conductors, and the fact that it is a global industry, it is clear that if substitution were required that industry would have been more than likely to shift production outside the EU. See also Table 3-2.

³³ CS Compound Semiconductor (2015): The GaAs Revolution. Available at: <https://www.compoundsemiconductor.net/article/97973-the-gaas-revolution.html>

³⁴ ICF International (2013): The potential impact on industrial competitiveness of restrictions on certain CMR 1A and 1B substances in articles: Scoping study for the application of art. 68.2 of REACH to CMR substances requiring priority action. Available at: http://ec.europa.eu/growth/sectors/chemicals/reach/studies/index_en.htm

³⁵ ECHA (n.d.): Gallium Arsenide registration dossier. Available at: <https://echa.europa.eu/registration-dossier/-/registered-dossier/13885>

Table 3-2: Impacts of risk management trigger sectors with respect to Gallium arsenide					
Legislation	Stakeholder	Negative impacts	Comments	Positive impacts	Comments
Carcinogens and Mutagens Directive	Semiconductors, photovoltaics and RF-communication and sensor systems industry sectors	Capital and operating costs of changes needed to ensure minimum exposures and safe working conditions	Costs should be low as industry states safe operating conditions are already in place	Reduction in the number of lost working days through absence of workers. Minimal worker exposures should ensure greater employee retention	No evidence of carcinogenic potential for MBM; ban based on the carcinogenicity of formaldehyde (see also below)
	Workers	None expected, as unlikely that manufacturers withdraw from EU for this reason alone	Some measures, such as increased personal protective equipment, may impact on quality of working conditions Residual risk of cancer through dermal and inhalation exposure	Potential reduction in the number of cancer cases linked to exposure to GaAs in the workplace Other potential health benefits from reduced workplace exposures exposure	Avoidance of a cancer case valued at €3.5 million About 80,000 employees work in Integrated Device Manufacturers in the EU*; not all will be exposed
	Society (general public)	None expected, as unlikely that manufacturers withdraw from EU for this reason alone	EU semiconductor industry is estimated to contribute \$28.4 bn directly to GDP, with a further \$77bn in indirect and induced effects	Potential reduction in health care costs to society with reduction in disease cases, should this occur	

3.4 Formaldehyde

Case Study 10 examines the impacts on a key downstream use sector of the harmonised classification for formaldehyde as a Carcinogen Cat 1B. This revised classification was implemented through the 6th Adaptation to Technical Progress (ATP) to the CLP Regulation published in the Official Journal of the European Union on 6 June 2014. The change was adopted and the deadline for the transition period was extended to 1 January 2016, meaning industry had until the 1 January 2016 to comply with the new classification. After 1 January 2016 the new Classification and Labelling rules must be applied to substances containing 0.1% free formaldehyde or above. The updated classification also introduced the additional hazard of Mutagen Cat 2.

This harmonised classification for carcinogenicity and mutagenicity will have an impact on the requirements that must be met by companies to maintain compliance with the relevant OSH regulations. Specifically the change in the carcinogen classification brings formaldehyde within scope of Carcinogens and Mutagens Directive, and requires additional measures that must be taken in workplaces where formaldehyde is encountered:

- Substitution – where technically possible due to its category 1B carcinogen classification, formaldehyde should be replaced in a process by a non-carcinogenic or mutagenic substance;
- Introduction of a closed system – where it is not possible to substitute formaldehyde the processes where it is used should be altered to closed systems;
- Where a closed system is not possible other steps must be taken to reduce exposure to as low a level as is technically possible.

This is in addition to the general control measures for carcinogens and mutagens mentioned in the Carcinogens and Mutagens Directive text (see Case Study 11 for a list).

Formaldehyde has a number of uses and applications including in glues and resins, as a chemical intermediate, in vaccines, in biocidal products and as a preservative in paints and coatings. It is therefore found in products widely used in the construction, automotive, aircraft, healthcare and clothing industries. It is also a process generated substance as it forms naturally from the degradation of airborne hydrocarbons and the combustion of hydrocarbons from both natural, such as forest fires, and manmade processes, such as automobiles exhausts.

As noted in Case Study 10, there is currently a recommendation from the Scientific Committee on Occupational Exposure Limits (SCOEL) for a binding occupational exposure limit (OEL). This is still under public consultation but the time for comments has passed. SCOEL recommends an 8-hour TWA of 0.3 ppm (0.369 mg/m³) and an STEL of 0.6 ppm (0.738 mg/m³).

The case study draws on work carried out to estimate the costs of a reduction in the OEL³⁶ for formaldehyde resin manufacturers as a subset of those that would be affected and notes that:

~70% of the 'plants producing formaldehyde indicated that they will have one-off costs, with only one of the plants stating it needs no improvements. All plants categorised as 'formaldehyde and

³⁶ TNO Triskelion et al. (2013): Analysis of the most appropriate risk management option for formaldehyde. Available at: <http://www.formacare.org/wp-content/uploads/2014/09/RMO-Report-Final-Report-final-version-clean-20131114.pdf>

Table 3-3: Impacts of risk management trigger sectors with respect to Formaldehyde					
Legislation	Stakeholder	Negative impacts	Comments	Positive impacts	Comments
Carcinogens and Mutagens Directive	Wood panel board manufacturers and employees	Costs from: substitution where feasible; introduction of closed systems; increased personal protective equipment	<p>Estimated one off costs for introduction of new equipment of around €56 million</p> <p>Potential to trigger other requirements e.g. under Seveso, with alternatives</p> <p>Annual sales of formaldehyde-based chemicals are approximately €9.5billion</p>	<p>Reduction in worker exposure and cancer cases</p> <p>Reduction in the number of lost working days through absence of workers</p>	<p>Average value of a lost working days is assumed at €300</p> <p>WHO's statistical value of life of €3.5 million for the EU</p>
	Professionals	<p>Costs from requirements to reduce workplace exposures</p> <p>Some alternatives may change work practices</p>	<p>Potential need to change PPP used, or introduce other measures</p> <p>Introduction of alternatives may lead to a shift in risks; potential for regrettable substitutions</p> <p>Potential impacts on costs of jobs, number of jobs completed, etc.</p>	<p>Reduction in future cancer cases</p> <p>Reduction in the number of lost working days through absence of workers</p>	<p>French data for 2010 suggest that over 1 million workers in the EU may be exposed to formaldehyde in the workplace</p> <p>Not clear to what extent reduction in future cancer cases may be offset by a shift in risk with move to alternatives</p>
	Society	Potential impact on wood panel board prices with move to alternatives, as well as increased impacts as part of product installation (e.g. due to increased setting times for resins)	Potential impact on wood panel board prices with move to alternatives, as well as increased impacts as part of product installation (e.g. due to increased setting times for resins)	<p>Reduction in consumer exposure to formaldehyde and hence in future cancer cases</p> <p>Reduction in lost working days</p> <p>Reduction in associated health care costs</p>	Not clear to what extent reduction in future cancer cases may be offset by a shift in risk with move to alternatives

Table 3-3: Impacts of risk management trigger sectors with respect to Formaldehyde					
Legislation	Stakeholder	Negative impacts	Comments	Positive impacts	Comments
Non-approval under Biocidal Products Regulation	Industry	Potential Costs from substitution and reformulation	<p>Would affect all 3 product types.</p> <p>A particular concern for PT22 and alternatives are severely limited and are unlikely to be as effective.</p> <p>Data on costs to industry not available.</p>	Reduction in worker exposure and subsequent cancer or infertility cases.	<p>Average value of a lost working days is assumed at €300</p> <p>WHO's statistical value of life of €3.5 million for the EU</p>
	Professionals	Some alternatives may change work practices	<p>Introduction of alternatives may lead to a shift in risks; potential for regrettable substitutions</p> <p>Some product types do not currently have adequate alternatives, where there is no biocidal active substance used risks may be posed to workers through exposure to microorganisms.</p>	<p>Reduction in worker exposure and subsequent cancer or infertility cases.</p> <p>Reduction in the number of lost working days through absence of workers</p>	Data on workers exposed to formaldehyde as a biocide is not available.
	Society	<p>Potential use of inadequate alternatives increasing the risk from microorganisms.</p> <p>Lack of embalming of the recently deceased.</p>	Potential increase in microbe related illness not clear.	Reduction in consumer exposure to formaldehyde and subsequent cancer and infertility cases.	Not clear to what extent reduction in future cancer cases may be offset by a shift in risk with move to alternatives

resin manufacture’ have indicated one-off costs. Approximately half of the plants categorised as ‘resin manufacture’ (10 of 21) do not yet require improvements at 0.3 ppm, while 16 of 21 plants need improvements with one-off costs at 0.2 ppm and a respondent for one plant indicated that at this level the plant would need to close’.

The estimated one-off costs for an OEL reduction for formaldehyde resin manufacturing plants to 0.3 ppm range from around:

- A minimum of €36 million;
- An average estimate of €56 million; and
- A high estimate of €64 million.

The study also looked at the availability of alternatives and identified technical feasibility issues for some manufacturers, which would result in significant higher economic and time costs. In addition, some of the alternatives such as p-MDI and phenolic formaldehyde resins could give rise to other regulatory concerns. For example, if the plant altered its process to produce phenol-formaldehyde resins, which have minimal free formaldehyde, then they would have to store large amounts of phenol on site. This could bring it into the scope of the Seveso Directive and not only affect the location of the quantities of substances stored but even the plant location. Replacing formaldehyde with phenol-formaldehyde resins would not only be a case of regrettable substitution in the case of bringing it under the Seveso Directive, but there may also be additional concern with regards to their skin sensitising and aquatic toxicity properties. See Table 3-3 for a summary of potential impacts.

Formaldehyde is used in biocides in the gaseous form; dissolved in water (formalin); and bound in formaldehyde releasers. The use of formaldehyde is currently under review for 3 product types (PT2 – disinfectants and algacides not intended for direct application to humans or animals, PT3 – veterinary hygiene, PT22 – embalming and taxidermist fluids)³⁷. As it is classified as a carcinogen 1B it would fall under the exclusion criteria of the Biocidal Products Regulation and as such, products which are currently available on the market would no longer be viable for authorisation. There are cases for exemption under the Biocidal Products Regulation but it is not clear as of yet whether formaldehyde will be granted an exemption. Formaldehyde is also a candidate for substitution and information for suitable alternatives has been requested for product types 2 and 3. RIVM have carried out a study on formaldehyde and formaldehyde releasers which found that there are “sufficient chemical alternatives for most disinfectants and preservatives containing formaldehyde”³⁸. It should be noted that no suitable alternative has been identified for the disinfection of litter bins for sanitary towels; or the preservation of human and animal corpses or biological tissues.

Although the RIVM study found that there may be chemical alternatives, some of them may not be suitable due to similar harmful properties; they may induce resistance; or release formaldehyde as a degradation product. It is clear that the replacement of formaldehyde with one of these alternatives needs to be suitably assessed in order to prevent regrettable substitution. Where fewer alternatives exist, the risk to both industry and society increases with the phase-out of formaldehyde. As formaldehyde is a biocide, there may be human health implications for its removal from products for

³⁷ PT2 – disinfectants and algacides not intended for direct application to humans or animals; PT3 – veterinary hygiene; PT22 – embalming and taxidermist fluids

³⁸ National Institute for Public Health and the Environment (RIVM) (2015) Initial inventory of alternatives to biocidal products containing formaldehyde or formaldehyde releasers. Available at: <http://www.rivm.nl/bibliotheek/rapporten/2015-0186.pdf>

which there are no (or limited) alternatives. This would be an unintended consequence of trying to protect human health from carcinogenic effects.

3.5 Lead metal

In terms of its regulation, a Binding Occupational Exposure Limit Value has also been set for lead and its ionic compounds of 70 µg/100ml in Directive 98/24/EC, with this requiring the monitoring of blood lead levels of workers exposed to lead. Member States are obliged to establish a corresponding national binding biological limit value for lead based on, but not exceeding, the Community limit value.

Lead is also subject to REACH restrictions for jewellery and most notably for use in articles supplied to the general public if the concentration of lead in those articles or accessible parts is equal to or greater than 0.05% by weight and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. This limit does not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0.05 µg/cm² per hour (equivalent to 0.05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article³⁹.

As lead is present unintentionally in many metal alloys and is highly toxic, separate migration limits have been set under the Toy Safety Directive (see Table 3-4). Lead should not be intentionally used in accessible parts of toys and limit values are to be set at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee.

Table 3-4: Migration limits			
Substance	Mg/kg in dry, brittle, powder-like or pliable toy material	Mg/kg in liquid or sticky toy material	Mg/kg in scraped-off toy material
Lead	13.5	3.4	160
Source: Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:170:0001:0037:en:PDF			

Lead and its compounds also appear in Annex II of the Cosmetic Products Regulation and are subsequently banned for use in cosmetic products. The precautionary principle has been used in both of these pieces of legislation, with the restrictions introduced prior to the existence of a harmonised classification for CMR properties as both toys and cosmetics are products which consumers may be exposed to on a regular basis. Lead also provides an example of where the Chemical Agents Directive has been used to establish a BOELV for such purposes.

In addition, lead has recently been given a harmonised classification for Reprotoxicity 1A, with this included into CLP by the 9th ATP (Commission Regulation (EU) 2016/1179). As detailed in Case Study 2 on metals classification, a specific concentration limit (SCL) of 0.3% has been set for lead metal (massive form) and a SCL of 0.03% has been set for the powder form.

³⁹ ECHA (n.d.): Annex XVII to REACH – Conditions of Restriction. Entry 63 – Lead. Available at: <http://echa.europa.eu/documents/10162/3f17befa-d554-4825-b9d5-abe853c2fda2>

Initially, it was proposed that a Specific Concentration Limit of 0.03% would apply to both lead massive and lead powder. Industry argued, however, that this proposed very low specific concentration limit for lead massive would have a significant impact on metal alloys⁴⁰ (mainly aluminium and copper) due to the fact that lead could be present as an impurity or in some cases was added to certain alloys for technical reasons (e.g. 80% of copper contains lead at >0.03%). In particular, the aluminium and copper sectors were concerned over the very low SCL proposed for lead metal.

Impacts identified by industry should the SCL of 0.03% have applied to lead metal included the following:

- Loss of by-products recycling (silver, sulphuric acid, polypropylene) from lead acid battery recycling due to levels of lead at >0.03% SCL adopted for lead massive;
- Impact on recycling of aluminium due to the need to dilute recycled materials with new material in order to be below the SCL, leading to increases of €200-300 in the price per tonne of recycled aluminium. The impact of this would be an increased cost to consumers of EU produced aluminium of €820-1,230 million per year;
- Impact on copper recycling of €700-1,200 per tonne due to the need to dilute recycled materials with new material in order to ensure concentrations below the SCL, leading to increased costs to consumers of EU copper of €1,470-2,520 million per year;
- Increased environmental costs if there would be a reduction in demand for EU recycled materials due to increased costs;
- Increased costs for the transport and storage of metal scrap which would become classified as hazardous waste, impacting on EU activities as well as the shipment of such materials outside the EU; in addition some scrap yards and other sites might become subject to Seveso III, leading to administrative and compliance costs; and
- Increased blood lead monitoring across wide range of sectors, as all workers handling alloys and scrap would essentially become 'lead workers', with the costs of such tests in the range of €10-€75 per worker.

Clearly, industry was anticipating that some of the above impacts (such as recycling) would be driven by the reluctance of those in downstream markets to be seen to be handling a material classified as a reproductive toxin, with linked impacts for handling and storage; in other words, the impacts would stem from perception of metal alloys produced in the EU by downstream markets, were they to become classified as hazardous due to the presence of lead at very low levels. In addition, industry noted that the proposed SCL was not aligned with requirements under other EU legislation. For example, lead in copper alloys is exempt under the RoHS and ELV at up to 4% in concentration; similarly, "lead free" is defined as being alloys with a concentration of lead lower than 0.1% in the RoHS and ELV.

3.6 TCEP

Table 2-3 set out the limits that exist under the Toy Safety Directive for certain substances and that are specific to toys for children under 36 months or for toys intended to be put in the mouth. One of these substances is Tris(2-chlorethyl)phosphate (TCEP), which is used as a flame retardant plasticiser and viscosity regulator in polyurethanes, polyester resins, polyacrylates and other polymers⁴¹.

⁴⁰ Which is defined as a mixture.

⁴¹ Scientific Committee on Health and Environmental Risks (2012): Opinion on tris(2-chlorethyl)phosphate (TCEP) in Toys. Available at:

Although TCEP is no longer used in the manufacture of toys in the EU, it has been detected in polyurethane foam used in toys and its presence in toys imported into the EU and sold on the EU market was identified as an issue.

One of the critical effects for risk characterisation of TCEP are carcinogenicity, and it has been observed to cause kidney tumours in rats and mice, thyroid tumours in rats and liver tumours in mice. No conclusion has been drawn on the relevance of TCEP induced tumours to humans, as there is a lack of data proving the mode of action, but, after considering all the data, the relevance to humans of renal and hepatic tumours cannot be excluded⁴². As such, TCEP has been classified as a carcinogen Cat 2 and, on the basis of its effects on fertility, a Reprotoxin category 1B under CLP. As a result, TCEP is subject to the automatic ban on CMRs under the Toy Safety Directive.

In order to fulfil the criteria for a derogation under points 4 and 5 of Part 3, Annex II, the Commission sought the opinion of SCHER on the safe use of TCEP in toys. The decisions that were sought dealt with whether or not a lower limit than that of the generic concentration limit for mixtures in CLP should be set, and if so, what that should be; and whether there are risks if TCEP is allowed in toys at or below the generic concentration limit in CLP for children over 36 months. The key findings were:

- The margins of exposure may not be adequately protective of human health, especially as TCEP is available via the oral, inhalation and dermal routes of exposure;
- No clear threshold could be established, but a provisional TDI was (13 µg/kg bw/d) and no additional exposure can be considered safe; and
Any limit should be set at the detection limit of a sufficiently sensitive analytical test method.
- The use of TCEP should be avoided in toys for children over the age of 36 months.

In a 2015 guide on TCEP use prepared by the British Toy and Hobby Association, a materials risk assessment was prepared for use by its members to ensure they were able to identify potential sources of TCEP within their supply chain. This materials risk assessment for its use in toys⁴³ is reproduced below in Figure 3-1, and illustrates that industry impacts are likely to have been centred on a few key materials and on Chinese imports. Nevertheless, the potential impacts on the sector and for exposed workers and children are summarised in Table 3-5.

In addition to the regulatory requirements set under the Toy Safety Directive, TCEP was also subject to authorisation under REACH – see also Table 3-5. No applications for its continued use were submitted, suggesting that industry was able to move away from the substance. As a result, one must assume that industry were able to find alternatives to the use of TCEP or to forego the need for it within some of the polymers; for example, not all polyesters require a flame retardant and may be able to meet flammability requirements on their own.

http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_158.pdf

⁴² Scientific Committee on Health and Environmental Risks (2012): Opinion on tris(2-chlorethyl)phosphate (TCEP) in Toys. Available at:

http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_158.pdf

⁴³ In addition to the uses identified in Figure 3-1, TCEP was also known to be used as a flame retardant in specialist paints prior to Authorisation requirements.

Table 3-5: Impacts of risk management trigger sectors with respect to TCEP					
Legislation	Stakeholder	Negative impacts	Comments	Positive impacts	Comments
Toy Safety Directive	Toy manufacturers	Reformulation and substitution of flame retardants Potential cessation of certain toys and with loss of jobs	Market for toys for mouthing by young children containing TCEP ~€7.5 million Unlikely	Improved consumer perception of the safety of toys on the EU market	TCEP example of regrettable substitution as used in place of brominated flame retardants in some cases
	Manufacturers of TCEP and of foams (potentially used in toys but also by other sectors)	Reformulation and substitution Potential cessation of certain products in EU manufacturers with loss of jobs	Potential need to invest in new processing equipment; product performance impacts, etc.	Potential reduction in male infertility Potential reduction in the number of lost working days through absence of workers	Roughly 200 workers (est. 144 males) linked to production of TCEP Around 2000 workers (est. 1400 males) linked to foam production
	Society: Children (vulnerable population)	None identified		Potential reduction in future male infertility due to reduction in exposures of infants Potential reduction in health care costs	Over 13,401,000 males under the age of 5 in the EU-28 in 2015 ⁴⁴ ECHA valuation for a case avoided of around €19,000
REACH Authorisation	Other sectors of use, including spray and non-spray applications (paints, textiles, furniture, etc.)	Reformulation and substitution Potential cessation of certain products in EU manufacturers with loss of jobs		Potential reduction in male infertility Reduction in the number of lost working days through absence of workers	3,600 workers (est. 2,550 males) linked to paint formulation; over 400,000 linked to sectors where other downstream uses may take place
	Society	Potential impacts on level of fire safety	Alternatives should provide equivalent level of protection	Potential reduction in future male infertility and health care costs	
Source of population estimates: RPA et al. (2011): Assessing the Health and Environmental Impacts in the Context of Socio-Economic Analysis Under REACH, Part 2, Final Report, ENV.D.1/SER/2009/0085r, prepare for DG ENV					

⁴⁴ Eurostat data.

Material	Background	Risk of non-compliance		
		EN71-9	App C	TSD
ABS	The presence of TCEP, TCPP and TDCP has not been identified in these polymers	Not in scope	Very Low	Very Low
Nylon				
HIPS				
PS				
PE				
PP				
PC	PC in electronic applications may be flame retarded	Not in scope	High	High
PVC	TCEP known to have uses as a plasticiser in PVC	Not in scope	High	High
Rubber	Some rubbers have been known to be flame retarded with organo-phosphorus flame retardants	Not in scope	Medium	Medium
PUF	Most common material to find these substances	Not in scope	High	High
Polyester	TCEP, TCPP and TDCP are still being actively marketed and sold in China for flame retarding textiles	High	High	High
Cotton	TCEP, TCPP and TDCP are still being actively marketed and sold in China for flame retarding textiles	High	High	High

Figure 3-1: TCEP materials risk assessment for toy manufacturers

Notes: App C refers to Appendix C of the Toy Safety Directive and legal restrictions introduced in 2015, while Toy Safety Directive refers to the restrictions introduced in 2013.

Source: British Toy and Hobby Association (2015): TCEP, TCPP and TDCP: Directive 2014/79/EU amending Appendix C of Annex II to Directive 2009/48/EC. Available at:

<http://www.btha.co.uk/wp-content/uploads/2015/06/TCEP-Guide-Version-1.pdf>

3.7 Ethanol

Ethanol is used in a variety of sectors, particularly as an industrial solvent and in many mixtures intended for consumer use, e.g. skin and surface detergents in hospitals and private households, detergents and cleaning products and in cosmetic formulations. Although there is currently no harmonised classification as a CMR, a dossier is currently being evaluated under the Biocidal Products Regulation and it is possible that ethanol could be given a harmonised classification as Carcinogenic Cat 1A and Reprotoxic Cat 1A at EU level. Ethanol proves an interesting example of risk management of CMRs due to its wide ranging application and the fact that some sectors are reliant on it as there are no suitable alternatives. The remainder of this discussion is based on a position paper prepared by the Verband der Chemischen Industrie e.V. (VCI)⁴⁵.

There are studies that provide evidence of carcinogenic and reprotoxic effects via the oral route of exposure. These studies are largely based on the consumption of ethanol as a beverage. Oral exposure is expected primarily in the consumption of foodstuffs and is much less likely for all other consumer practices and products, professional use and occupational health and safety. Inhalation and dermal exposure are the pathways of concern for all other uses except from use in a foodstuff.

⁴⁵ VCI (2015): Impacts of classification under the CLP Regulation on other pieces of legislation – example ethanol, personal communication.

Even though there is not expected to be any oral exposure to ethanol under the scope of EU chemicals legislation, it may be classified as a carcinogen pursuant to Annex I, point 3.6.2.1 of CLP whereby a classification can be made based on only one route of exposure “if it can be conclusively proved that no other route of exposure exhibits the hazard”. As such, ethanol would be classified as carcinogenic based on oral exposure.

The VCI position paper argues that the cost, resources and use conditions which would arise as a legal consequence of a C or R classification for ethanol would be disproportionate to the risk posed by the use of ethanol outside of foodstuffs and medicinal products. This classification is also not considered to increase the protection of human health. For example, in 2013, 60 million hectolitres of ethanol were produced in the EU and 7 million hectolitres were imported. Only around 10% of this was used in foodstuffs meaning that the impact of a classification would fall mainly on other sectors.

Carcinogens and Mutagens Directive

Under the Carcinogens and Mutagens Directive, the first priority would be the substitution of ethanol in products and processes. This may not always be possible in the short-term as ethanol has different functions in different fields. Industry argue that ethanol is obtained from renewable resources (from fermentation or agricultural raw materials) and, where substitutions are available, then ethanol would be replaced by a petrochemical solvent which will have its own human health and environmental impacts. Where substitution is not considered possible, companies would need to employ other forms of risk management from the risk management hierarchy of the Carcinogens and Mutagens Directive, all of which may result in costs. Dermal and inhalation exposure of workers to ethanol is below critical ethanol concentrations and are not considered to pose a risk to workers, but the OSH legislation would have to be adopted in light of a C or R classification.

Biocidal products

If ethanol was to be classified as a Carcinogen Cat 1A or a Reprotoxin Cat 1A, then it would meet the exclusion criteria under Article 5 of the Biocidal Products Regulation. This means that it must meet one of the derogation criteria so that Member States can authorise biocidal products. Under Article 4 it would only be granted an approval for 5 years and then would have to go through the renewal process. Under Article 19 ethanol would not be authorised for making available on the market for the general public. It also would not be given Union authorisation as it meets the exclusion criteria, therefore a manufacturer would have to apply for a national authorisation and then for mutual recognition for all other Member States. This will result in increased workloads and associated costs.

Cosmetic products

If ethanol was to be classified as a Carcinogen Cat 1A or Reprotoxin Cat 1A, then it would be banned under Article 15 of the Cosmetic Products Regulation unless a derogation is obtained. However, this would require additional workload and cost and the outcome can be uncertain. Sectors that may be affected include detergents (professional and consumer); motor fuels; in vitro diagnostic/ medical devices; process solvents and analytics; printing inks and varnishes. In addition, ethanol is an important constituent of cosmetic products, particularly skin creams, facial tonics, deodorants, perfumes, sunscreen, oral care products, nail varnishes, mascara and lipstick. The concentrations vary but can be as high as 90% in perfumes, hairsprays and deodorant sprays. There are currently no substitutes for ethanol in the perfume industry. See also Table 3-6 for a summary.

Table 3-6: Impacts of risk management trigger sectors with respect to Ethanol					
Legislation	Stakeholder	Negative impacts	Comments	Positive impacts	Comments
Cosmetics Regulation	Cosmetics industry	Reformulation and substitution; cessation of some products due to a lack of substitutes	Currently no substitute for some applications, such as perfumes.	Potential reductions in lost working days – but impacts not known	Carcinogen for oral exposure only
	Workers	Job losses in the fragrance industry in particular due to a reduction in production of ethanol	660,000 direct jobs in the fragrance industry, 940,000 direct, indirect and induced jobs.	Reduction in worker exposures but impacts not known	
	Society	Decrease in contribution to EU economy	Fragrances: Direct economic benefits: €30 billion Indirect multiplier impacts through purchases: €13 billion Induced multipliers due to additional consumption spending; €8 billion	Reduction in consumer exposure to ethanol but impacts not known Reduction in associated health care costs	Oral exposure only relevant so no reduction in health impacts for consumers linked to cosmetics
General downstream due to CLH	Industry and workers	Reformulation and substitution; cessation of some products due to a lack of substitutes Job losses in the fragrance industry in particular due to a reduction in production of ethanol	Approximately 15,000 tonnes per annum used in alcoholic solvents. Market for ready-for-use disinfectants: €50 million in Germany alone. Market for ethanol in glass cleaners: €20 million in Germany alone. Market for hand sanitisers: €80 million in Germany (all virucidal products are ethanol-based, other substances are used within this market)	Unclear to what extent there may be oral exposures to ethanol, and hence any reduction in relevant exposures	Only sectors of relevance are foodstuffs and medicinal products
	Society	Decrease in contribution to EU economy			

Cosmetics industry respondents provided information on the type of actions they took as a result of an ingredient in formulations being classified as a CMR under CLP. Table 3-7 summarises these responses in terms of the percentage of cases in which these actions were taken. It is interesting to note that 67% of respondents sought a derogation at least once. It is difficult to gauge how effective the process for gaining a derogation for a CMR substance in a cosmetic product is, however, as so far a derogation has only been sought for three or four substances out of the 1,480 currently listed CMRs in the Classification and Labelling Inventory (CLI).

Table 3-7: Actions taken by cosmetics companies as a result of ingredients being impacted by classification of a substance as CMR 1A, 1B and 2 under CLP			
Response	Percentage of respondents that took this action	Percentage of cases in which this action was taken	Mean %
We demonstrated that the substance complied with food safety requirements	0	-	-
We provided an analysis to demonstrate that there are no suitable alternative substances available	0	-	-
We demonstrated that the substance would be used in a product category with known exposures, and that these were safe	67%	20%	20%
We provided the evidence needed by the SCCS to conclude that the substance was safe for use in cosmetic products	67%	20-25%	22.5%
We removed the substance from our formulations	100%	25-100%	68%
We stopped producing the end formulations relying on the substance (withdrew the products)	67%	25-80%	52.5%
Other.... 'In 25%, work on impurity level to meet safety requirements on unavoidable traces as defined under the Cosmetic Products Regulation'	33%	25%	25%

As can be seen from the above table, in addition to demonstrating safe use in some cases, all respondents had removed substances from formulations (with this requiring reformulation of products) and a significant percentage had stopped producing the end formulation. Two different sources of information provide data on costs that can help in understanding what types of impacts these translate to for companies.

A study⁴⁶ carried out in 2007 by RPA for DG Enterprise on the impacts of the then Cosmetics Directive on the everyday operation of the cosmetics industry in Europe, derived estimates of different compliance costs, including the costs of adapting the composition of products to comply with the legislation. This included estimates of the costs to companies when an ingredient was added to the list of ingredients prohibited for use in cosmetics (Annex II of the Directive) and a list of ingredients with restricted uses⁴⁷, which provides some context to the potential impacts that might

⁴⁶ RPA (2007): Impact of European Regulation on the EU Cosmetics Industry, Final Report, prepared for DG Enterprise and Industry, September.

⁴⁷ Annex II of the Directive listed over 1,300 substances that were prohibited for use in the composition of cosmetics products (negative list). The 7th Amendment also prohibited the use of substances which were

arise in relation to ethanol or other cases where an ingredient is affected by a new harmonised CMR classification. As can be seen from the table, the costs to companies can vary from just a few thousand Euro to many tens of thousands in terms of the costs of adapting product compositions and placing those new products on the market. These variations in cost will depend largely on whether the ingredient to be replaced is a key functional component of the product and the availability of suitable alternative ingredients with identical or similar performance/function. If the claims made by the VCI are correct, the costs could be high in the case of ethanol and a ban on its continued use in cosmetic products.

Table 3-8: Indicative Costs of Adapting the Composition of Products when an Ingredient is Added to the Prohibited or Restricted List of the Cosmetics Directive		
Range of Costs (Average One-off Cost per Formulation)	Percentage of Respondents	
	Costs of Adapting the Composition of Products when an Ingredient is Added to the Prohibited or Restricted List of the Cosmetics Directive	Costs to Put a Product on the Market with a New or Modified Composition Due to Changes in Ingredients
Below €500	12%	0%
€500 - €1,499	18%	20%
€1,500 - €4,999	12%	27%
€5,000 - €9,999	18%	20%
€10,000 - €24,999	24%	13%
€25,000 - €99,999	12%	20%
Over €100,000	6%	0%
Total	100%	100%

Other factors identified by respondents which could significantly affect the costs include:

- Whether any changes in processing and manufacturing are associated with handling the new ingredient;
- Packaging or ingredient write-off costs and generation of new label artwork to reflect the change in ingredient labelling (see Section 3.2.1);
- Potential loss of sales, implications for global supply and disruption to business (e.g. where resources are transferred from innovation);
- The time available to implement an ingredient restriction/ban following Commission decision; and
- Difficulties associated with the generation of stability data, testing, research and development and formulation development.

The magnitude of these cost figures appears low when compared to estimates available from other sources. For example, a study undertaken for the Food and Drug Administration⁴⁸ found that:

classified under the Dangerous Substance Directive as Cat 1 and Cat CMRs, with the potential for risk assessment based exemption for Category 3 CMRs. Annex III listed over 90 substances which cosmetics products may only contain subject to the restrictions and conditions laid down (restricted list).

⁴⁸ White et al. (2002): Cost of Reformulating Foods and Cosmetics, Final Report, prepared for the DHHS/Food and Drug Administration Centre for Food Safety and Applied Nutrition, RTI Project Number 08184.003.

- For a minor ingredient, the total costs of substitution vary from around a mid-point value of \$40,000 to \$97,000, with a high of \$200,000 to \$230,000 for a critical minor ingredient with either functional effects or safety effects; differences in costs depend on what steps in the reformulation process are considered relevant, although these costs estimates assume that there is no need for market testing or for manufacturing process changes;
- For a major ingredient, the total costs of substitution vary from a mid-point value of around \$264,000 to \$270,000, with a high of \$677,000 for ingredients with functional and safety effects.

These estimates do not account for any increases in ongoing costs (OPEX) due to the need to use higher cost ingredients, changes in processing or changes in the yields of products. Similarly, the above figures do not account for the fact that reformulation may have to take place across a range of products and there may therefore be economies of scope.

3.8 Costs related to the loss of plant protection products

As none of the above case studies relate to a substance impacted under the Plant Protection Products Regulation, more general information has been drawn from the literature on the potential costs of developing an active substance. These come from work by Phillips McDougall that appears to be carried out regularly as an up-date for those in the sector. The costs of developing new active substances are reported to be as follows⁴⁹:

- Increase of \$30 million (11.7%) in the average cost of discovering, developing and registering a pesticide active to \$286 million between 2005-08 and 2010-14;
- Development costs \$147 million (remained the same over the two periods); 45.8% increase in the costs of environmental chemistry studies to \$35 million was offset a 13% fall in the costs of field trials, which was the largest single cost in the development cycle, accounting for 32.2% of the total spend on product development. This can be attributed to a rise in the level of environmental safety data required by regulatory bodies;
- Total cost of agrochemical R&D expenditure in 2014 for the 11 companies surveyed, including the top six, was \$2,625 million, a value equivalent to 5.4% of their agrochemical sales; and
- The expectation of R&D expenditure in 2019 was an increase of 22.6% to \$3,207 million, at an average annual rate of increase of 4.1%.

The study by Phillips McDougall also looked at the average number of new active ingredients that are synthesised and subjected to biological research in order to lead to the registration of one new crop protection product. The number of active ingredients increased by over 14% between the 2005-08 period and 2010-14 to over 159,000, with this being more than three times the number researched in 1995 (52,500). Despite the high number of products entering the agrochemical R&D chain, the average number of products which make it through to the developmental stage has declined from an average of four in 1995 to only 1.5 on average in 2010-14.

⁴⁹ Phillips McDougall (2015): Agrochemical Research and development: The Cost of New Product Discovery, Development and Registration, Industry R&D Expenditure in 2014 and expectations for 2019. Available at: https://issuu.com/cropprotection/docs/r-and-d_report_2016_final

4 Evaluation

4.1 Introduction

As noted in Section 1, the evaluation of the legislation for this case study is focused on subsets of the criteria regarding effectiveness and efficiency, although relevance and coherence are also considered. In the context of this case study, environmental risks are not addressed given that the focus is on CMR classification for human health only. Also, as noted in Section 1, the case study has been carried out through a review of literature, an analysis of the legislative texts and stakeholder interviews. Any response derived from consultation is the opinion of the stakeholder and not necessarily that of the consultant.

4.2 Effectiveness

4.2.1 Introduction

For the purposes of this case study, we have considered the following questions with regard to effectiveness:

- Does the EU legislative framework for the risk management of chemicals meet the primary objective of ensuring a high level of protection of human health and the environment?
- Which factors were taken into account in identifying the appropriate risk management approach, whether based on generic risk considerations or specific risk assessment (e.g. characteristics of the substance, exposure, vulnerable groups, legal certainty and predictability, transparency, flexibility, enforceability, costs/benefits for public authorities, costs/benefits for industry, costs/benefits to society)? Were these factors appropriately considered? Are any factors missing?
- To what extent does the chemicals legislative framework effectively take into account the protection of vulnerable groups (e.g. children, pregnant women)?

4.2.2 Meeting the objective of ensuring a high level of protection of human health and the environment

One of the core objectives of the EU chemicals legislative framework is to ensure a high level of protection to human health and the environment⁵⁰. It is not possible to define what this objective means in practice, other than it may be assumed to include the promotion of the safe use of products being placed on the market through reducing exposure to hazardous substances.

Chemicals are present in every aspect of our lives but they can cause serious health impacts if not properly regulated. Not only can they have immediate impacts on our health but background exposure can cause them to be present in our bodies and result in chronic long-term health effects. Specific groups of chemicals are controlled by their own legislation, such as those in this case study: biocides, cosmetics, plant protection products, toys and food contact materials. The identification and classification of hazardous substances under the CLP Regulation acts as a starting point for risk

⁵⁰ As this case study is concerned with CMR substances, the environment is not considered.

management in these pieces of downstream legislation. The protection of human health is encouraged through synergies between legislation such as professional and consumer product legislation and OSH legislation.

For example, DGUV statistics for Germany show that occupational diseases from exposure to pesticides have decreased to less than five per year⁵¹. This may be due to increased awareness on health and safety in workplaces, the pro-active adoption of better risk management measures, the restriction/withdrawal of some hazardous substances, the reduction of the workforce in sectors where workers are particularly exposed to those hazardous chemicals, and/or technological progress in the production processes. Nevertheless, the chemicals legislation is a determinant and confounding factor of many of these aspects and has played a major role in reducing the number of cases of occupational diseases.

Each piece of legislation shares the same objectives but uses different specific risk management measures. There are two main approaches to risk management that are used in order to meet the objectives of the chemicals legislative framework: those based on generic risk considerations; and those based on specific risk assessment. A generic (hazard-based) approach to risk management aims to ensure the highest level of protection, as exposure to a hazardous substance from a certain use is prevented. A specific (risk-based) approach to risk management does not remove exposure without a detailed assessment, considering the nature, magnitude and duration of exposures from a particular use. Both of these approaches are aimed at ensuring a high level of protection, but they differ in their basis.

Cancer incidence

It is very difficult to assess whether or not the aims of the chemicals legislative framework have been met with regards to CMRs, due to the long latency periods between exposure to the causative agent and diagnosis of the disease. Substances have been required to be classified according to CLP as of 1 December 2010 and mixtures since 1 June 2015. As such, the longest period of time that has elapsed since the CLP Regulation has been enacted is approaching 6 years for substances and just over 1 year for mixtures. As a result, it is not possible to ascertain from statistical data whether or not any reduction in reported related illnesses can be attributed to the risk management measures (RMMs) that stem from a harmonised classification for CMR under CLP. It should be noted that, of the pieces of legislation that are covered in this case study, only one (the Carcinogens and Mutagens Directive) was in force in its current form before the CLP Regulation was adopted. As such, regulation of chemicals is taken as a whole to illustrate how it can impact trends in cancer incidence.

Occupational cancer is more easily measured than that of consumers' as it can be attributed to an industry, making it somewhat easier to discern if there is a link between exposure and occurrence of cancer, especially if a certain cancer is observed in workers of a certain industry. The ETUI has estimated that 53% of occupational deaths were from cancer. There were 102,517 cases of occupational cancer in the EU28 in 2011; and an estimated 95,000 fatal occupational cancer cases for the EU-27 in 2007. Occupational cancer has also been found to be responsible for 5.3-8.4% of all cancers⁵².

⁵¹ RPA (2016): Study on the Calculation of the Benefits of Chemicals Legalisation on Human Health and the Environment. Report for the European Commission.

⁵² ETUI (2015): Eliminating occupational cancer in Europe and globally. Available at <http://www.etui.org/Publications2/Working-Papers/Eliminating-occupational-cancer-in-Europe-and-globally>

Pesticide exposure has been associated with non-Hodgkin's lymphoma (NHL), soft tissue sarcomas and leukaemia in agriculture workers; and leukaemia in children whose mothers were occupationally exposed or during pregnancy or in children that have been exposed. There may also be a link with other cancers and pesticide exposures, including bladder, stomach, pancreatic, lung, multiple myeloma, Hodgkin's disease, colorectal cancers, ovarian and oesophageal cancer⁵³. Table 4-1 provides an overview of pesticides and their associated cancers⁵⁴.

Table 4-1: Pesticides associated with cancer	
Cancer Site	Pesticide(s)
Lung	Dieldrin
Colon	Trifluralin
Rectum	Chlordane
Leukaemia	Chlordane, Heptachlor,
All lymphohematopoietic cancers	Alachlor,
Melanoma	Carbaryl
Source: Weichenthal S. et al. (2010): A Review of Pesticide Exposure and Cancer Incidence in the Agricultural Health Study. Environ Health Perspect, 118, pp. 1117-1125.	

The Cancer Council of Western Australia has concluded there is no increased cancer risk from cosmetics, specifically the use of Parabens, Alpha Hydroxy Acid and Phthalates⁵⁵. Cancer Research UK has also concluded that the scientific evidence for cosmetics causing cancer is not sufficient⁵⁶. The American Cancer Society concluded that more data is required for evidence that the substances used in cosmetics may cause cancer⁵⁷.

However, examples of benefits do exist. Acrylamide, which has been used in cosmetics, and which has been associated with thyroid, adrenals and testis cancer, was subject to Cosmetics Directive 76/768/EC and 2002/304/EC. This limited acrylamide concentrations to 0.1 mg polyacrylamides/kg product (non-rinse) and 0.5 mg/kg products in other products. Exposure before the legislated measure was 0.36 µg/kg bw/day and 0.004 µg/kg bw/day after the measure respectively. The number of incidences of effect decreased from 2,880 before the measure to 32 cases after the measure⁵⁸.

⁵³ CHEM Trust (2010): A Review of the Role Pesticides Play in Some Cancers: Children, Farmers and Pesticide Users at Risk? Available at: <http://www.chemtrust.org.uk/pesticides-and-cancer/>

⁵⁴ These have been taken from a study by the AHS in the US but have been cross checked with a CLH in the EU. There are more than this, it is for illustrative purposes.

⁵⁵ Cancer Council Western Australia (2015): Cosmetics and Cancer. Available at: <https://www.cancerwa.asn.au/resources/2015-07-14-cosmetics-and-cancer-myth-fact-sheet.pdf>

⁵⁶ Cancer Research UK: Cosmetics and toiletries. Available at: <http://www.cancerresearchuk.org/about-cancer/causes-of-cancer/cancer-controversies/cosmetics-and-toiletries>

⁵⁷ American Cancer Society (2014): Cosmetics. Available at: <http://www.cancer.org/cancer/cancercauses/othercarcinogens/athome/cosmetics>

⁵⁸ Schuur G. et al. (2008): Health impact assessment of policy measures for chemicals in non-food consumer products. RIVM report 320015001: Available at: http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2009/januari/Health_impact_assessment_of_policy_measures_for_chemicals_in_non_food_consumer_products

Stakeholders are of the opinion that the legislative framework has the ability to meet its objectives if it reflects reality rather than theory. Opinion is split between the suitability of a specific risk assessment based approach and a generic risk assessment, or hazard-based approach to risk management, in terms of their respective ability to meet the objectives of the EU chemicals legislative framework. A hazard-based approach assumes that if a classification is given then the substance cannot be used safely, based on the precautionary view that unacceptable levels of exposure will occur regardless of any risk management measures (e.g. due to misuse, a failure of operators to adhere to recommended risk management measures or due to the view that consumer exposure will always occur whenever a substance is present in consumer products). There is also concern that the combination effect of CMRs may have a negative impact on human health even when exposures from a single product are reduced to a minimum.

Member States were asked the extent to which they agree with the statement that certain pieces of legislation meet the objective of European chemicals legislative framework (Table 4-2). There are dissenting views on this issue and it is very much dependent on the legislation concerned. Very few of the Member States provided more details but those that did focused on the Toy Safety Directive and the Cosmetic Products Regulation. One Member State authority commented that they strongly disagreed with the statement with regards to the Toy Safety Directive. They believe that the restriction on CMRs in accessible parts of toys above the CLP generic concentration limit did not provide a high level of protection to child health as there is the possibility that a CMR may be harmful below the concentration limit stated in CLP. Of particular concern are non-threshold CMRs where a safe level of exposure cannot be determined. In such cases, the generic concentration limits are outlined in Tables 3.5.2 (germ cell mutagenicity), 3.6.2 (carcinogenicity) and 3.7.2 (reprotoxicity) of Annex I of the CLP Regulation.

Table 4-2: Member State responses on whether or not legislation delivers a high level of protection for human health (n= 14 max.)						
Legislation	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Don't know
Regulation (EC) No 1223/2009 on cosmetic products	0%	22%	11%	33%	11%	22%
Directive 2009/48/EC on the safety of toys	0%	12.5%	25%	25%	0%	37.5%
Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	0%	0%	14.3%	14.3%	0%	71.4%
Regulation (EC) No 1107/2009 on plant protection products	0%	0%	0%	66%	0%	33%
Regulation (EU) No 528/2012 on biocidal products	0%	0%	0%	63.6%	27.2%	9%

Carcinogens and Mutagens Directive

The Carcinogens and Mutagens Directive is considered by all stakeholders who contributed to the targeted consultation (industry, NGO, academia and Member States) to provide an appropriate approach to achieving a high level of protection whilst acknowledging that there are currently, and may continue to be, carcinogens and mutagens in the workplace. Its hierarchy of risk management measures, with priority given to substitution, is considered to be appropriate and effective as it aims to remove hazardous substances where technically feasible, but also allows for other measures

where this cannot be met. It is acknowledged that it is not always possible to meet the requirements of the upper end of the hierarchy due to financial constraints, a lack of alternative substances or current operating procedures, as illustrated by the Gallium arsenide case presented in Section 3. The lower levels of the hierarchy, such as the use of personal protective equipment (PPE), aim to reduce exposure to a “safer” level where elimination of a substance is not possible, and are effective when supported by enforcement at the national level.

Consultees also note that in the case of process-generated CMRs (an issue for formaldehyde, see also Case Study 10), a hazard-based approach (resulting in complete removal of CMR substances) would not be suitable as it is not possible to eliminate the substance without changing an entire process; as a result, a risk-based approach is more suitable. The arguments against such an approach include the fact that the Carcinogens and Mutagens Directive reflects a fundamentally different approach from the Chemical Agents Directive (which is risk based, rather than hazard based); in this respect, arguments against the approach set out in the Chemical Agents Directive include, for example, that exposures to reprotoxins should in any event be reduced as a result of the recommended risk management measures and operating conditions of use included in Safety Data Sheets under REACH.

Cosmetics Regulation

All industry respondents (100%) to the targeted questionnaire for the cosmetics industry believed that a hazard-based approach is not suitable for cosmetics, and that the approach should remain risk-based. One respondent pointed out that a risk-based approach is the *“fundamental principle upon which the EU cosmetics legislation has been introduced and continues to be based, as characterised by the obligations of the Responsible Person and the existence of dedicated procedures for the assessment of cosmetic ingredients by an independent scientific committee and their potential regulation under the annexes of the Cosmetics Regulation”*.

Respondents believe that a CMR classification should trigger a risk assessment by the SCCS, with the outcome of this being managed under the Cosmetic Products Regulation. The justification for retaining a risk-based approach is that many cosmetic ingredients are low exposure products, and this makes automatic triggers unnecessary and unjustified. Retention of the risk-based approach is considered by stakeholders to appropriately ensure efficient risk management of all cosmetic ingredients, as cosmetic products have well defined and known uses and exposures.

Ethanol is an example of where basing cosmetic products risk management on generic risk considerations would have a net negative impact on the cosmetics industry and the availability of products for consumers, as the risk posed is negligible when products are not intentionally misused. One industry stakeholder has claimed that the Cosmetic Products Regulation ensures a high level of protection of human health and this can be shown by the very few incidences highlighting safety concerns over the last 40 years. NGOs and Member States made no comment on the approach taken for cosmetic products specifically, although NGOs are more strongly for risk management to be based on generic risk considerations for CMR substances.

4.2.3 Factors considered in risk assessment

The generic approach to risk management is based on the intrinsic properties of a substance and its subsequent harmonised classification. There is no risk assessment carried out in order to decide on the risk management of these substances with the exception of active substances and products under the Biocidal Products Regulation and the Plant Protection Products Regulation. Although there is an automatic ban on CMR substances in biocidal and plant protection products, a risk

assessment is carried out in the approval and authorisation of active substances and products which may allow for derogation from this automatic ban where criteria are met. These criteria include a number of factors as described below.

It should be noted that the Cosmetic Product Safety Report under the Cosmetic Products Regulation and the conformity assessment under the Toy Safety Directive are not considered to be risk assessments under the specific approach to risk management, as they are for information purposes and not for the approval of products being placed on the market or risk management decisions.

Table 4-3: Are characteristics and use adequately considered in risk assessment for CMRs?		
Legislation	Use of the substance	Notes
Biocidal Products Regulation	Yes	With application for derogation
Carcinogen and Mutagens Directive	Yes	In employer assessment
Cosmetic Products Directive	Yes	With application for derogation
Food Contact Materials (plastics) Regulation	No	
Prior Informed Consent Regulation	No	
Plant Protection Products Regulation	Yes	With application for derogation
Toys Safety Directive	Indirectly	In small parts, etc.

With respect to the factors taken into account in identifying risk management measures, stakeholder opinions vary. When asked whether the characteristics of a substance are given enough consideration in hazard and risk assessment for risk management purposes, stakeholders unanimously believed that they were and considered this to be a positive. The use of the substance is also considered to be adequately considered in risk assessment, including misuse. Intentional misuse is not included which is considered to be appropriate, as this may cause RMMs to be overly cautious. The uses of substances of concern are not taken into account in a hazard-based approach and this is considered by some to be incorrect as exposure to a CMR may not exist under certain uses, such as within a closed system. For risk-based approaches, the use of the substance is taken into consideration and this is considered to be correct for biocidal products, plant protection products and cosmetic products in particular. Foreseeable issues of misuse, such as a child sucking on a toy, are also taken into account in risk assessments. Intentional misuse, such as solvent abuse, are not taken into account, which is considered appropriate by most stakeholders as this may lead to unnecessarily harsh restrictions on use, or removal from the market.

A key factor regards consideration of vulnerable populations. There are conflicting views as to whether or not vulnerable populations are adequately taken into account in risk assessments. It appears that views differ depending on what piece of legislation is being investigated. One stakeholder claimed that protection of vulnerable populations from plant protection products is not sufficiently taken into consideration, as it is possible to spray crops which border a domestic garden, exposing children and the elderly or sick. An industry stakeholder, however, believes that all risk assessments examine different groups, including vulnerable populations. Of the Member States who responded to the consultation, 44% believed that too little weight was given to the protection of vulnerable groups, whilst 56% believed that appropriate weight was given.

One authority noted that vulnerable populations are not taken into account in the Carcinogens and Mutagens Directive although some are covered by other pieces of legislation such as the Pregnant Workers Directive (92/85/EEC) and the Young People at Work Directive (94/33/EC). An example of where consideration of vulnerability may be lacking with regard to cancer is that of night workers.

There is a proven link between night shifts and occupational cancer, with such working patterns identified as making people more vulnerable to chemical exposures.

Table 4-4 sets out the populations that are considered in risk assessments carried out under the different legislation, highlighting the degree to which pregnant and nursing mothers, children, and the elderly are specifically taken into account.

Table 4-4: Vulnerable populations considered in risk assessments	
Legislation	Vulnerable populations taken into consideration
Biocidal Products Regulation	Pregnant and nursing women, the unborn, infants and children, the elderly, workers and residents
Carcinogen and Mutagens Directive	No - other OSH legislation protects pregnant workers and young workers
Cosmetic Products Directive	Children under three years of age, the elderly, pregnant and breastfeeding women and people with a compromised immune system
Food Contact Materials (plastics) Regulation	None
Plant Protection Products Regulation	Pregnant and nursing women, the unborn, infants and children, the elderly, workers and residents
Prior Informed Consent Regulation	None
Toys Safety Directive	Children (under the age of 14)

Although the Carcinogens and Mutagens Directive does not explicitly identify the need for employers to consider pregnant workers or young workers, there is separate legislation specific to Pregnant Workers and Young Workers and the Chemical Agents Directive also places a more general duty on employers.

Under the Cosmetic Products Regulation, vulnerable populations must be taken into account in the SCCS assessment on the safe use of a cosmetic product. It is interesting to note that it is only the Cosmetic Products Regulation that mentions “people with a compromised immune system”. There is no explanation for this specific inclusion.

The conditions for granting the authorisation of a biocidal product include “*the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects*”⁵⁹. The definition of a vulnerable group in the Biocidal Products Regulation is “*persons needing specific consideration when assessing the acute and chronic health effects of biocidal products. These include pregnant and nursing women, the unborn, infants and children, the elderly, and, when subject to high exposure to biocidal products over the long term, workers and residents*”. Particular care is taken in the exposure assessment in order to assess the pathways of exposure relevant for vulnerable groups.

One of the conditions for approval of an active substance under the Plant Protection Products Regulation is that “*they shall not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available, or on*

⁵⁹ Article 19(1)(b)(iii) of Regulation (EU) No. 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

groundwater”⁶⁰. It must also “have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available, or on groundwater”⁶¹. In the testing of candidates for substitution, the possibility of exposure of vulnerable populations has to be taken into account in order to assess the significant difference in risk.

Although toys must meet the requirements of REACH, the “provisions should also be adapted to the particular needs of children, who are a vulnerable group of consumers”⁶². This means that “new restrictions on CMR substances, in accordance with CLP should be provided for on account of the special risks that these substances may entail for human health”⁶³. There is also an extra provision for young children: “in order to ensure adequate protection in the case of toys involving a high degree of exposure, it should be possible to adopt implementing measures establishing specific limit values for chemicals used in toys intended for use by children under 36 months and in other toys intended to be put in the mouth, taking into account the requirements of Regulation (EC) No 1935/2004 and the differences between toys and materials that come into contact with toys”⁶⁴. This comitology, although being considered a useful action, has been criticised by stakeholders as they believe that it should be extended to children above the age of 36 months; although the mouthing behaviour of children is most common up to 36 months, it is not exclusive to that age range.

Another issue that has been raised with regards to children as a vulnerable population is the use of generic concentration limits for CMRs based on those set out in CLP. These are generic concentration limits for a mixture classification, which were not derived with the aim of protecting children (they are based on adults). As children are more susceptible to the effects of CMRs due to their body weight, lack of organ development and behaviour, the limits are considered by many stakeholders as reflecting an unacceptable level of risk. Many are of the opinion that whilst these generic concentration limits may be applicable to some CMRs (e.g. some threshold), they will be too high for others which will pose a risk at concentrations below that concentration (e.g. non-threshold).

It has been observed that although it is possible to differentiate between routes of exposure in the classification of CMRs, such as nickel bis(2-ethylhexanoate) which has the classification H350(i) (carcinogenic 1A, inhalation only), this is not carried forward to downstream legislation. Where a ban exists on the use of CMR substances under the Biocidal Products Regulation, Plant Protection

⁶⁰ Article 4(2)(a) of Regulation (EC) No. 1107/20096 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

⁶¹ Article 4(3)(b) of Regulation (EC) No. 1107/20096 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

⁶² Recital 21 of Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.

⁶³ Recital 21 of Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.

⁶⁴ Recital 24 of Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.

Products Regulation, Cosmetic Products Regulation, Toy Safety Directive, Food Contact Materials Regulation, there is no differentiation and the ban applies to those with the classifications in Table 4-5 as a whole. In these cases, it is possible that substances could be prohibited for use in a product when, due to their use scenario, they pose little to no risk (excluding intentional misuse) as only one exposure pathway results in the CMR effect. It is not clear how many substances are affected by this lack of differentiation, but ethanol is one that would clearly be impacted. Where it is used in cosmetics and biocides there should be no oral exposure, the route for which evidence of carcinogenic effects has been observed. It should be noted that a CLH for CMR effects does not exist yet but due to the application for approval of ethanol as a biocidal active substance, a CLH could be expected. If the CLH differentiates between exposure pathways then the ban on use without taking account of the use and exposure scenarios would likely have negative impacts which could be avoided by allowing for differentiation in classification in downstream legislation.

Table 4-5: Hazard statement codes used in downstream legislation for the risk management of CMRs		
Mutagenicity	Carcinogenicity	Reprotoxicity
H340 – May cause genetic defects (Mut. Category 1)	H350 – May cause cancer (Carc. Category 1)	H360 – May damage fertility or the unborn child. (Repro. Category 1)
H341 – Suspected of causing genetic defects. (Mut. Category 2)	H351 – Suspected of causing cancer. (Carc. Category 2)	H361 – Suspected of damaging fertility or the unborn child. (Repro. Category 2)

4.2.4 Socio-economic considerations and derogations

Socio economic factors

It would appear that the Biocidal Products Regulation is the only piece of legislation that includes the potential for socio-economic factors to lead to a derogation. Under the Biocidal Products Regulation, Article 5(2) requires evidence to meet one of the specified criteria in order for the derogation from the automatic ban to be granted. Two of these criteria are based on the socio-economic impacts. A derogation may be granted if:

- It is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or
- Not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.

The first point is not considered to be a direct assessment of the socio-economic impacts of the ban on CMRs, but it does examine the impact of the ban through considering the prevention or control of a serious danger. An example of this would be that of the impact on farmers as a result of not preventing or controlling a serious danger to animal health. As animals are a product for farmers to trade, e.g. as meat or dairy, the consequences of not protecting them and subsequently compromising the health of livestock are clearly socio-economic as well as animal welfare based. The second point is a direct link to the socio-economic impacts of removing a substance from the market based on its hazard classification.

The fact that the Biocidal Products Regulation is the only piece of legislation analysed for this task that includes a derogation based on socio-economic considerations is considered to be a gap by many of the stakeholders, including industry, civil society and Member States. The Plant Protection

Products Regulation does not have a similar derogation and no justification for this difference with the Biocidal Products Regulation has been identified from a review of the literature. If a pesticide is removed from the market due to its hazard classification with no consideration of the socio-economic impacts of that ban then there may be unforeseen consequences. Pesticide resistance is a significant problem and there may be cases arising where only one pesticide product is suitable for a particular use. If this is the case, then there can be considerable impacts on crop yields, for those crops which cannot be adequately protected by the pesticides that are available; as such, there can be direct impacts on market actors and food security. This lack of a socio-economic derogation for pesticides appears at odds with the ability to gain such a derogation under the Biocidal Products Regulation.

Table 4-6: Socio-economic factors taken into account with regards to risk management for CMRs

Legislation	Socio-economic factors
Biocidal Products Regulation	Yes
Carcinogen and Mutagens Directive	Yes
Cosmetic Products Directive	No
Food Contact Materials (plastics) Regulation	No
Prior Informed Consent Regulation	No
Plant Protection Products Regulation	No
Toys Safety Directive	No

The Carcinogens and Mutagens Directive takes into account the technical feasibility of implementing the hierarchy for risk management. This means that employers must meet all steps of the hierarchy which they can feasibly implement, e.g. if it is not economically viable to substitute a substance then they must employ the risk management measures below this. Socio-economic considerations are also taken into consideration for the setting of BOELVs.

Industry stakeholders are of the opinion that the impacts on manufacturers, downstream supply chains and consumers are not adequately taken into account in most of the risk management decision making processes considered here. One industry association stakeholder opined that *“the way regulations operate now is over protective and as such, valuable substances, the essential tools for farmers, are being lost and thus putting EU farming at a disadvantage in the global market”*. Another stakeholder has commented that *“if society wants affordable food commodities all year round then the continued use of PPP is essential and necessary. To realise a sustainable agricultural market in Europe, farmers must be allowed the tools to deliver crops competitively in a global market”*.

The consideration of socio-economic impacts can be considered to be important in meeting two of the objectives of the chemicals legislative framework (innovation and competitiveness) (and it may also aid in ensuring a high level of protection of human health and the environment if it helps avoid regrettable substitutions leading to shifts in risk)⁶⁵. By considering socio-economic impacts, substances may not be removed from the market if they are fundamentally important and their removal would have a significant impact on society. The removal of substances from the market can sometimes hinder innovation as money that would normally be spent on R&D is moved instead to

⁶⁵ See for example Fantke P. et al. (2015): From incremental to fundamental substitution in chemical alternatives assessment, Sustainable Chemistry and Pharmacy, Vol 1, pgs 108. Available at: <http://www.sciencedirect.com/science/article/pii/S2352554115300024>

substitution and reformulation costs. The removal of substances can also reduce the number of options available to consumers and so reduce competition.

Although both of these impacts are important, there needs to be a balance struck between these and protection of human health and the environment. It has been observed that there has been lobbying for socio-economic impacts to be taken into account in the classification process under CLP, which may reduce the impact of automatic bans in downstream legislation. The classification process is the first step to risk management and it is a scientific process. As mentioned previously, it is based on the intrinsic properties of a substance. It does not take into account use, exposure or socio-economic impacts of risk management, as these are the responsibility of downstream legislation, with each varying depending on the sector. It is generally agreed that this should remain the case (see also the Task 1 Report), and that any modifications that need to be made to the linkage between the outcomes of harmonised classification should be addressed in the downstream legislation.

Derogations and effectiveness

Derogations and exemptions exist under four of the seven pieces of legislation considered in this study. Table 4-7 provides an indication of what criteria are considered in the derogations from the ban on CMRs. As noted above, the Biocidal Products Regulation is the only piece of legislation considered in this case study that has a broad spectrum of derogation criteria, including socio-economic considerations; alternatives; and use of a committee to form an opinion on the safe use.

The Carcinogens and Mutagens Directive has been included even though these criteria are not derogations as such, they are considerations that must be made in order to decide on the right risk management measure to be implemented. This includes the potential to take into account the availability of alternatives and the socio-economic impacts on individual operators. The case of gallium arsenide and formaldehyde cases highlight the importance of the flexibility of the Carcinogens and Mutagens Directive for industry in the functioning of their practice and the protection of their workers.

It should be noted that there are different considerations for candidates for substitution under the Plant Protection Products Regulation (as noted by a “?” in the table). As mentioned earlier, it is not clear why the Biocidal Products Regulation contains more provisions for a derogation than the Plant Protection Products Regulation, particularly in the case of socio-economic considerations, given that there may be very similar impacts from the removal of a pesticide compared with a biocide. There are also ways in which to get CMRs placed on the Union list for use in food contact materials but as this is carried out under the Plastics Regulation, it has not been considered a derogation from the rule under the Food Contact Materials Regulation.

Derogations and exemptions from the ban of CMRs under the legislation concerned have proved a contentious issue. Some civil society and Member State authority stakeholders are of the view that derogations prevent legislation from meeting the objective of a high level of protection of human health and the environment. It has been said that the use of derogations violates the rules of the precautionary principle and there should be no exposure to CMRs irrespective of the proposed use, as there is no “safe” threshold. They argue that when derogations are employed, they should be on a case-by-case basis and should only be granted in cases where the use of a CMR is essential or the benefits to society significantly outweigh the risks.

Other Member State authority and industry stakeholders believe it is correct to have derogations but that some changes could be made to ensure that they meet the objective of continuing to protect human health. For example, it has been suggested that the Plant Protection Products

Regulation could have a derogation based on potency, as this would assist in the ability to determine the degree to which a substance may cause cancer, thus providing significant additional information on which risk assessment and management could be made. It has also been suggested that some derogations could be made broader in order to allow for a more harmonised approach to chemicals management, for example by introducing the same criteria for derogation under Plant Protection Products Regulation as apply under the Biocidal Products Regulation.

Table 4-7: Possibility for derogation from ban on the use of a CMR and implications for effectiveness				
Legislation	Feasible alternative	Socio-economic factors	Exposure/Risk/ Safe Use	Effectiveness implications
Biocidal Products Regulation	✓	✓	✓	Only one of the criteria needs to be met for a derogation to be granted. The Biocidal Products Regulation may be more effective with respect to the functioning of the market, competition and innovation than the other legislation; it should still be effective in relation to risk management, as one would expect derogation based on feasibility and social interest considerations to ensure these outweighed residual risks.
Plant Protection Products Regulation	- ?	-	✓	Derogation based on EFSA decision regarding “negligible exposure”. No consideration given to the availability of feasible alternatives or socio-economic or social interest considerations. Thus, while this may be effective in protecting against exposure to a CMR, it may result in a shift in risks or impact on the effectiveness of the legislation in meeting its objectives of contributing to the functioning of the market, the wider economy and competitiveness. Different rules apply for candidates for substitution that have been comparatively assessed.
Cosmetic Products Regulation	✓	-	✓	Derogation based on SCCS decision regarding residual risks following industry submission of a risk assessment. Consideration of the feasibility of alternatives under the derogation criteria. No consideration given to socio-economic or social interest considerations. Thus, while this may be effective in protecting against exposure to a CMR, it may result in a shift in risks or impact on the effectiveness of the legislation in meeting its objectives of contributing to the functioning of the market, the wider economy and competitiveness.
Toy Safety Directive	✓	-	✓	Derogation based on SCCS/SCHEER decision regarding residual risks following industry submission of a risk assessment. Consideration may be given to the availability of alternatives in line with Article 46 but this is not a given. No consideration given to socio-economic or social interest considerations. Approach effective in protecting against exposure to a CMR, but it may result in a shift in risks or impact on the effectiveness of the legislation in meeting its objectives of contributing to the functioning of the market, the wider economy and competitiveness.
Carcinogens and Mutagens Directive	✓	✓	✓	Not a derogation per se, but hierarchy within the Carcinogens and Mutagens Directive requires employers to consider worker safety when moving from substitution to measures for reducing exposures; socio-economic factors can be taken into account. Carcinogens and Mutagens Directive is considered effective in that it requires a reduction in exposures to CMs in the workplace, although it does not reduce such exposures to zero. As it enables other factors to be taken into account, it is more effective in also contributing to the other objectives of the legislation.
Food Contact Materials Regulation	-	-	?	No derogations are possible, with this indicating a high level of effectiveness in protecting consumers from exposure to CMRs from food contact materials. The lack of derogations may impact on the effectiveness of the legislation in meeting its objectives of contributing to the functioning of the market, the wider economy and competitiveness. CMR substances may be added to the Union list for plastics after they have been assessed by EFSA and authorised for use. This is not considered a derogation under the Food Contact Materials Regulation as it is a component of the Plastics Regulation.

4.3 Efficiency

4.3.1 Introduction

For the purposes of this case study, we have considered the following questions with regard to efficiency:

- What are the costs associated with the chemicals legislative framework for: regulators at EU and national level; industry, including SMEs; workers and consumers; and society, economy in general?
- What are the benefits associated with the chemicals legislative framework for: regulators at EU and national level; industry, including SMEs; workers and consumers; and society, economy in general?
- Are the adopted risk management measures precise and clear enough?
- Are they easy or burdensome to put in place?

The focus of this case study is on the actions that are triggered by a substance when given a harmonised classification for CMR properties. The focus in relation to efficiency is on the costs that may be triggered from such a classification, with this including both direct and indirect effects, and whether any benefits are witnessed as a result of the risk management approaches employed. Benefits are not examined in detail due to the difficulties in estimating benefits and overlaps with other work (e.g. see the Task 1 report and predictions in reductions in cancer cases over time). These costs will be linked to the types of risk management required under the different legislation, where this may vary from substance withdrawal to making adjustments to workplace conditions to ceasing certain activities. This is illustrated by the series of tables and the discussion provided in Section 3 of this case study.

Table 4-8 summarises the risk management measures that are triggered under the different legislation once a substance has been given a harmonised classification for CMR properties, starting with those triggered under CLP. As can be seen from this list, under much of the legislation, a likely outcome is the need to withdraw the substance from use within the products regulated by the different sectoral legislation. In this respect, it is important to recognise that the Carcinogens and Mutagens Directive, for example, is cross-sectoral and applies to all workplaces where exposure to a CMR may take place. Similarly, although the Biocidal Products Regulation is focused on specific sets of chemicals, biocidal products may find applications across a range of different sectors (e.g. paints and coatings), all of which may be impacted.

Table 4-8: Summary of legal requirements triggered under different legislation	
Legislation	Risk management requirements triggered by CMR classification
CLP Regulation	Changes in labelling, Safety Data Sheets and potentially packaging.
Cosmetic Products Regulation	Withdrawal of substance use from products if no exemption is granted following a risk-based evaluation and for Cat 1A and 1B if there are no suitable alternatives. Specific labelling and any other procedures as determined by SCCS if exempted.
Toy Safety Directive	Withdrawal from the market if no derogation can be granted in line with Part 3 of Annex II.
Regulation on Plastic Materials in Contact with Food	Withdrawal of product from the market if substance is not added to the Union list following a risk assessment; reformulation to meet migration limits may be required.
Regulation on Plant Protection	For Cat 1A and 1B, withdrawal of active substance from the market

Table 4-8: Summary of legal requirements triggered under different legislation	
Legislation	Risk management requirements triggered by CMR classification
Products	unless exposure is negligible and where residues on food and feed do not exceed default values for maximum residue levels of pesticides; in the case of mutagens, there is no potential exemption.
Biocidal Products Regulation	For Cat 1A and 1B, withdrawal of active substance from market unless exemptions apply based on negligible risk, essentiality, or disproportionate negative impacts on society and the availability of substitutes.
Carcinogens and Mutagens Directive	Hierarchy of measures to be applied, starting with substitution and where this is not technically feasible involving prevention of exposure.
Prior Informed Consent Regulation	Export of a CMR Cat 1A or 1B is not allowed.

Thus, for any given substance, the actions triggered by a CMR classification will vary depending on the uses of the substance and whether it is specific to a single industrial sector/area of application or is used across a range of sectors, and whether the legislation and its implementation has implications primarily for industrial users, professional users or consumers, i.e. the general public.

It is understood that the formal adoption of a new classification typically takes around 18 – 24 months. Impacts under other legislation will then arise either immediately or soon after. For instance, under the Carcinogens and Mutagens Directive, when substitutes cannot be identified, measures would need to be taken during manufacturing activities that involve the substance (unless already in place). These might include engineering measures aimed at group protection (improved ventilation, use of closed systems, etc.), personal protection equipment, separation of operations/personnel, medical surveillance, etc. These could cause significant disruption and come at a considerable cost.

After inclusion of a CMR into Annex VI to the CLP Regulation, the European Commission regularly enacts restrictions for the use of these substances in consumer products. For example, entry 28 of REACH Annex XVII regulates the restriction in consumer products of substances classified as CMRs (categories 1A and 1B). As soon as a substance is included by way of a Commission Regulation in the relevant tables (Appendix 2) under this entry, the substance cannot be used for final consumer uses or placed on the market any longer if a concentration limit of 0.1% by weight is exceeded.

Under the cosmetics, toys, biocidal products, plant protection products and food packaging legislation, a risk assessment would need to be undertaken and other supporting evidence developed (e.g. availability of alternatives) with the aim of securing a derogation or exemption, or the substance would have to be withdrawn from the market.

Where waste contains a substance known to be a Carc Cat 1B in a concentration of over 0.1% by weight that waste needs to be classified as hazardous by HP 7 under the Waste Framework Directive. Consequently, transboundary movement of wastes containing the substance may be hindered under the Basel Convention, as well as under the Prior Informed Consent Regulation.

In addition to the above legislative drivers, harmonised classification as a CMR may also trigger market effects, which generally are difficult to predict. The potential loss of a substance, especially if it is used in a range of different applications, will prompt many companies to review their business plans product portfolios when planning for the future. This in turn may lead companies to relocate certain manufacturing activities outside the EU where CMR classification does not apply or where there are no parallel risk management requirements.

Finally, a new CMR classification will impact on downstream users' perceptions of a substance and on consumer perceptions. There will be an immediate impact from the classification on perceptions as to the safety of using a substance, regardless of whether there is a relevant route of exposure for a given application. In addition, if use is allowed to continue as a result of derogations in some applications, this can send mixed messages to markets and lead to confusion; consumers in particular may find it perverse that a carcinogen could be present in some products but not in others and may avoid using products that contain a CMR even though its use has been assessed as being safe.

4.3.2 Costs versus benefits

The case studies presented in Section 3 of this case study illustrate the types of cost versus benefit trade-offs that can arise from the triggers that exist in downstream legislation after a substance has gained a harmonised classification for CMR properties.

On a case by case basis:

- The MBM case illustrates a situation where there is the potential for the future non-approval of a biocidal active substance which is known as a formaldehyde-releaser under the Biocidal Products Regulation due to the presence of formaldehyde at very low concentrations, below those set in CLP as the limit for classification (i.e. below 0.1%). The current approval requires that use in the manufacturing biocidal formulations occurs within automated systems and that products containing MBM are appropriately labelled according to CLP and the Biocidal Products Regulation. The product will come up for re-approval and, as it falls under the Biocidal Products Regulation, there is the potential for derogation on technical feasibility or potentially social interest grounds, which may be appropriate given that industry hold that no evidence has been provided of the carcinogenic potential of MBM (as opposed to skin irritation/corrosion), and submissions regarding the rate of release of formaldehyde from formulations.
- Gallium arsenide illustrates the potential importance of taking socio economic factors into account. In this case, research carried out for the Commission identified no feasible alternatives, and mandatory substitution could have had significant impacts for the semiconductor, photovoltaics and RF-communication and sensor industries – key enabling technologies for the EU economy estimated as contributing around €100 billion to GDP directly, indirectly and through induced effects. Assuming that worker exposures are reduced to as far as possible in line with the requirements of the Carcinogens and Mutagens Directive, the potential for future cancer cases and associated impacts on workers, their families, health care systems and employers should be minimised.
- Formaldehyde is examined in Case Study 10 with this case study adding consideration of potential impacts under the Biocidal Products Regulation (similar to those for MBM). Case Study 10 highlights the potential for high costs from a ban on the use of formaldehyde but also the potentially very significant benefits given the number of workers exposed; it also highlights the potential for regrettable substitutions to alternatives that could result in a shift in risks from consumers to workers. It also highlights issues with regard to the 18 month transition period following a Commission decision on a classification for it to come into force under downstream legislation such as the Carcinogens and Mutagens Directive.
- The lead metal case is hypothetical, in that the final classification decision drew on the possibilities within CLP to set different specific concentration limits for the massive versus

the powder forms. However, it also illustrates the range of potential effects that may stem from a harmonised classification, due to market reactions to CMR classifications. Although some of these impacts may not have arisen in practice, the case study highlights the potential for unintended impacts to arise from the linkages that exist within the legislative framework.

- The TCEP case highlights the potential value of the automatic triggers within the Toy Safety Directive in ensuring the protection of children as a vulnerable population. In this case, it appears that industry could move to alternatives, or at least could ensure that concentrations of TCEP in foams were kept below the regulatory threshold set in the Toy Safety Directive; furthermore, this should include not only EU manufactured toys but also imported toys. As no applications for authorisation were submitted under REACH, it would appear that industry in the EU has moved away from its use. This case study also illustrates the potential for risk management to result in regrettable substitutions, in this case with TCEP being adopted as a substitute for the use of brominated flame retardants⁶⁶.
- Ethanol is a hypothetical case in that it currently does not hold a harmonised classification for carcinogenicity. It is also an interesting case in that there is only a single route of exposure linked to cancer effects – via the oral route. However, the downstream legislation does not necessarily make such a distinction, and there is the potential for restrictions on its use in a range of products, including large numbers of cosmetic products. Studies have shown that the costs to the cosmetics industry of reformulating products due to the loss of a key ingredient can be significant; in this case it is not clear what the benefits of such a requirement would be, given that exposure from cosmetics would not be via the oral route. In such a case, it should be possible for industry to gain a derogation based on a risk assessment. However, other consumer products, such as disinfectants, cleaning products, etc. will also be impacted which may have important socio-economic functions for which there are limited feasible alternatives.

4.4 Relevance

For the purposes of this case study, we have considered the following questions with regard to relevance:

- Do the original needs still exist or are parts of the legislative framework now redundant?
- To what extent do the objectives of the legislative framework for chemicals meet the need for enabling/ promoting the circular economy?
- To what extent does the chemicals legislative framework lead to substitution of hazardous chemicals with safer alternatives or technologies where justified human health, environmental and socio-economic considerations?

Table 4-9 summarises the conclusions drawn against these questions, with further discussion provided below.

⁶⁶ A “group” approach to flame retardants may have identified this potential, although several of the brominated flame retardants did include an assessment of alternatives, including chlorinated phosphates (e.g. the Risk Reduction Strategy for Decabromodiphenyl ethers). There was less information on the hazards of TCEP at the time, however, and undertaking risk management on a substance by substance basis limited the potential for ensuring that such regrettable substitutions did not take place.

Table 4-9: Assessment of relevance							
Evaluation question	CLH under CLP	Biocidal Products Regulation	Plant Protection Products Regulation	Cosmetic Products Regulation	Toy Safety Directive	Carcinogens and Mutagens Directive	Food Contact Materials Regulation
Do the original needs still exist?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Meeting the need for enabling/promoting circular economy?	Depends on what CLH decision triggers under other legislation	Indeterminate – may depend on sector and function of CMR at the product level	Unlikely – pesticides are not re-used or recycled, although there is a link to Directive 2009/128/EC aiming to achieve the sustainable use of pesticides	No – cosmetic products are end use products are not fed back into the system	Possibly – removal of hazardous substances may allow for the recycling of certain toys, although this will depend on their composition	Possibly – substituting the hazardous substance should remove it from downstream use and so in certain cases enable the circular economy. This is not possible for all hazardous substances.	Possibly – removal of hazardous substances may allow for the recycling of certain plastic food contact materials, although this will depend on their composition as not all plastics are recyclable
Substitution of hazardous chemicals with safer alternatives or technologies?	N/A - substitution is considered in downstream legislation but is likely to be based on the CLH of a substance	Yes - contains the conditions for substances to be considered candidates for substitution, aside from prohibiting the use of certain hazard classifications	Yes - contains the conditions for substances to be considered candidates for substitution, aside from prohibiting the use of certain hazard classifications	Yes/ no – there are no conditions for candidates for substitution but substitution is encouraged through the prohibition of certain hazard classifications	Yes/ no - there are no conditions for candidates for substitution but substitution is encouraged through the prohibition of certain hazard classifications	Yes – the first step of the hierarchy to be met, where technically feasible, is to substitute the CM substance	Yes/ no - there are no conditions for candidates for substitution and alternatives or substitutes are not mentioned in the legal text but substitution is encouraged through the prohibition of certain hazard classifications

Table 4-9: Assessment of relevance							
Evaluation question	CLH under CLP	Biocidal Products Regulation	Plant Protection Products Regulation	Cosmetic Products Regulation	Toy Safety Directive	Carcinogens and Mutagens Directive	Food Contact Materials Regulation
Socio-economic consequences with relevance for citizens and stakeholders taken into account?	No, this is based on the intrinsic properties of a substance	Yes - contained in the derogations under Article 5(2)	No	No	No	Yes – the technical feasibility of meeting the hierarchy for protection of workers is considered when deciding which step of the hierarchy can be met	No

4.4.1 Summary

Both the automatic hazard-based and the specific risk-based approach to risk management are relevant as the varying applications of CMRs will have different implications and both are aimed at avoiding exposure to hazardous chemicals. The generic approach to risk management removes CMRs before exposure can occur, with this type of approach mainly focused on protection of consumers and professional users. This may contribute to a significant reduction in risks from CMRs if the requirements are properly enforced and exposures are themselves significant. Six of the seven pieces of legislation in this case study follow this approach.

The approach employed in the Carcinogens and Mutagens Directive helps to prevent exposure to CMRs, even when it is not possible to remove them entirely from the workplace, through the establishment of priorities in terms of the actions that should be taken by employers. This is considered to be a combined approach to risk management as it includes the generic approach (the classification of a C or M triggers the need to meet a hierarchy of actions) and further implementation measures (the employer must assess which action can be employed in their workplace, starting at the top of the hierarchy and working their way down where it is not possible to meet an action). This is important as it must be recognised that it is not always possible to eliminate a CMR entirely, especially if they are process-generated. A more pure risk-based approach, such as that which exists under the Chemical Agents Directive, would also help ensure that employers did not move to unsuitable alternatives or that their investment in new RMM was efficient from a risk perspective.

The specific approach to risk management is most relevant in cases where the exposure to a CMR is known. In these cases, it can be determined through a risk assessment whether the use of the substance would be safe or whether it would still pose a risk to the user. An example of this approach would be a plant protection product used by professionals only, wearing personal protection equipment not carrying the same level of risk of exposure as a child playing with a malleable toy such as playdough.

As discussed in the Task 1 report, if it is possible to differentiate routes of exposure as part of classification in the downstream legislation then, where there is only one route of exposure which is of concern, this could be better taken into account within the legislation considered here, and also under other legislation such as REACH. This may help to combat unintended economic consequences from the removal of a substance such as ethanol because of a generic hazard classification. At present, this would only work in legislation that has a specific approach to risk management as that with an automatic response to a CMR classification do not currently differentiate between routes of exposure. Where derogations exist in legislation that uses the generic approach to risk management, then it is clear that consideration is given to routes of exposure and classifications where this is identified. If it has been proven at classification stage that a substance poses a hazard through only one route of exposure, then this may be an appropriate consideration for derogation purposes.

In response to the targeted consultation, the hazard-based approach to risk management is considered to be the most suitable approach by civil society in terms of combatting exposure to CMRs. They believe that exposure should be eliminated in all cases where this is possible and that a hazard-based approach is the most reliable and efficient way of doing so. From their perspective, this is a particularly relevant approach for legislation directed at consumer and professional user safety, where exposure to CMRs should be discouraged. In contrast, industry prefers a risk-based approach to risk management as it believes that prohibiting the use of all CMRs is not necessary if the substance does not present a risk to the end-user due to a lack of exposure. Member State

authorities provided mixed views on this issue, with some in favour of retaining generic triggers and others seeking a more risk assessment based approach across all downstream legislation

4.4.2 Legislation specific remarks

The only link to CLP in the Cosmetic Products Regulation is that of substances classified as CMRs. In this case, there is a ban on their being used in cosmetic products, but a derogation can be sought. Industry has criticised this approach to risk management of CMRs, as they are of the opinion that as the exposure and use of cosmetic products is known, and a risk assessment (Product Safety Assessment) is carried out for all cosmetic products, then an automatic ban is not needed.

An interesting point put forward by one stakeholder was in reference to the global reach of European legislation: *“One of the additional elements to take into account is the global impact of the European Cosmetics Regulation. Other countries or regions in the world (e.g. Asia) follow the European Cosmetics Regulation and, consequently, regulated ingredient restrictions for Europe are being copied in other legislations. This makes it even more important to ensure that the risk assessment and management processes are driven by the Cosmetic Products Regulation and that hazard-based approaches banning safe uses are avoided”*.

As described in Section 1.5.1, stakeholders do not all consider the classification of ethanol as a carcinogen 1A or reprotoxin 1A as relevant to the protection of human health, as it is based on one route of exposure which they claim is not relevant to the chemicals legislative framework⁶⁷. This is not the case as ethanol is present in some mouthwash which would make it fall under the Cosmetic Products Regulation. If that mouthwash claims antiseptic or antibacterial properties then it may also be subject to the Biocidal Products Regulation.

If the generic approach to risk management could differentiate between routes of exposure then it may make it easier to derogate when a route of exposure is not of concern. If ethanol was given a classification of Carcinogen Cat 1A or Reprotoxin Cat 1A, then it would be banned from use as a biocide or in cosmetic products. If the classification was given for the oral exposure route only (the only one which has been proven) and the subsequent risk management allowed for a derogation based on negligible exposure scenarios then ethanol may be prevented from being banned in certain products. It may well be allowed to continue to be a constituent of both professional and consumer products where the oral route of exposure is not possible/probable (misuse is not included).

4.5 Coherence

For the purposes of this case study, we have considered the following questions with regard to coherence:

- To what extent are the legal acts of the chemicals legislative framework consistent in attempting to reach the stated objectives?
- To what extent are the legislative provisions referring to various hazards?
- Can differences in hazard identification, risk assessment and risk management measures, as well as the provisions between different pieces of legislation be justified?

⁶⁷ VCI (2015): Impacts of classification under the CLP Regulation on other pieces of legislation – example ethanol.

- To what extent does the legislative framework meet its objectives consistently in cases where the same chemical is used for different purposes and where the same chemical is used for different purposes and where the uses fall under different pieces of legislation?

Hazard identification is not required under the pieces of legislation in this case study (with the exception of the Carcinogens and Mutagens Directive and for process generated and non-chemical CMRs), as they rely on a CLP classification for any risk management or risk assessment related to CMRs. As all of the pieces of legislation covered by this case study have risk management measures that are triggered automatically, this suggests general coherence in the approach to CMRs across the EU chemicals legislative framework. The Plant Protection Products Regulation and Biocidal Products Regulation require a risk assessment in order to approve substances and authorise products but CMRs are still subject to an automatic ban (based on exclusion criteria).

Although the different pieces of legislation employ different explicit risk management measures, this appears justifiable as the target population and the use scenarios are different. It is clear that OSH legislation such as the Carcinogens and Mutagens Directive will not employ the same risk management measures as the Cosmetic Products Regulation, as they have different targets; OSH is concerned with reducing exposures in a work environment, whilst the Cosmetic Products Regulation is concerned with reducing exposure from a product which has been placed on the market.

Although CMR substances are banned under some of the legislation considered in this case study, there are differences with respect to which categories of classification are subject to which risk management measure. A CMR category 1A or 1B shall be subject to prohibition in those that ban their use, whereas for CMR category 2 there are slight differences. The Cosmetic Products Regulation and the Toy Safety Directive prohibit the use of CMR category 2 substances, but the Plant Protection Products Regulation and Biocidal Products Regulation only prohibit the use of categories 1A and 1B. This cannot be attributed to the Cosmetic Products Regulation and the Toy Safety Directive being consumer legislation, as plant protection products and biocidal products can also be purchased by consumers. This distinction between categories of CMRs is expected to be due to differences in terms of the population at risk and the potential modes for exposure; but it is also considered to reflect a lack of coherence by stakeholders.

It is expected that having a coherent approach to the protection of human health from CMRs would prevent confusion amongst economic actors, as they will be aware that consumer and professional use products cannot contain a CMR substance. This coherent approach should contribute to the functioning of the single market, as economic actors are working to the same risk management measures and these are applicable across the framework, without discrimination against certain products. However, it must also be borne in mind that the criteria for derogations vary between legislation, as summarised in Table 4-10. This lack of coherence with regard to derogations may be justified, as differences in the use of a substance will determine what provisions will need to be met in order to gain an authorisation for use.

Table 4-10: Examples of derogations or exemptions from the automatic ban on CMRs and where similarities lie between those taken under chemicals legislation

Examples of derogations or exemptions	Cosmetic Products Regulation	Toy Safety Directive	Plastic materials and articles intended to come into contact with food Regulation	Biocidal Products Regulation	Plant Protection Products Regulation
No alternative substances	✓	✓		✓	
Opinion of a Committee or Expert Group on safe use or meeting of approval criteria	✓	✓	✓	✓	✓
For use in a product with known exposure	✓				
Complies with the requirements of another piece of legislation (e.g. food safety legislation, REACH)	✓	✓			
Meets the generic concentration limits for mixtures under CLP		✓			
Inaccessible		✓			
Does not exceed Maximum Residue Limits (MRLs)					✓
Exposure is negligible under the proposed conditions of use					✓
The risk is negligible under the proposed conditions of use				✓	
Socio-economic impact (e.g. not allowing use of the substance will have a disproportionate impact on society when compared with the risk)				✓	

The requirement for proof that there is no alternative for the substance of concern shows that substitution is being introduced not only through the provisions for candidates for substitution but also through derogation criteria. This requires considerable resources and may be costly for industry but it is important if the EU chemicals legislative framework is to meet its objectives, and if the European Commission is going to take steps towards a non-toxic environment. The Plant Protection Products Regulation is, however, an interesting exception to this requirement to prove that there is no alternative. It is unclear as to why this is the case, other than that it may be addressed by the “candidate for substitution criteria”.

Industry and Member State stakeholders have highlighted an issue with the term “negligible” in the derogations for both the Biocidal Products Regulation and Plant Protection Products Regulation. It should be noted that the exact wording is different for each derogation as the Biocidal Products Regulation speaks of the “risks” being considered to be negligible and the Plant Protection Products

Regulation speaks of “exposure” being negligible. It is not clear as to what is meant by the term “negligible” and this leads to confusion for industry when they attempt to build a dossier for derogation and it also makes it difficult for Member States when they are performing their initial assessment of the document before it goes to the EFSA pesticide unit.

Where there are derogations for the automatic ban on CMR substances under the pieces of legislation concerned, derogations can be sought for carcinogens, mutagens and reprotoxins in all pieces of legislation except the Plant Protection Products Regulation. In this case, there is no derogation from the ban on mutagenic substances of category 1A and 1B. It is not clear why a derogation does not exist for mutagens as there is no comment on this in the legal text and no guidance note. A suggestion for why this lack of derogation may exist is that mutagens are non-threshold substances and thus a safe level of use cannot be derived. Although this may be an effective way of protecting humans from the effects of mutagens, it leads to inconsistency as some carcinogens are also non-threshold substances (although one could assume that non-threshold carcinogens would find it more difficult to obtain a derogation).

An issue has been raised with regards to differences in hazard classification under ECHA and EFSA. Where an active substance is lacking a CLH, particularly for CMR properties, EFSA may decide to classify it themselves in order to aid in their assessment of the substance. This classification will be based on Member State recommendations. Stakeholders from all sectors believe that classification should be carried out by one Agency only and that should be ECHA. This is discussed further in Task 2.

5 Conclusions

From stakeholder consultation it would appear that there is no definitive answer as to whether there is one risk management measure (automatic, further assessment, or further implementation measures) which is preferred across the EU chemicals legislative framework. This is understandable given the different perspectives of stakeholders and that different pieces of legislation have different scopes and will need to respond to certain issues differently in order to function in the most effective and efficient way.

The general consensus from NGOs is that risk management based on generic risk considerations (possibility 1) should be applied to all legislation, as this is the only way to ensure that exposure to CMRs is truly prevented. Of the industry stakeholders who participated in this consultation, the general consensus is that the most appropriate approach to risk management is based on specific risk assessment (possibility 2) as this has the ability to reduce exposure without removing substances from the market and industrial processes when they do not present a risk. If a hazard-based approach is employed then it should always trigger further assessment.

Member State responses showed no real consensus on the approach to be taken, but did agree that hazard identification should be undertaken by one Committee and the subsequent classification should then be used as the basis for any risk management decision. The majority of public authorities that responded to the open public consultation believed that the chemicals legislative framework should remain as it is. The results by group are shown in Table 5-1.

Table 5-1: Extent to which respondents agreed with statements relating to the extent that EU chemical and chemical-related legislation should... (n=296)								
Chemicals legislation framework overall should ...	Group 1 (citizens) (n=32)		Group 2 (industry) (n=182)		Group 3 (public authority) (n=35)		Group 4 (NGO/others) (n=47)	
	No.	%	No.	%	No.	%	No.	%
a. Be more oriented towards specific risk assessments (i.e. differentiate more between chemicals depending on their use despite the possibility of prolonged discussions and implementation delays)	11	17%	151	72%	6	12%	14	25%
b. Be more oriented towards generic risk considerations (i.e. take more cautious approaches, despite the possibility that certain uses of a chemical that are in the interest of society might be restricted)	11	17%	5	2%	7	14%	23	41%
c. Remain as it is because the balance is more or less right (i.e. the legislation ensures appropriate application of specific risk assessments and generic risk considerations)	3	5%	23	11%	18	37%	9	16%
d. I don't know	7	11%	3	1%	4	8%	1	2%
No answer	31	49%	28	13%	14	29%	9	16%

The opinions on the need for derogations and their suitability are largely positive from all stakeholders, although there are some who believe that derogations break the precautionary principle and definitely should not be employed for consumer products.

The chemicals legislative framework appears to be generally effective at meeting the objective of ensuring a high level of protection for human health with regards to CMR substances. Such substances are subject to risk management based on generic risk considerations in most cases, particularly for professional and consumer products, which should help to reduce exposure and in turn reduce the incidence of CMR related illness. Where there needs to be a different approach, such as in the case of OSH legislation where it is not necessarily possible to remove a CMR substance from the workplace, using a specific risk assessment based approach is considered to be the most effective; it reflects the individual needs of the workplace and what adaptations can be made in order to offer the best level of protection to their workers.

Efficiency of the current approaches to risk management is more difficult to ascertain as cost and benefit data is lacking. There is not a particular issue with regards to the timing of risk management measure requirements, with most stakeholders believing that there is adequate time to be able to meet the new measures relevant to them⁶⁸. The exception to this is illustrated by the formaldehyde case (see also Case Study 10), where the transition period for responding to a new harmonised classification and the need to adopt measures under the Carcinogens and Mutagens Directive, is considered too short to enable companies to undertake the full research and development processes needed to identify and commercialise substitutes rather than adopt a measure lower down the hierarchy or controls.

The case studies presented in Section 3 of this report highlight the wide range of costs that may arise under the different legislation as a result of a harmonised classification. This includes:

- Costs of product withdrawal, in terms of lost revenues;
- Costs of substitution, including reformulation, process changes, testing, and marketing, as well as re-labelling and packaging in line with CLP and sector specific requirements;
- Impacts stemming from perceptions of products, with this anticipated as triggering changes in market demand for a substance. In the lead case, this was illustrated by the concern over the potential SCL of 0.03% for lead metal and the fact that this may lead to the need to dilute scrap aluminium and copper as part of recycling to ensure that recycled materials were not classified;
- Impacts triggered in relation to waste management, transport and storage;
- Costs arising from changes in processes and procedures at facilities due to the need to take measures to reduce exposures, under the Carcinogens and Mutagens Directive; note that these could include impacts on processing speeds, downtime, etc. (as also noted in relation to reformulation of cosmetic products for example); and
- Potential shifts in risks due to the move to an alternative with similar or other hazardous properties, thus resulting in a regrettable substitution;
- Indirect effects resulting from the above, for example, increases in environmental emissions due to any impacts on recycling, changes in materials that lead to increased waste arisings, etc.

Offsetting these of course are the potential human health benefits, including the reduction in cancer, developmental and other disease, and the benefits of these in terms of reductions in the loss

⁶⁸ With the exception of the cosmetics industry.

of life, reductions in health care costs and reductions in lost working days for employers. The extent to which there is a balance between such impacts will obviously depend on exposures, the economic value of the activities relying on the CMR substances and the availability and technical feasibility of alternatives.

On balance, the most efficient way of avoiding outcomes which do not reflect a balance between costs and benefits is for legislation to take technical and economic feasibility into account as part of risk management decision making. This suggests that if the chemicals legislative framework is to employ risk management measures based on generic risk considerations, then there needs to be the potential for derogations based on risk and feasibility considerations, as a minimum, and also potentially on social or socio-economic grounds. This failure to take such factors into account is cited by academics as one of the reasons for regrettable substitutions in the past. For example, Abelkop et al (2014)⁶⁹ note that applying the substitution principle without the appropriate comparative risk analysis may result in the premature replacement of existing chemicals with those that may be just as hazardous, or may be less toxic but carry a greater potential for release and exposure; although the authors also note that robust comparative risk analyses need a high level of information and can be resource and time intensive. Similarly, Lofstedt (2014)⁷⁰ argues that substitutes may not serve the same economic utility as the original chemical, thereby generating other types of risks to human health and the environment. For example, the substitution of lead from solders in electronic and electrical equipment with lead-free solders had the consequence of creating failures to the board of the components and of operating at higher temperatures, with higher energy consumption. Moreover, the European Commission (2012) notes that lead free solders may need an increased amount of rosin added to the flux, where rosin fumes have been identified as cause of occupational asthma.

Whether or not derogations should always take into account socio-economic factors is more debatable. Some leeway is required in order to maintain the market and to allow for some essential substances to be used. In this respect, Scientific Committees and Expert Groups are an important way of deciding whether or not a CMR substance should be granted a derogation as the evidence provided in the risk assessment is assessed by experts in the required field. Similarly, technical feasibility should be a core consideration. However, it is less clear that derogations based on socio-economic factors are necessary across legislation. There are already socio-economic based derogations in the Biocidal Products Regulation and similar derogations could be employed for the Plant Protection Products Regulation. For the Cosmetic Products Regulation and the Toy Safety Directive, socio-economic derogations may be less appropriate as these pieces of legislation are more concerned with consumer safety and a vulnerable population. It is clear that the chemicals legislative framework and its need to protect human health will continue to be relevant as it is not possible to totally eliminate the presence of hazardous substances, particularly CMRs. In order to maintain a fully functioning market, the objectives of encouraging innovation and competition are important and will remain relevant. The market changes continuously and is vulnerable to shifts inside and outside the EU, which sectors will need to keep up with.

⁶⁹ Abelkop A. D. K. and Graham J. D. (2014): Comment – Principles and tools of chemical regulation: a comment on ‘the substitution principle in chemical regulation: a constructive critique’, *Journal of Risk Research*, 17(5), pp. 581-586. Available at: <https://spea.indiana.edu/doc/research/working-groups/PrinciplesToolsChemicalRegulation.pdf>

⁷⁰ Lofstedt R. (2014): The substitution principle in chemical regulation: a constructive critique, *Journal of Risk Research*, 17(5), pp. 543-564. Available at: <http://www.tandfonline.com/doi/abs/10.1080/13669877.2013.841733>

Case Study 12: Use of CLP classifications as the basis for waste management

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1 Waste Case Study

1.1 Overview

The open public consultation, targeted data collection and interviews carried out as part of the Fitness Check have identified a range of waste related issues, that impact on both legislative coherence and potentially in relation to recycling and circular economy objectives. For example, consultation with Member State authorities indicates that, in some Member States, if a product label contains the ‘corrosive’ pictogram then recycling of the container is not permitted¹. Also, child-resistant closures are used as a decision criterion to exclude the container from recycling.

- CLP pictograms are used as the basis for waste sorting in the Walloon region of Belgium.
- Under German packaging legislation, manufacturers and distributors of hazardous products that are sold in packaging must ensure that the used and emptied packaging can be returned free of charge within a reasonable distance from the final user. If possible, the packaging waste should be recovered. The definition of ‘hazardous contents’ is currently still linked to the classification under the old Dangerous Substances Directive and Dangerous Preparations Directive, but could be transferred 1:1 to CLP.

These waste management measures are neither required under the CLP nor under the Waste Framework Directive (2008/98/EC).

In addition, Member States and industry have raised issues with respect to inconsistencies concerning the Waste Framework Directive and CLP. The classification of wastes draws on CLP classification of substances contained in the wastes, but also partly uses other systematic approaches to classify the waste. There are elements that do correspond to the approaches used under CLP to classify mixtures (defining generic threshold values, using summation approaches) but in parts deviating from the methods set out by CLP. Some classification criteria in Annex III of the Waste Framework Directive make use of own limit values, e.g. HP 13 sensitising with a limit of 10% compared to a limit value of 0.1% or 1.0% for skin sensitisers under CLP², or own calculation methodologies, e.g. the summation of acute toxic substances under HP 6³. Another example of such differences will be discussed in more detail in this case study for environmental hazards (HP 14 “Ecotoxic”).

Finally, the potential for newly agreed harmonised classification under CLP to give rise to concerns over the recyclability of materials has been raised in relation to metals classification (this is discussed in Case Study 2).

¹ See also draft guidance document EU-COM (2015) “On the definition and classification of hazardous waste” Draft Version from 8 June 2015, Chapter A.4.1. Packaging waste and contents. Available at: http://ec.europa.eu/environment/waste/pdf/consult/Draft%20guidance%20document_09062015.pdf

² See Annex I section 3.4.3.

³ “When more than one substance classified as acute toxic is present in a waste, the sum of the concentrations is required only for substances within the same hazard category.” CLP also requires summation across categories by summation of the acute toxic estimates (ATE) in relation to their concentration.

1.2 Case study aims and approach

This case study is not intended to be as extensive and detailed as many of the other case studies; rather it takes the form of a less in-depth examination of linkages.

The aim of the case study has been to examine the following:

1. The nature of the linkages between waste legislation and CLP, with respect to reliance on CLP for classification purposes;
2. The impact of reliance within the waste framework on the CLP ecotoxicity classification for the aquatic environment with respect to any impacts that the approximation to CLP has had on disposal or re-use of certain waste streams;
3. Issues regarding the classification of a waste as hazardous and the consequences of such classification for recycling; in particular, the case study investigates the legislative and non-legislative constraints to recycling. In particular, the focus is on consideration of the presence and (potential) bioavailability of substances of concern in certain waste streams as a constraint to allowing their recycling (metal/alloys, plastics, etc.)

The information required for this case study has been mainly gathered through desk-based research although interviews have also been undertaken with selected industry associations and national competent authorities.

2 Assessment of Waste Classification and Link to CLP

2.1 Background

The Waste Framework Directive (Directive 2008/98/EC⁴) is the key element to ensure safe handling of waste in the EU. It defines a regulatory framework for the handling of waste and is further specified by other pieces of EU regulation and national rules when implemented in Member States. The Waste Framework Directive sets out criteria to distinguish between the waste and non waste status of materials or objects. Article 3 lays down definitions for the beginning of the waste status while criteria for the End of Waste (EoW) status are defined by Article 6 of the Directive.

The Waste Framework Directive distinguishes between different types of waste and the hazards that are linked to these waste types. It is important to note that the scope of waste classification is not identical to that of chemicals classification under CLP. While the latter only refers to “substances” and “mixtures” as defined in Article 2 of the Regulation, the Waste Framework Directive applies to all waste that is included in the scope of Article 2 of the Directive and fulfils the definition of Article 3. This also includes objects that were excluded from the scope of CLP classification when they become waste, such as articles as defined under Article 2 of CLP. Waste classification also applies to some mixtures that are excluded from CLP but which need to be classified when they become waste, such as pharmaceuticals or cosmetics.

Waste classification also differs from CLP in its general approach as to how waste can be classified. The approach for waste classification is set out in Article 7 of the Waste Framework Directive. Following its classification a waste code is assigned to the waste. If the waste is considered hazardous, the waste code has an additional asterisk. The waste classification approach consists of three complementary elements:

- Direct assignment of a waste to an Entry of the List of Waste (LoW): A waste can be assigned to a hazardous or non-hazardous entry in the LoW (Commission Decision 2000/532/EC, as amended) taking into account its origin and composition.
- Classification based on the hazardous properties (HP) of the waste according to the criteria laid down in Annex III of the Waste Framework Directive. This approach is based on a similar system as the classification performed under CLP assessing the content of chemical substances and defining thresholds (link to CLP classifications). A waste is described already by origin and/or type but further assessment is needed to decide if it is hazardous or not. This assessment is performed according to criteria that are to a large extent based on the classification approach of the chemicals legislation under CLP⁵.
- Testing of wastes: As a third option for waste classification, testing can be applied to a waste. In cases where the results of the test are contradictory to the results of the assessment based on the content of the substances in the waste and the application of the

⁴ Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (Text with EEA relevance) (OJ L 312, 22.11.2008, p. 3–30).

⁵ Introduced in 2014 by Commission Regulation (EU) No 1357/2014 of 18 December 2014, OJ L 365, 19.12.2014, p. 89–96. Available at: <http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=celex:32014R1357>

criteria laid down in Annex III of the Waste Framework Directive, the testing result will prevail⁶.

In the following sections, details of the classification approach will be described and some potential differences and experiences from the practical implementation in Member States and the waste sector will be highlighted. It should be noted that this case study considers the approach outlined in Annex III of the Waste Framework Directive, which is based on CLP (but does not directly rely on CLP). It is also important to note that the main issue identified (through the consultation process and desk research) with regards to waste is the lack of harmonisation in the implementation in the Member States of (at least some) of the classification provisions of the Waste Framework Directive. Some hazardous properties left room for interpretation, for instance as regards classification for ecotoxicity. As a result, there were several interpretation approaches leading to a situation that some waste streams have been classed as hazardous in some Member States and non-hazardous in others. This was also the case with regards to the previous Directive on hazardous waste (Directive 91/689/EEC).. This, to date has not been effectively solved and is considered to be the aspect that is likely to give rise to the greatest costs to waste handlers (and is therefore deemed to be a more important issue than the inconsistencies identified in relation to CLP).

2.2 Linkages between waste legislation and CLP

The core element of the EU legislative framework with regard to waste classification is the Waste Framework Directive, which sets out in recital 1:

[...] “the legislative framework on the handling of waste in the Community. It defines key concepts such as waste, recovery and disposal and puts in place the essential requirements for the management of waste, notably an obligation for an establishment or undertaking carrying out waste management operations to have a permit or to be registered and an obligation for the Member States to draw up waste management plans. It also establishes major principles such as an obligation to handle waste in a way that does not have a negative impact on the environment or human health, an encouragement to apply the waste hierarchy and, in accordance with the polluter-pays principle, a requirement that the costs of disposing of waste must be borne by the holder of waste, by previous holders or by the producers of the product from which the waste came” (Recital 1 of the Waste Framework Directive).

The aim of the regulation is to establish requirements that trigger safe handling of waste and therefore avoid negative impacts on human health and the environment. An important part of this is identifying the hazards that can be linked to a waste, to ensure appropriate handling of waste streams. This covers, for example, information on the physical properties of a waste that might influence the treatment in installations and require special storage requirements, or the human health properties that are linked to the concentrations of hazardous substances and would need to be considered when risk management measures are implemented in a waste treatment process to avoid exposure of workers or environmental compartments⁷.

⁶ Annex of Decision 2014/955/EU (LoW) in the paragraph on “Assessment and Classification”.

⁷ This is not exclusively the task of the Waste Framework Directive but also accompanying pieces of EU legislation such as the Directives established for occupational health and the Industrial Emissions Directive (IED).

The Waste Framework Directive and CLP are linked with each other as the classification of waste makes use of elements implemented by CLP, as intended by the regulator (see below).

Recital 14 of the Waste Framework Directive states:

*[...] “The classification of waste as hazardous waste **should be based, inter alia, on the Community legislation on chemicals**, in particular concerning the classification of preparations as hazardous, including concentration limit values used for that purpose. Hazardous waste should be regulated under strict specifications in order to prevent or limit, as far as possible, the potential negative effects on the environment and on human health due to inappropriate management. Furthermore, it is necessary to maintain the system by which waste and hazardous waste have been classified in accordance with the list of the types of waste as last established by Commission Decision 2000/532/EC⁽³⁾, in order to encourage a harmonised classification of waste and ensure the harmonised determination of hazardous waste within the Community.*

The classification of waste was formerly linked in part to the system that existed under the Dangerous Substances Directive and the Dangerous Preparations Directive (via the so called H-criteria⁸ defined in Annex III of the Waste Framework Directive). In order to adapt Annex III to the changes resulting from the transition of the previous chemicals legislation to CLP, this Annex of the Waste Framework Directive was also replaced in 2014 by Commission Regulation 1357/2014⁹.

The general scope of Annex III was not changed, but some of the hazardous properties (HP)¹⁰ for the classification of waste were fully aligned with the classification system for the respective classification criteria of Annex I of CLP while others differ with regard to limit values and application of summation rules. An example for the first instance is HP 13 “Sensitising” with limit values of 10% applied to substances contained in the waste that are classified with an H317 or H334 (highest limit value possible without classification <1%). An example for the different summation rules is HP 6 “Acute Toxicity” that does not foresee summation across categories (substances classified as Acute Toxicity 1 are summed up and those that are category 2 substances are summed up, however, category 1 and category 2 substances are not summed together). Another difference that can be highlighted is that specific limit values according to CLP for individual substances are not taken into account for waste classification¹¹. It is not clear how this impacts on the waste classification. Two outcomes are possible in principle:

- CLP specifies a limit value that is lower than a generic limit value (e.g. several nickel or lead compounds have a lower value for carcinogenic effects, 0.01 %) => the CLP classification would be triggered at lower concentrations. However, it can be the case that most wastes that may contain such substances originate from sources that are classified as hazardous due to their origin, hence, there will be no impact.

⁸ Hazard criteria.

⁹ Commission Regulation (EU) No 1357/2014 of 18 December 2014 replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives (OJ L365, 19.12.2014, p. 70)

¹⁰ The name was changed from H-criteria to **Hazardous Properties-criteria (HP)** to avoid confusion with the hazard statements (H-statements) under CLP.

¹¹ This was also the case before Annex III and the List of Waste were revised, but it remains one of the differences between CLP and waste classification therefore it is mentioned here.

- CLP specifies a higher specific limit value (e.g. for corrosive effects of some acids) => the waste classification is stricter than CLP.

The exact effect can only be assessed for specific waste streams. It is furthermore important to note that waste is assessed for all substances contained within it for all endpoints. Even if the CLP and the Annex III limits are different for a specific endpoint/property, this does not mean the component does not trigger a classification at a similar concentration level for another hazard property, as substances often have more than one hazardous property.

The definition of waste and the definitions of substance, mixture and article have some significant impacts on the two classification approaches. While the main objective of classification under CLP is to inform the user of chemical substances and mixtures, the main task of waste classification is to ensure that waste is handled in a way that ensures that it has no negative impact on the environment or human health and to avoid inappropriate waste management¹². This is a general difference between waste classification and CLP. While CLP's main aim is to describe the hazards of substances and mixtures and to communicate these along the supply chain (via the label and also integrated into the safety data sheet according Article 31 of the REACH-Regulation), the first step of the waste classification is to describe the properties of the waste; this is then potentially followed by further assessment with regards to its properties to determine further treatment of the waste. As a result, articles under CLP are not classified, but they do have to be classified under the Waste Framework Directive when they become waste.

The communication on the hazards of wastes is established on different levels:

- The waste codes already indicate the main hazardous components, e.g. :
 - 01 03 04* acid-generating tailings from processing of sulphide ore.
 - 05 07 01* wastes containing mercury.
- The waste is assessed according to the HP criteria and may be classified because of the content of individual substances. The HP criteria responsible for waste classification are often communicated with the waste in the respective documents needed for the waste transport.

In many cases, the level of information generated to classify waste and perform waste handling operations, including the use of waste in the production of new products, is adequate. However, in practice the information on waste-specific composition can be limited and waste handlers can face information gaps on composition details which can cause problems; this can especially be the case when they want to perform recycling operations resulting in products destined to uses subject to demanding standards with regard to impurities (e.g. when the non waste material is a substance or a mixture and detailed information is required to undertake a classification according to CLP and provide safety data sheets under REACH). In some cases waste may not be suited for recycling but rather has to remain under the waste regime and handled in other treatment operations, such as energy recovery (if suited) or disposal with the preconditions laid down in Article 13 of the Waste Framework Directive. In other cases recycling may only be possible for certain limited uses of the recovered material where safety can be ensured.

¹² The proper management of the uses of chemical substances and mixtures in the chemicals legislation is not a task under CLP but is addressed by REACH, which complements CLP in this regard.

Besides Annex III of the Waste Framework Directive, the classification of waste is also regulated via Article 7 of the same Directive, which sets out further requirements for the classification of wastes including the so-called “List of Waste” (LoW) that establishes further rules for the classification of all types of waste. The LoW is implemented by Commission Decision 2104/955/EU¹³. Some general features are described below.

2.3 Structure of the List of Waste

The LoW is a list of waste types that are split into different chapters. The chapters each represent a certain type of waste or are defined by the origin of the waste. Typical examples include “Wastes from organic chemical processes” or “Municipal Waste”. The chapters are further subcategorised into another two tiers. Different levels within these tiers are represented by a six digit number (two numbers for each tier), for example:

07 Wastes from Organic Chemical Processes
07 02 **wastes from the MFSU of plastics, synthetic rubber and man-made fibres**
07 02 13 waste plastic
07 02 14* wastes from additives

Wastes that are marked with an “*” are hazardous wastes.

In principle there are three options for the classification of waste streams:

1. A waste of a certain type or origin is always “non-hazardous waste”. Municipal waste covers sub-chapters that do not contain any hazardous wastes:

20 03 **other municipal wastes**
20 03 01 mixed municipal waste
20 03 02 waste from markets
20 03 03 street-cleaning residues
20 03 04 septic tank sludge
20 03 06 waste from sewage cleaning
20 03 07 bulky waste
20 03 99 municipal wastes not otherwise specified

Although in certain cases one could imagine that hazardous substances might be contained in a specific waste stream identified by this type of entry, such waste cannot be classified as hazardous in the meaning of the Waste Framework Directive and assessed by the HP criteria laid down in Annex III unless a Member State specifically addresses that waste according to Article 7(2) of the Waste Framework Directive. These wastes are also called “Absolute non-hazardous waste”.

2. Wastes from other sources are assumed to be hazardous in any case unless a Member State comes to the conclusion that no HP criteria of Annex III applies according to Article 7(3) of the Waste Framework Directive. Again these wastes are not assessed by applying the HP criteria. They are referred to as “Absolute hazardous wastes”, for example:

¹³ COMMISSION DECISION of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council (Text with EEA relevance), (OJ L 370, 30.12.2014, p. 44–86)

07 02 wastes from the MFSU of plastics, synthetic rubber and man-made fibres

07 02 01* aqueous washing liquids and mother liquors

07 02 03* organic halogenated solvents, washing liquids and mother liquors

07 02 04* other organic solvents, washing liquids and mother liquors

07 02 07* halogenated still bottoms and reaction residues

07 02 08* other still bottoms and reaction residues

07 02 09* halogenated filter cakes and spent absorbents

07 02 10* other filter cakes and spent absorbents

3. Other wastes can be either hazardous or non-hazardous depending on their composition (which is assumed to vary within the same origin / generic process). The LoW comprises two similar entries, commonly called mirror entries. One represents the waste that is hazardous according to at least one of the HP criteria listed in Annex III of the Waste Framework Directive; the other one does not fulfil any of these criteria. An example can be:

07 02 wastes from the MFSU of plastics, synthetic rubber and man-made fibres

07 02 14* wastes from additives containing hazardous substances

07 02 15 wastes from additives other than those mentioned in 07 02 14

The arrangement is typical, in that there is one waste that fulfils the criteria for being hazardous while the other one refers to its mirror entry via quotation of the six-digit LoW entry number.

2.4 General link between CLP and Annex III of the Waste Framework Directive and the LoW

Annex III of the Waste Framework Directive and the provisions for assessing a waste, and whether or not the hazardous or the non-hazardous entry needs to be selected, are based on some of the classification rules of CLP Annex I and on the tests laid down in Regulation EU No. 440/2008¹⁴. Although some similarities can be observed, like the references to the test method and the classification of the substances that can be present in waste, differences with regard to the overall approach as to how limit values are applied exist. Nevertheless it has to be stated that the revision of Annex III of the Directive did generate a higher level of harmonisation in waste classification but some differences still remain. For example, specific concentration limits from CLP Annex VI Table 3.2 are not applied in the classification of waste, only the limit values of Annex III of the Waste Framework Directive are used. This is the case if harmonised M-factors are defined for environmental hazards but also when substances have specific limit values due to human health endpoints. A specific example is benzo[a]pyrene which has a specific concentration limit of 0.01% under CLP for carcinogen category 1B and would have a limit value under HP 7 of 0.1%. The same is the case for several nickel compounds, some cadmium and tin compounds (with these limit values defined in Annex III of the Waste Framework Directive). In most cases, the waste legislation makes use of the generic concentration limits of the corresponding hazard category of CLP. Deviations from this can be justified for practicality reasons and might also be compensated by the use of the absolute hazardous entries in the LoW. Article 7(7) states that the principles of the LoW should be appropriate and clear for users especially for small and medium enterprises. Therefore

¹⁴ Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance)

simplification of calculation methods can be justified when at the same time no adverse effects for the environment or human health occur.

Usually the classification of substances and mixtures is regulated under CLP and the classification of waste under the Waste Framework Directive (with the differences described below). To the authors' knowledge the main exception is the classification that needs to be performed to assess if a waste treatment plant falls in the scope of the Seveso III Directive. Here it is indicated that waste needs to be treated as if it was a mixture, i.e. according to the classification system of CLP if a certain risk potential is given that is linked to the presence of substances (in a waste) in the establishment, treatment of the waste and the potential to cause a major accident¹⁵. This would be the case if the waste has “equivalent properties in terms of major-accident potential”. For wastes that are very much like substances or mixtures (for example, solvents), this requirement seems to be logical and straight forward. In the case of more complex waste (and with regard to the chemical composition) this requirement leads to some difficulties when assessing the waste, in terms of having sufficient information to determine the presence of hazardous substances contained in the waste and which are relevant for Seveso. Also, the term “equivalent properties in terms of major-accident potential” is not further elaborated and gives reason for discussion.

Other key differences of the two classification systems are set out below.

2.4.1 Physico-chemical hazards

In relation to physico-chemical hazards, waste classification as hazardous is based on the following:

1. **HP 1 “Explosive”:** waste which is capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings. Pyrotechnic waste, explosive organic peroxide waste and explosive self-reactive waste is included.
2. **HP 2 “Oxidising”:** waste which may, generally by providing oxygen, cause or contribute to the combustion of other materials.
3. **HP 3 “Flammable”:**
 - flammable liquid waste: liquid waste having a flash point below 60°C or waste gas oil, diesel and light heating oils having a flash point >55°C and ≤75°C;
 - flammable pyrophoric liquid and solid waste: solid or liquid waste which, even in small quantities, is liable to ignite within five minutes after coming into contact with air;
 - flammable solid waste: solid waste which is readily combustible or may cause or contribute to fire through friction;
 - flammable gaseous waste: gaseous waste which is flammable in air at 20°C and a standard pressure of 101.3 kPa;
 - water reactive waste: waste which, in contact with water, emits flammable gases in dangerous quantities;

¹⁵ Note 5 of Annex I part 1 of Directive 2012/18/EU (Seveso III) states: “...In the case of dangerous substances which are not covered by Regulation (EC) No 1272/2008, including waste, but which nevertheless are present, or are likely to be present, in an establishment and which possess or are likely to possess, under the conditions found at the establishment, equivalent properties in terms of major-accident potential, these shall be provisionally assigned to the most analogous category or named dangerous substance falling within the scope of this Directive. ...”

- other flammable waste: flammable aerosols, flammable self-heating waste, flammable organic peroxides and flammable self-reactive waste.

If waste is to be assessed for one of these properties, it is to be tested¹⁶ according to the same tests as a chemical mixture (if appropriate and proportionate). This is in line with the approaches under CLP, which do not foresee direct classification based on the content of the individual substances but require further assessment of the mixture. In the event that a mixture classified as explosive under CLP becomes waste without dilution with other substances or mixtures, it can be assumed that the waste will be classified for HP 1 as well. The same is true for categories of CLP that are linked to HP 2 or HP 3. If waste collectors undertake a separate collection of flammable liquids, then despite its disposal and change in legal status, the respective HP 3 category will be met.

On this basis, one can conclude, with regard to physico-chemical hazards, that there is a 1:1 alignment with the classification rules of CLP. It should be noted that some wastes that can be linked to flammability (e.g. solvent wastes) are often absolute hazardous waste in any event, regardless of the solvent content in the waste.

2.4.2 Human Health hazards

In relation to human health hazards, waste classification as hazardous is based on the following:

1. **HP 4 “Irritant — skin irritation and eye damage”**: waste which on application can cause skin irritation or damage to the eye.
2. **HP 5 “Specific Target Organ Toxicity (STOT)/Aspiration Toxicity”**: waste which can cause specific target organ toxicity either from a single or repeated exposure, or which can cause acute toxic effects following aspiration.
3. **HP 6 “Acute Toxicity”**: waste which can cause acute toxic effects following oral or dermal administration, or inhalation exposure.
4. **HP 7 “Carcinogenic”**: waste which induces cancer or increases its incidence.
5. **HP 8 “Corrosive”**: waste which on application can cause skin corrosion.
6. **HP 10 “Toxic for reproduction”**: waste which has adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring.
7. **HP 11 “Mutagenic”**: waste which may cause a mutation that is a permanent change in the amount or structure of the genetic material in a cell.
8. **HP 13 “Sensitising”**: waste which contains one or more substances known to cause sensitising effects to the skin or the respiratory organs.

All HP criteria for human health hazards are based on the assessment of the presence of hazardous substances that were classified according to CLP and for the corresponding hazard category in Annex

¹⁶ Although it should be noted that testing is not always necessary. Note that Regulation 1357/2014, which amended Annex III, states, for example for HP 3, that waste shall be assessed "where appropriate and proportionate, according to test methods..."

of the regulation that is linked to the same end point. When doing this it does not matter if the waste is constituted of a substance or a mixture in the meaning of CLP or articles that would not have been classified under CLP, only the presence of the substance in the waste is relevant and thereby the hazardous property has to be assigned to the waste. It is possible to deviate from the approach based on applying the calculation methods set out in Annex III of the Waste Framework Directive, by performing tests on waste. This can be useful when there are grounds to consider that the calculation methods could underestimate or overestimate the hazard properties of a given waste. For most hazard properties the test results prevail over the results of the calculation method.

When a waste is assessed to determine whether or not it is classified as HP 4, one has to determine if substances are present above certain threshold limits that are classified Skin corr. 1A (H314), Skin irrit. 2 (H315), Eye dam. 1 (H318) or Eye irrit. (H319). Substances classified Skin corr. 1B and 1C are not mentioned under HP 4 and therefore are not included in the assessment. Furthermore, the limit value for the concentration of substances classified Skin irrit. 2 and Eye irrit. 2 under HP 4 is 20% instead of 10% under CLP. Hence, the application of the limit values differs slightly between HP 4 of the Waste Framework Directive and the respective categories, skin effects and eye damage.

Full alignment between CLP and Annex III of the Waste Framework Directive is realised for HP 7 “Carcinogenic”, HP 10 “Toxic for Reproduction” and HP 11 “Mutagenic”, with the exception that for the classification of waste no specific concentration limit values are applied, even though these are defined by a harmonised classification under CLP. This is not only the case for CMR substances but also for all other end points addressed by Annex III (e.g. specific concentration limits for corrosive endpoints, acute toxicity or STOT).

An example is given in Table 2-1 below for lead alkyls which are classified via a harmonised classification. If full alignment with CLP were to be realised, a waste containing 0.05% of lead alkyls would need to be classified according to HP 5. In fact, the generic concentration limit used in Annex III (10% for STOT RE2) is 200 times higher for this endpoint. For the endpoint ‘toxic to reproduction’, the difference is only a factor of 3 but it still varies from CLP.

Table 2-1: Harmonised Classification of Lead Alkyls ¹⁷ for the end points Repr. and STOT points RE and corresponding Hazardous Properties and limits under Waste Framework Directive Annex III				
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Specific limit values for the CLP classification of a mixture	Hazardous Property (HP)	Limit values for classification of a waste
Repr. 1A	H360Df	Repr. 1A; H360D: C ≥ 0.1%	HP 10 “Toxic for reproduction	0.3%
STOT RE 2 *	H373	STOT RE 2; H373: C ≥ 0.05%	HP 5 “Specific Target Organ Toxicity (STOT)/Aspiration Toxicity	10%

2.4.3 Non GHS hazards

One HP criterion does not have a respective category in CLP (and the GHS), HP 9 infections. This criterion is waste specific and strongly dependent on the current practices of the health system of

¹⁷ Index number 082-002-00-1, C&L Inventory <http://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/153461>

the EU Member States. It is not a direct chemical hazard, although many microorganisms produce toxins. However, a hazard caused by biological material is not in the scope of the chemicals legislation. Therefore, the implementation is not further operationalised at the Union level and is instead left to national implementation.

Other hazards represent EU-specific hazards not covered by Annex I of CLP and therefore are not part of the GHS. These hazards are listed in Annex II of CLP and originate from the old classification system of the Dangerous Substances Directive and the Dangerous Preparations Directive that were intended to be maintained upon introduction of the GHS. These HP criteria are:

1. [...] *“HP 12 “Release of an acute toxic gas:” waste which releases acute toxic gases (Acute Tox. 1, 2 or 3) in contact with water or an acid.
When a waste contains a substance assigned to one of the following supplemental hazards EUH029, EUH031 and EUH032, it shall be classified as hazardous by HP 12 according to test methods or guidelines.” [...]*
2. [...] *“HP 15 “Waste capable of exhibiting a hazardous property listed above not directly displayed by the original waste”.
When a waste contains one or more substances assigned to one of the hazard statements or supplemental hazards shown in Table 9, the waste shall be classified as hazardous by HP 15, unless the waste is in such a form that it will not under any circumstances exhibit explosive or potentially explosive properties.*

Table 9: Hazard statements and supplemental hazards for waste constituents for the classification of wastes as hazardous by HP 15

Hazard Statement(s)/Supplemental Hazard(s)	
May mass explode in fire	H205
Explosive when dry	EUH001
May form explosive peroxides	EUH019
Risk of explosion if heated under confinement	EUH044

In addition, Member States may characterise a waste as hazardous by HP 15 based on other applicable criteria, such as an assessment of the leachate. “[...]”

HP 12 is designed to address processes that can take place during waste treatment and transport that are linked to the reactions of the several components contained in a waste and that might lead to the formation of acute toxic gas. Such a waste does not contain the gas originally (which would be covered by HP 6) but it is generated from the waste components themselves, e.g. on storage or transport or subsequent management. How the assessment of this HP criterion has to be performed is not indicated in Annex III of the Waste Framework Directive. There is a general link to the testing regulation for REACH purposes (Regulation (EC) No. 440/2008), but there is also no test included that is suited to test this endpoint. This leaves the HP criterion to further implementation through guidance (and it is understood that discussions on this issue have started in the Commission).

A similar situation exists for HP 15 that also covers hazards that are not directly linked to the original waste or to specific situations. One hazard statement of CLP referred to is part of Annex I of CLP (and which is covered by GHS) and can therefore be tested, while all of the others are included in Annex II. The classification of the waste is not linked to a test that shows the waste has the property but on the assumption that a waste has the property when substances already known to be classified with one of the H/EUH Statements are contained in the waste. Limits are not provided but

declassification can be done when there is proof that a hazard does not apply. How the proof is utilized is not further described.

2.4.4 HP 14 “Ecotoxic”

Ecotoxicity is not currently based on CLP. A general definition of ecotoxicity is given in Annex III of the Waste Framework Directive:

[...]“HP 14“Ecotoxic”: waste which presents or may present immediate or delayed risks for one or more sectors of the environment.”[...].

This is supplemented by the following note:

[...]“Note

Attribution of the hazardous property HP 14 is made on the basis of the criteria laid down in Annex VI¹⁸ to Council Directive 67/548/EEC.” [...]

This clarifies that for the time being the “old” Dangerous Substances Directive should have been applied to assess ecotoxicity for waste. In practice this requirement was not implemented in many Member States one for one. Some Member States applied chemical analysis in combination with the application of the calculation methods of the chemicals legislation or parts thereof, whereas others undertook biotesting and some a combination of both¹⁹. Currently a revision of Annex III of the Directive with regards to HP 14 is under discussion. This proposal sets out clear criteria that are based on the hazard categories for aquatic toxicity and ozone depletion of the CLP. This would therefore lead to an increased harmonisation of the chemicals and waste classification and clear guidelines for Member States on how the criterion would need to be implemented in national legislation, leading to greater harmonisation of the EU single market. However, this may also result in additional burden for waste handlers in countries that applied methods for the classification of HP 14 that differed from the classification approach linked to chemicals legislation.

The current proposal covers the CLP categories Aquatic acute 1 and Aquatic chronic 1 and 2 and does not take M-factors into account. Thus, there will be some deviation from the approach taken under CLP; however, this is coherent at least for harmonised classifications as specific limit values are also excluded, which may be justified due to the reduced complexity. Other options were also discussed before this proposal was submitted for discussion. These ranged from full coverage of all substances classified for aquatic effects but with an exclusion of M-factors, or the inclusion of only the highest hazard categories (Aquatic acute 1 and Aquatic chronic 1 and 2) with M-factors²⁰. Other options have recently been assessed in a study commissioned by the Nordic Council²¹.

¹⁸ See Annex VI of the Waste Framework Directive at the website of the Commission: Available at: http://ec.europa.eu/environment/archives/dansub/pdfs/annex6_en.pdf

¹⁹ See chapter 3 of EU-COM study on HP 14 (Bio-Deloitte (2015): Study to assess the impacts of different classification approaches for hazard property “HP 14” on selected waste streams. Available at: <http://ec.europa.eu/environment/waste/studies/pdf/H14.pdf>

²⁰ For comparison see “Technical Proposal for the review of the hazardous properties” Working document (2012) of a Member State working group. Available at: <http://ec.europa.eu/environment/waste/framework/list.htm>

²¹ Nordic Council (2016): “Hazardous waste classification: Amendments to the European Waste Classification regulation - what do they mean and what are the consequences?”, Nordic Council of Ministers, Nordic

The actual assessment approach seems to have limited effect on the assignment of HP 14 as long as at the same time only generic cut-off limits are applied. This can be shown by the following example: A review of registration dossiers of some metals shows that M-factors of these metals are in the range 10 - 100:

- Cadmium has an M-factor of 10 for the non-massive form (acute and chronic);
- Lead has an M-factor of 10 for acute effects, 1 for chronic effects; and
- Chromium has no M-factor.

The concentration limits for the classification of a mixture that contains these substances would be the following if CLP were to be applied as part of self-classification:

- Cadmium: 0.025%
- Lead: 0.025 and 0.25%
- Chromium: 0.25%

One has to remember that in this case the resulting concentration limit for the classification would become the cut-off limit for these substances at the same time. Therefore, the concentration limit for the classification of waste according to HP 14 for Aquatic toxic category 1 substance without M-factors would be 0.25%. Note that also only the generic cut-off limits are applied for the classification of wastes. Hence, only substances above a concentration of 0.1% are included in the calculation of the overall HP 14 assessment for category 1 substances. In consequence an application of M-factors would only be reasonable if at the same time the cut-off limits were changed. At this point in time, however, there are no agreed criteria, so the above example is hypothetical.

It should be further highlighted that some of these metals have additional hazard classifications under CLP that would also trigger waste classifications. For example, cadmium is also classified as carcinogenic cat. 1B, with this leading to a classification limit of 0.1% for HP 7. This would be below the derived limit for HP 14 (same cut-off). Hence, if the cut off for both of these HP would have been exceeded by a substance, then HP 7 already applies at lower concentration limits than HP 14 and the waste will be classified in any case.

Similarly, lead metal has a classification as toxic to reproduction with a limit value for HP 10 of 0.3% therefore slightly higher than for HP 14.

In the study by the Nordic Council (2016)¹⁷, data were collected and analysed from bottom ashes that originated from Danish incineration plants. The results indicate that this waste will at least be ecotoxic as the analysed compounds were classified aquatic category 1 (acute or chronic) in large parts irrespective of the method applied. In fact neither copper (analysed as copper powder) nor tin (analysed as metallic tin or ZnO) are classified in these categories or have M-factors higher than 1 (resulting in limit values of 2.5%).

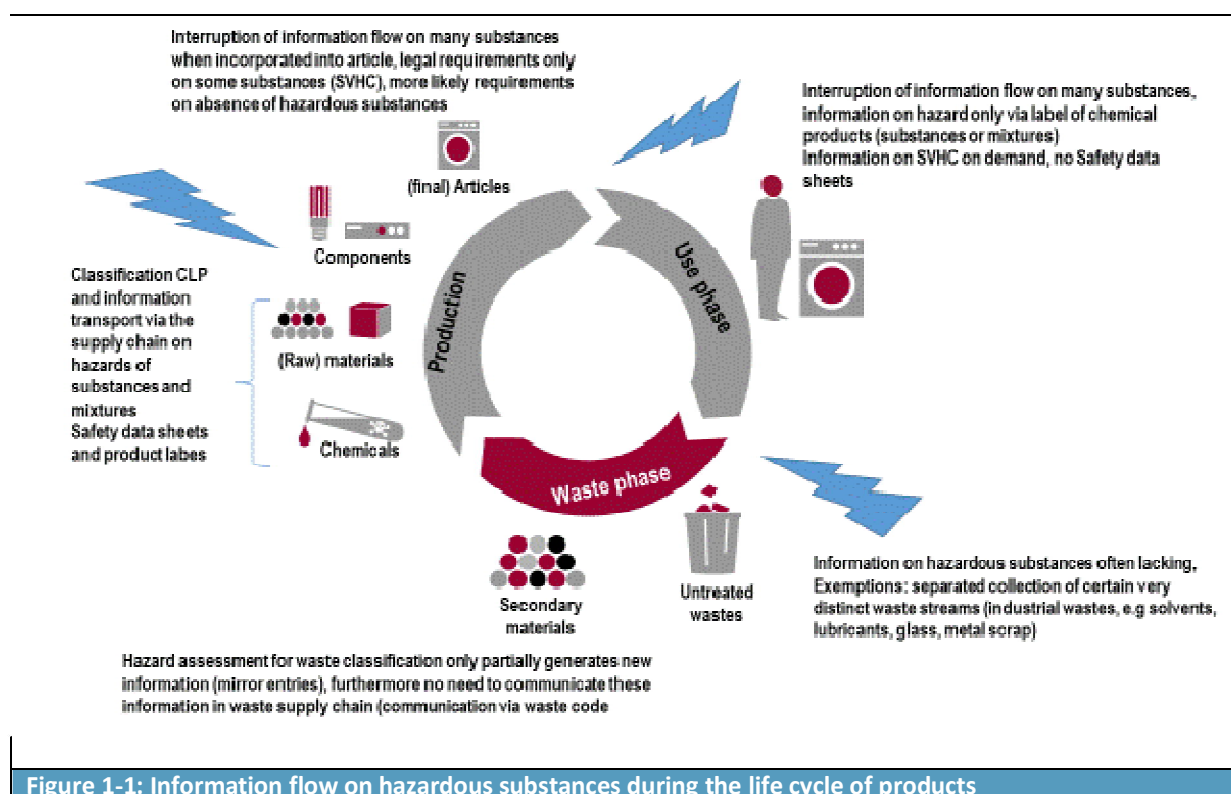
This is different when copper is present in the waste in a different compound. There has been a decision that copper oxide shall be classified (harmonised) with an M-factor of 100. This would reduce the limit for classification of a waste to 0.025% if M-factors were used for waste classification and may therefore have an impact on the amount and types of waste that would need to be classified. However, it is still highly problematic to decide what should be assessed when waste

Council of Ministers Secretariat, Nordisk Affaldsgruppe (NAG). Available at: <http://norden.diva-portal.org/smash/get/diva2:927423/FULLTEXT01.pdf>

streams are analysed for classification reasons as the composition is often very heterogeneous. In fact the substances that were identified as the most hazardous for the aquatic environment are treated less conservatively when M-factors are not part of the waste classification. Furthermore it is not clear which exact compound is contained in a waste, especially when it originates from rather “undefined sources” compared to the manufacture of a mono constituent substance during chemical production.

2.5 Hazardous classifications and recycling

The usual life cycle of a product (which can be a substance, a mixture or an article) is defined by the production of raw materials, finishing of the product and a service life/use, as well as a waste phase. During the various production steps, hazardous substances can be integrated into the product. The requirements to communicate on the content of hazardous substances in a product change when chemicals become or are incorporated into articles. The information flow on the hazardous substance content in articles is completely interrupted when (consumer) articles are discarded and become waste. As a consequence, in the waste phase information on hazardous substances is only present in well defined waste streams, often of industrial origin and derived from the use of chemicals rather than articles (see Figure 2-1 below).



For many waste streams, therefore, there is no or only very limited information available on the substances contained within it. The classification of wastes does not (re-)generate this kind of information (or only does so partially), because its main aim is to ensure waste streams can be handled in a way that prevents the occurrence of negative effects for human health and the environment. Hence, waste codes may be used to steer the waste streams to appropriate treatment facilities and to enable the relevant risk management measures to be applied therein to prevent related releases. This does not necessarily provide the level of detailed information that would be desired when converting waste into new products.

In this respect, waste classification is frequently not sufficient to identify the relevant chemical composition. As long as waste ends up in energy recovery, incineration or landfill, the differentiation of hazardous and non-hazardous wastes in combination with the six digit waste code, may provide enough information on the composition of the waste to enable them to be safely managed (although this may not be the case for wastes classified as hazardous). When recycling is the aim of the waste treatment operation, more information usually needs to be obtained. Such additional information on the waste may be generated and provided, if it needs to be characterised to comply with other pieces of applicable legislation (e.g. for transport or landfilling). In other cases, recyclers need to work closely with waste operators to ensure that wastes meet specified requirements (e.g. with regard to sources and content).

Where wastes are classified as hazardous, this can have consequences for recycling activities:

- Closed loop recycling could be used to enhance resource efficient production. It is very much dependent on the specific use and the system that a material is handled in. A well-known example is the closed loop recycling of hard PVC in long lasting products like profiles for windows, doors and pipes etc. Recycling material used in these kinds of products may contain up to 10 times the concentration of cadmium than is contained in new virgin material. Due to the fact that very limited migration from the material is observed and the length of time the products are in the use phase, the cadmium is still in the material at the point of disposal. The recycling potential of hard PVC materials is very high, but keeping the material in the supply chain will extend the phase out of cadmium from the life cycle of such materials. If such life cycles are not well controlled, there can be contamination to other products on the market. It remains to be determined whether or not this is acceptable, depending on the scientific proof that risks derived from the different products are either adequately controlled or are negligible.

It should be noted that when materials cease to be waste, they become subject to full REACH and CLP requirements. There is therefore an obligation to identify all constituents that contribute to classification. Furthermore processes such as authorisation under REACH might apply to specific substances in the material. A case by case assessment would be the result of such a process that would ensure that no unwanted effects occur on the reuse of such materials. An example for such a process was the recycling of PVC containing DEHP, where an authorisation has been granted by the EU Commission following the recommendations by RAC and SEAC.

- Recycling where waste is used directly to produce an article, with the aim of a broad application spectrum, may also take place. In such cases, there may be the potential for the recycled substances or mixtures to contain unidentified ingredients. This is an aspect that has to be managed by the recycler, as legislation such as REACH will apply to the end article (Articles 7 or 33) and the recycler has a duty towards workers under OSH legislation. The recycler can collect information from the first life cycle if there is good access to the producers and they are willing to provide information on substance composition; if this is not possible, the recycler will need to test the material to define it. By this process of careful assessment, he can ensure that various product requirements are met and that the substance or the mixture he places on the market can be used in products again (as indicated in the criteria for the end of waste in Article 6 of the Waste Framework Directive).

Another way to ensure a high level of protection and high quality of the recycled substances or mixtures can be obtained by the definition of “End of Waste criteria” as foreseen by Article 6 of the

Waste Framework Directive. Discussions regarding some wastes (glass, aluminium scrap, plastics) have shown that this process can be very complicated. If well defined material is in the scope of the end of waste criteria, it might be appropriate to define specific requirements for certain assumed presence hazardous substances (as the case for more or less closed loops of material), regardless of the waste is classified as hazardous waste or not²². The exclusion of hazardous waste or requirements by recyclers that an end of waste material may not be classified as hazardous according to CLP poses a significant barrier for recycling; acceptability of the recycling of such materials may need to be based on a range of factors, including economic, environmental, health and socio-economic.

²² Given the different approach for waste classification there can be absolute non hazardous waste streams that still do contain hazardous substances, leading to a classification under CLP if the material reaches the end of waste status being a mixture and not an article.

3 Evaluation

The aim of classifying a waste as hazardous is to prevent damage to human health and the environment. Therefore, the link to the CLP system is considered to be effective, as it covers (most) of the hazards one could expect from a waste with regard to toxicity/ecotoxicity. This approach is, however, only applied in addition to the LoW. This takes account of the heterogeneity of wastes and the lack of detailed information on the composition of wastes and hence facilitates work for the waste operators. Whether or not wastes with absolute classifications in the list of waste are classified in full coherence with the classification that would result from applying the CLP-based approach and the testing approach is something upon which it is not possible to conclude in general terms.

The use of the CLP hazard categories for classifying wastes as hazardous is regarded as being relevant as waste can be considered as a mixture of substances (in different types of matrices) which could be released during waste treatment operations and hence expose humans and the environment. In order to ensure safety during the waste stage, the provision of relevant information to the operators is necessary. In particular where wastes are input materials to recycling and recovery processes, the current waste classification system does not ensure a sufficient information flow that could enable classification of the generated product (substance/mixture). On the other hand, it is quite challenging for waste handlers to classify articles (and materials which are constituted by complex matrices) when they become waste by using mixture related approaches. Often substance information is lacking for the individual materials in several parts of the article and hazardous substances are not equally located across the article as it would be the case in mixtures.

The classification systems of CLP and waste are deemed to be coherent regarding the types of hazards and the methods to identify if a hazard applies (i.e. assessment of components or testing). The systems are not coherent with regard to all of the criteria as to when one of the hazards applies (limit values, summation etc.). The waste classification and the CLP classification systems are not coherent in the way they are implemented. As CLP is a regulation, all requirements are implemented automatically in all Member States. The Waste Frame Work Directive needs national implementation leading to the interpretation of the hazardousness of waste based on its origin (application of LoW entries) or the interpretation of HP criteria.

**Case Study 13: Linkages between CLP and
Seveso III Directive, including risk management
under Seveso III**

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1 Introduction

1.1 Aim of the Seveso Directive and its overall role in the chemicals legislation framework

The first Seveso Directive was introduced in the EU as a reaction to major accidents involving chemicals in industrial establishments. It was established as far back as 1982 and was a blueprint for numerous pieces of legislation including an international framework for major accidents under the supervision of the United Nations¹. Since then, Seveso has been updated twice. The current version is the so-called Seveso III Directive (Directive 2012/18/EU²). The general aims of the Seveso Directive are to prevent major accidents in industrial establishments where chemical substances are handled and to limit the consequences of an accident if an event occurs (although prevention measures have been established). All contacted stakeholders acknowledge its benefits. Criticism is limited only to specific parts of the Directive. These aspects are discussed and documented in this case study. Firstly, a short general description of some of the main instruments and mechanisms is provided.

In contrast to other pieces of EU legislation, the application of Seveso does not result in the automatic application of a certain risk management measure. There is no mechanism that defines an immediate consequence e.g. “if a certain substance is in use, the establishment must have a...”. Instead, it defines criteria that identify when establishments must undergo the procedures set out in the Directive. It provides a set of measures that are dedicated to facilitating a risk assessment, focusing specifically on potential major accidents (prevention and reaction) involving operators and on the establishment itself but, additionally, including an assessment of the surrounding area, as well as of the infrastructure at a local and, potentially, regional level (e.g. a river basin).

The risk assessment under Seveso can make use of other risk assessments performed under different pieces of legislation, e.g. communicated under Regulation EC No. 1907/2006 (REACH³), the management of occupational health issues under the workers directive or the prevention of emissions if an installation is a plant that falls under the Industrial Emission Directive (IED). Risk management measures (RMM) established due to these legal frameworks may already feed into the Seveso assessment process and contribute to a situation that establishes a high level of protection against major accidents. This may even result in situations where no further measures on the level of the establishment are necessary. The perspective of the Seveso Directive is, however, broader and includes a regional perspective taking account of interactions between the establishment, the surrounding environment and coordination with the external emergency reaction organisation (including the local authorities, police, fire brigade, etc.)

¹ United Nations Economic Commission for Europe: Convention on the Transboundary Effects of Industrial Accidents <http://www.unece.org/env/teia.html>

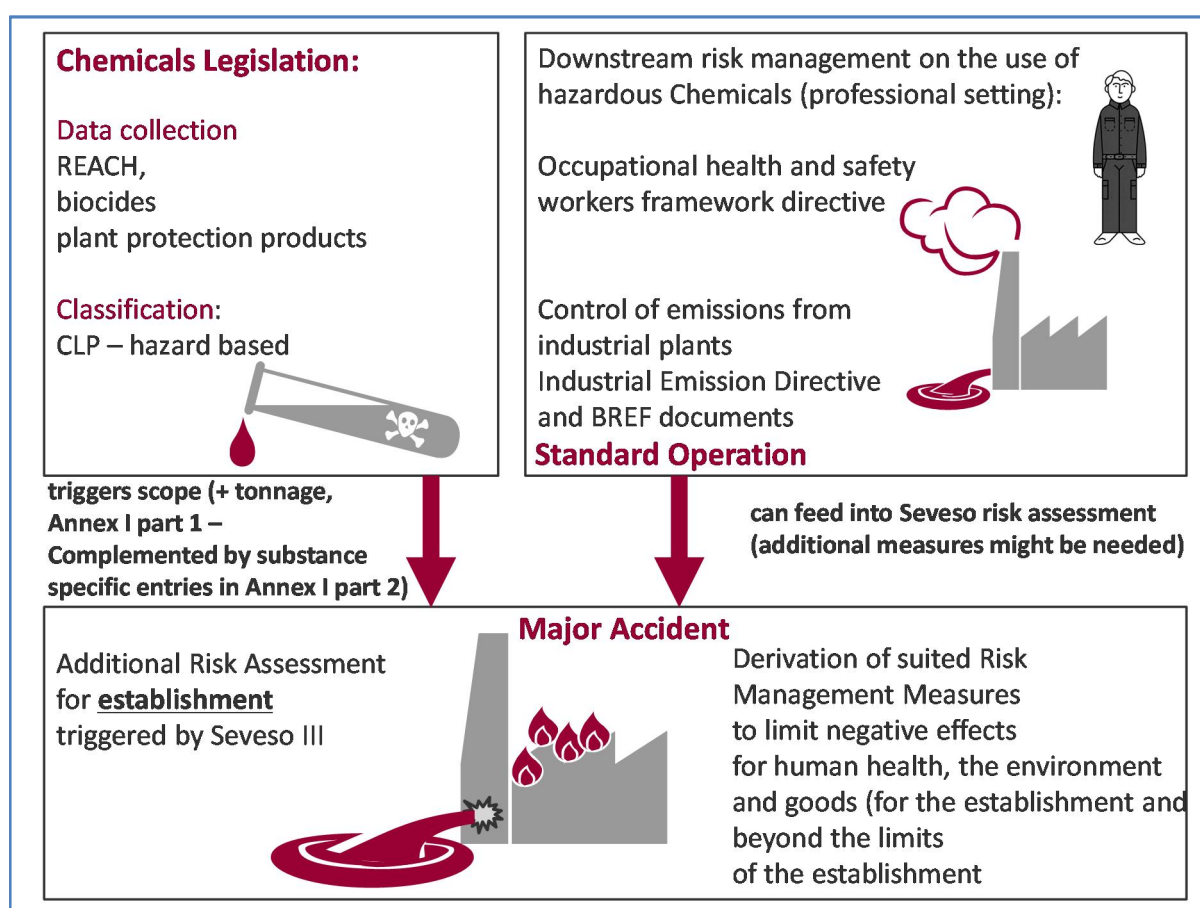
² OJ L 197, 24.7.2012, p. 1–37,
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:197:0001:0037:en:PDF>

³ Registration Evaluation and Authorisation of Chemicals.

Since the early 1980s the definition of the scope of the Seveso Directive was operationalised in two ways:

1. Generic inclusion in the scope of the Seveso Directive: The classification of handled substances in combination with the handled amount defines whether an establishment comes under the scope of the Seveso Directive; and
2. Specific inclusion in the scope of the Seveso Directive: Specific substances that have been identified as having the potential to cause a major accident, or respectively, cause major damage in an accident not necessarily caused by the substances themselves, in combination with a handled amount that is seen as relevant, may result in an establishment coming in scope.

The following picture shows the main regulatory fields that influence the scope and the risk assessment performed under Seveso III.



The EU-framework of chemicals legislation for assessing and managing the risks that occur from the use of chemicals is based on various pieces of legislation. Some of these such as REACH, the Biocidal Products Regulation or the Plant Protection Products Regulation trigger data collection on the hazardous properties of the substances that fall under their respective scope. CLP⁴ (Regulation (EC) No. 1272/2008) implements a system to categorise the hazardous properties of substances and mixtures and provides a standardised communication system on hazards. It categorises hazards by hazard class and includes standard phrases for their communication (H-statements). It also includes

⁴ Classification, Labelling and Packaging.

a standard communication with regard to the safe handling of substances and mixtures via the precautionary statements (P-statements). The CLP system thereby already provides very generic information on risk management measures for safe use, storage and disposal of substances and mixtures but also in case of accidental exposure of humans or accidents at sites where chemicals are used.

This case study focuses in particular on the links between CLP and other downstream legislation. A range of legislation relates to the safe use of chemicals at industrial sites, including Occupational Health and Safety and REACH. This legislation is also complemented by the Industrial Emissions Directive (IED) which focuses on emissions to the environment through the implementation of best practice in industrial processes with regard to pollutants, therefore ensuring a high level of protection of the environment. Under IED this is, amongst others, achieved through application of technologies described in reference documents (BREFs⁵) which in addition to preventing emissions might also provide specific measures that at the same time contribute to achieving safe risk levels.

It should be noted that the scope of the Seveso III Directive and the IED are not identical. An establishment falls under the Seveso Directive if specific named substances or substances belonging to a certain hazard category (based on their classification according to CLP) are present above a specified tonnage (the so called “qualifying quantities”). These substances and categories, as well as the qualifying quantities, are included in the Directive’s Annex I. In these cases, risks have to be assessed and appropriate risk management measures have to be implemented. These include, for example, the Major-Accident Prevention Policy (MAPP), a safety report or the tasks to be carried out by Member State authorities for land use planning. Under IED, it is basically the result of the type of establishment and the presence of a substance in certain tonnages is a secondary consideration. Whilst not all Seveso establishments fall under the scope of IED (and vice versa), this does not prevent operators from using relevant aspects of BREFs.

1.2 Case study objectives

The Seveso Directive was updated in 2012. Amongst other modifications, this update aligned its Annex I to CLP⁶. This was necessary because there had been a transition from the former system for classifying substances and mixtures established by Directive 67/458/EEC (for substances - DSD) and Directive 1999/45/EC (for mixtures – DPD). The transition period lasted from the entry into force of CLP on 20 January 2009 to the final repeal of both Directives on 1 June 2015⁷.

Studies were commissioned in the EU to assess:

1. The effects of the proposed GHS Regulation of CLP on downstream legislation⁸; and
2. The impacts of the revision of the SEVESO Directive, e.g. described in a Commission staff working document⁹.

⁵ Best Available Techniques Reference Document, c.f. JRC website under <http://eippcb.jrc.ec.europa.eu/reference/>

⁶ Transition from Seveso II [Directive 96/82/EC](#) to Seveso III [Directive 2012/18/EU](#)

⁷ The Seveso II directive was also repealed by that date.

⁸ Analysis of the Potential Effects of the Proposed GHS Regulation on Its EU Downstream Legislation (DG Enterprise) and Addendum (Commission Services, August 2006) <http://ec.europa.eu/DocsRoom/documents/11827/attachments/9/translations/en/renditions/native>

Both studies predicted a rather limited effect due to the implementation of the changes at the present time, and there is currently no clear indication that there will be significant impacts with regard to the system implemented by Annex I of Seveso III¹⁰. Nevertheless, it is acknowledged that, at an individual level, companies might change their Seveso-site status (either becoming or no longer being subject to Seveso) as a result of the modified classification system under the CLP and the direct link between CLP and Seveso III.

This case study, therefore, focuses on the link between hazard classification under CLP and the mechanisms included under Seveso, to demonstrate the individual impact at the level of single establishments or substances. This requires an understanding of the mechanisms of change in the classifications under CLP that trigger impacts under Seveso. The case study also includes some reflections on Article 4 of the Seveso III directive, including the mechanism used to exclude substances from the scope of Seveso III, because this is often criticised by stakeholders for being ineffective (including stakeholders contacted in connection with this case study).

The key questions addressed by the case study are:

- What is the role of Seveso in the broader EU RMM framework, i.e. to what extent is it coherent with the framework (overlaps, gaps, inconsistencies) and what are the best practice lessons that could be learned from its approach?
- What risk management measures apply under CLP (communication via a label and safety data sheet) compared to those that apply under Seveso III; in other words, what communication is required under Seveso and how does this communication fit with/provide added value to the system of communication required in the chemicals legislative framework?
- What are the links between CLP and Seveso and what consequences could arise from these links? Key questions include: what consequences does a change in the classification of a substance (e.g. by a CLH) trigger under Seveso; what mechanisms characterise the process, and how do these vary compared to other legislation?

Examples are used in this case study for purely illustrative purposes, for instance, to describe the consequences triggered by a new or revised CLH or the consequence of using a generic entry in Part 1 of Annex I of Seveso III or a specific entry according to Part 2. The clarity of the roles and obligations of the various actors subject to the Directive are also detailed. This additionally includes an analysis of the provisions of Article 4 under Seveso and the consequences of such an exemption with regard to the example substances.

⁹ Commission Staff Working Paper Impact Assessment Accompanying document to the Proposal for a Directive of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances COM(2010) 781 final SEC(2010) 1591 final, /* SEC/2010/1590 final */ <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52010SC1590>

¹⁰ Based on information from the Commission, the reassessment of various establishments to determine whether they should fall within the scope of Seveso III led to the observation that many should already have been treated under Seveso II, but had not been identified as such. Hence, the potential increase in Seveso establishments might also be partly caused by this effect.

1.3 Methodology

The case study draws on desk research and stakeholder consultation, mainly via targeted interviews with an (unrepresentative) group of stakeholders as listed in Table 1-1. The desk research is based on a legal analysis and a review of the relevant literature. This is used to briefly describe the elements that define the scope of the Seveso III Directive with regard to the consequences of changed classifications and the additional risk management measures required as a result. This includes procedures to assess and communicate hazards and risks as well as to implement RMMs.

Table 1-1: Stakeholder interviews	
Institution	Type
European Commission (DG Environment)	Regulator
European Chemical Industry Council (Conseil Européen des Fédérations de l'Industrie Chimique – Cefic)	Stakeholder group (Industry association)
Association Européenne des Métaux (Eurometaux)	Stakeholder group (Industry association)
CONCAWE	Stakeholder group (Industry association)
CEPE	Stakeholder group (Industry association)
German Environment Agency (UBA)	National authority
Danish Environmental Protection Agency	National authority
UEAPME	Industry association
European Environmental Bureau (EEB)	Stakeholder group (NGO)
NGO representative	Stakeholder group (NGO)

2 Detailed Description of the Issues

2.1 Changes introduced under Seveso III

The overall structure and principles of how the Directive works have been in place since Seveso I was established in 1982. They were affirmed by the introduction of the Seveso II Directive in 1996. This was subsequently amended in 2003. Seveso III was eventually adopted in 2012 and became fully applicable in 2015. These changes were accompanied by the usual processes of evaluation and assessment of impacts taking into account, amongst other things, socio-economic considerations and changes in EU legislation on the classification of chemicals.

The main changes from Seveso II to Seveso III, which are relevant for this case study, relate to Annex I which affects the establishments that are included in the scope of the Directive. Annex I of the Seveso III Directive is in part based on CLP hazard categories. It was revised in line with the changes introduced by CLP¹¹, with no intention of extending its general scope on a systematic level; some extension and exclusion in scope could not be fully avoided, however, due to some of the structural changes introduced by CLP (see, for example, the first bullet point below). The changes with relevance to this case study concern in particular:

- **The classification of substances as T+, T and Xn** (very toxic, toxic and harmful) under the DSD does not map directly to the hazard categories acute toxic 1, 2 and 3 in CLP. Therefore, some of the substances concerned fall into different categories of acute toxicity, with a different qualifying quantity; this may lead to some establishments now falling within the scope, whilst others fall out of the scope or change from upper-tier to lower-tier and vice versa¹²;
- **The addition of the new hazard class of specific target organ toxicity (single exposure), STOT SE, category 1.** The endpoints that qualify a substance as STOT SE have been established as a new category under CLP. The same endpoints were previously already covered under the categories of T+, T criteria in the DSD. However, some substances formerly included under “toxic” are now excluded through the removal of STOT RE 1¹³. It is not quite clear how the introduction of the various STOT categories influences the determination of the Seveso III status, but it can be assumed that some substances will extend the scope of Seveso (new substances are identified under CLP), while other establishments which were previously included are no longer covered by Seveso III because of STOT RE 1;
- **Changes in the definition of flammable liquids** (different flash points). This may lead to re-classification and different qualifying quantities (QQs¹⁴) being applicable;

¹¹ Information in this section was derived from analysis of the Seveso III Directive and the publication: Wilday J., Fraser S., Fullam B., Ashcroft S., and McCann R., ‘Estimating possible impact of the Seveso III Directive for the UK to inform negotiation and implementation; in Symposium Series No 159.

¹² The Convention on the Transboundary Effects of Industrial Accidents was also adapted to the GHS system for these specific endpoints by a decision at the 8th meeting conference of parties in December 2014 <http://www.unece.org/env/teia/cop8.html#/>

¹³ Covered T R48/23, R48/24, R48/25. A search in the classification and labelling inventory delivered 273 substances that show a harmonised classification for STOT RE 1. Nine substances are classified as STOT SE 1 (harmonised).

¹⁴ For this case study the QQs are referred to as the “threshold” which is the more commonly used term in the context of Seveso.

- **Changes in classification of environmentally hazardous substances** due to different classification methods for mixtures under the CLP Regulation. This may lead to re-classification and different thresholds being applicable; and
- **Additional substances are included in the list of named substances**, which includes substances to which different thresholds apply (either higher or lower) than those that would normally apply according to their generic classification under Part 1. The reason for including many of those substances was to avoid too many changes in the scope of the Seveso III Directive as compared to the former version.

An impact assessment regarding the introduction of Seveso III concluded that this introduction might not lead to an overall increase in the number of establishments affected. While some establishments (342 or +3.4 %) might newly fall under the scope of the Directive due to the different system, others that were previously included might now be excluded (415 or -4.1 %) because some substances might be classified less strictly under CLP. As the Seveso III Directive is still in the process of transposition in many Member States (including large Member States such as Germany), this case study will not consider the impacts of the new Directive on the number of sites affected in detail. If such effects are reported by stakeholders, these will nevertheless be noted in the report to provide a contribution to possible future assessment activities.

In addition, Article 4 of the Seveso III Directive was introduced to allow the exclusion of substances from its scope after assessment at EU level, if it can be proven that a substance cannot cause an accident or add to an accident's severity. In particular, Article 4 was introduced to be able to respond to unwanted effects from the alignment with CLP and subsequent changes to later regulation (see recital 11 of Seveso III). One of the aims in aligning Seveso III with CLP was to maintain or increase the level of protection (recital 9). This resulted in the intention to establish a 1:1 translation from the old system of chemicals classification to CLP to keep the general scope of the Directive.

Further changes introduced by Seveso III include:

- Strengthening citizens' rights on access to information, justice and participation in decision-making;
- Improving the way information is collected, managed, made available and shared;
- Introducing stricter standards for inspections, ensuring a more effective implementation and enforcement; and
- Clarifying and updating of provisions, including streamlining and simplification to reduce the administrative burden.

2.2 Role of Seveso in the broader EU RMM framework

The Seveso Directive was introduced in 1982 as a reaction to several large accidents, with the aim of preventing major accidents which involve dangerous substances and, if they cannot be prevented, to limit their consequences for human health and the environment. From the beginning, the common link with other parts of chemicals legislation was defined by the hazardous properties that are present in establishments. Annex I of the Seveso III Directive contains a list of hazard categories that trigger the inclusion of an establishment in the scope of the Directive. While CLP is exclusively based on the hazard posed by substances and mixtures, Seveso contains various elements that are risk based. The way in which these elements influence the scope of Seveso III is demonstrated by some examples below.

It is always important to keep in mind that the scenario to be handled by Seveso is not the “business as usual” but the major accident scenario. As a result, operators of such establishments are obliged to conduct the relevant risk analysis to identify and implement the appropriate risk management measures. Member States shall ensure that operators take necessary measures to prevent major accidents and to limit their consequences for human health and the environment, and that they document their efforts (Article 5) including:

- Notification of all concerned establishments (Article 7);
- Deploying a major accident prevention policy (Article 8);
- Producing a safety report for upper-tier establishments (Article 10);
- Producing internal emergency plans for upper tier establishments (Article 12); and
- Providing information in the event of accidents (Article 16).

Other relevant tasks, including communication to the public and coordination of affected industrial sites (land use planning and domino effects), are mandated as the responsibility of the Member States. Obligations for authorities comprise:

- Producing external emergency plans for upper tier establishments (Article 12);
- Deploying land-use planning for the siting of establishments (Article 13);
- Making relevant information publically available (Article 14);
- Ensuring that any necessary action is taken after an accident including emergency measures, actions to ensure that the operator takes any necessary remedial measures and informing the persons likely to be affected (Article 17);
- Reporting accidents to the Commission (Article 18);
- Prohibiting the unlawful use or operation of establishments (Article 19); and
- Conducting inspections (Article 20).

Additionally there are some rights for citizens defined by Seveso:

- The public concerned needs to be consulted and involved in the decision making for specific individual projects (Article 15);
- Subject to the conditions outlined, Member State authorities need to make available any information held pursuant to the Seveso Directive (Articles 14 and 22); and
- Access to justice needs to be granted on the cases listed in Article 23.

Through these different tasks and provisions, Seveso sets up a system that ensures the prevention of major accidents within an establishment and sets out risk assessment obligations along with specific measures that need to be derived. It additionally extends the system beyond the level of individual establishments, enables Member States to implement measures at a regional level and takes into account neighbouring installations, infrastructure and environmental conditions (rivers, etc.).

As noted earlier, sites fall into the scope of the Seveso III Directive based on:

- a. Specific hazards (Annex I part 1 and note 5); and/or
- b. Specific substances (Annex I part 2).

The substances that are addressed by Annex I are either those that may cause a major accident (e.g. explosives (section P1a/b), pyrophoric substances (section P7) or ammonium nitrate), or intensify accidents like fires or explosions (e.g. flammable substances (several categories from section P) or oxygen). Other categories of substances (groups) do not contribute to the accident itself but cause

major effects upon release during an event such as a flood or a release (leakage). Examples of such hazard categories include acute toxicity (section H) and ecotoxicity (section E). Some substances with specific hazards, such as carcinogenicity, are specifically named (entry 33 part 2).

2.3 Elements of risk assessment for operators of establishments under Seveso III

2.3.1 Notification of Establishments

Operators of establishments have the obligation to assess whether or not they fall under the scope of Seveso III, and if so, to inform the Member State authority. This notification covers information on the establishment (location, responsible persons, substances that lead to the classification as Seveso establishment). It furthermore requires the operator to inform all establishments that could be affected in the case of an accident or even are likely to interact with the establishment and increase the effect of a major accident, even though these establishments are not covered by the scope of Seveso III. Significant changes in the tonnage of substances handled in an establishment are also reason for notification (in advance before any changes occur).

2.3.2 Major Accident Prevention Policy

Both lower-tier and upper-tier establishments are to develop a Major Accident Prevention Policy (MAPP) according to Article 8 of the Directive, including a description of management's roles and responsibilities and the company's commitment towards the continuous improvement of accident prevention measures. The MAPP can be seen as an organisational measure and requirements to submit a MAPP or not to the relevant authorities is regulated via national law. The MAPP has to be updated at regular review periods no more than five years apart, so continuous revisions are foreseen.

Article 8.5 specifies that the MAPP should be implemented by “[...] *means, structures and by a safety management system*” which should be appropriate with regard to the type and extent of accident risk and the complexity of the organisation. Whereas upper-tier establishments need to follow Annex III with regard to their safety management system, lower-tier establishments need only take the respective principles into account.

2.3.3 Safety management system

Establishments need to implement a safety management system in accordance with Annex III of the Directive, which sets out the areas the system should cover such as identification of hazards, operational control, monitoring of performance etc. No specific methods and tools are recommended and existing systems can be used but the general management system principles are provided in relation to the prevention and management of accidents. Lower tier establishments may also use other appropriate means to ensure measures are implemented, but basically the principles of Annex III should also be taken into consideration.

The analysis of accident risks includes the development of major accident scenarios, the assessment of their probability under conditions of normal and abnormal operation, as well as an assessment of possible accident causes and their interrelations. Furthermore, the likely impacts in terms of substance emissions and their distribution within the establishment, the (neighbouring) establishments and the environment are to be identified.

2.3.4 Safety report

Upper-tier establishments are to submit a safety report to the competent authorities, in accordance with Annex II, which identifies all relevant activities taken. It should document the implementation of the MAPP and the safety management system. Furthermore, it should also document that major accident hazards and possible major accident scenarios have been identified and necessary measures have been taken to ensure prevention and limitation of the consequences of such accidents. It also provides information that demonstrates that the establishment is adequately set up with regard to standard operation, maintenance and technical infrastructure. It further documents that an internal emergency plan has been drawn up and provides additional relevant information to the authorities to draw up an external emergency plan and inform public authorities sufficiently, so they can decide, for example, on the siting of new activities or developments around existing establishments.

One aim of CLP is to categorise chemical substances and mixtures according to their hazards and to inform users of the presence of these hazards. Beyond the information on hazards, it also provides information on risk management of these hazards via the precautionary statements. According to Article 2 of CLP these are defined as:

“...“precautionary statement” means a phrase that describes recommended measure(s) to minimise or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use or disposal;...”

These cover general measures and measures for prevention of unintended exposure, in case of an incident with the chemicals (reaction) during storage and with regard to waste treatment. Some of the precautionary statements address situations that can be linked to unintended situations and are assigned to categories addressed under CLP which may be covered by Seveso III as well. As a consequence of REACH Article 34¹⁵, these general precautionary statements should trigger an implementation step at the recipient's site. This is complemented by further refinement and follow-up measures under the Seveso III Directive. Additional specific measures have to be drawn-up and implemented. An indication of risk management with regard to accidents is given for the hazard categories set out in Annex I of Seveso III below.

2.3.5 Internal Emergency plan

All upper-tier establishments are to draw up internal emergency plans and supply Member State competent authorities with sufficient information for them to draw up external emergency plans. Emergency plans include information on the actions to be taken in the event that a major accident actually occurs; in particular it specifies that the following objectives shall be covered:

- Containment and control of incidents so as to minimise the effects and limit damage to human health, the environment and property;
- Implementation of measures to protect humans and the environment from the effects of an incident;
- Communication of necessary information to the relevant authorities and the general public; and
- Plans to restore and clean-up the environment following a major accident.

¹⁵ Article 34 of REACH obliges the downstream user to assess and apply the information received with the safety data sheet – this includes the precautionary statements.

2.4 Impacts of classification changes and listing in Annex I

2.4.1 Overview of potential impacts

Prior to placing a substance or a mixture on the market, Article 4 of CLP obliges manufacturers, importers and downstream users to classify the respective substance or mixtures according to Annex I of CLP. Some classified substances and mixtures fall under one or more of the hazard categories listed in Annex I of the Seveso III Directive. If the sum (of the amounts) exceeds the threshold for at least one of the categories in Annex I of Seveso III, the establishment falls under the scope of the Seveso III Directive.

Classifications based on Article 4 of CLP are the so-called “self-classifications” and are conducted by the operator placing the substance or mixture on the market. In addition, Articles 36 to 38 of CLP set out the process called “harmonised classification and labelling”. As this process results in a legally defined classification, it is binding for the substance and the respective hazard category. Harmonised classifications for industrial chemicals normally exist for:

- Respiratory sensitisation Cat.1;
- Germ cell mutagenicity Cat 1a, 1b or 2;
- Carcinogenicity Cat 1a, 1b or 2; and
- Reproductive toxicity.

Additionally, active substances used in biocidal and plant protection products undergo harmonised classification for all categories. If there is a need, classification for categories other than those listed above for substances that are not active substances is possible on a case-by-case basis. Hence, harmonised classifications are also possible for categories mentioned in Annex I of Seveso III.

Harmonised classifications for substances are listed in Annex VI of CLP. Hazards that are not included in the legally harmonised part of a substance classification need a self-classification for all other hazard categories; in other words, just because a hazard is not listed in Annex VI of CLP, a substance may still be self-classified for that hazard and suppliers must ensure that all appropriate classifications are assigned.

The classification of a substance may change over time, e.g. when new data is available for the substance (e.g. from the data generation process under REACH) or classifications are based on the weight of evidence and data undergo a new evaluation. According to Article 15 of CLP, manufacturers, importers and downstream users need to implement proportionate measures to inform themselves of new scientific evidence that may result in the re-classification of substances.

Classifications may also change due to alterations in the classification system or its rules, as occurred with the move from the DSD and DPD to CLP, when the limits between the categories of acute toxicity changed. Any subsequent changes in classifications (e.g. substances no longer being classified for the higher category of acute toxicity) could have been due to the new system rather than a change in hazard data.

Other examples of the impact of a change in the classification system are the changes implemented for the category “hazardous to the aquatic environment chronic category 1”. When CLP initially entered into force, M-factors for highly toxic substances were set by assessment of lethal concentration (LC)¹⁶ or effect concentration (EC₅₀)¹⁷ data. Commission Regulation (EU) No 487/2013

¹⁶ Lethal Concentration.

of 8 May 2013 introduced a change from these data to no observed effect concentration (NOEC)¹⁸ data, which establish a somewhat different approach. This could in turn lead to changes in the classification of mixtures even if the formulation has not been changed.

The new or changed classification of a substance, regardless of whether it is a harmonised classification or a self-classification, may have an influence on whether a piece of downstream legislation applies and which (specific) requirements are triggered under this legislation. Due to the close relationship between substance and mixture classifications, and the number of pieces of downstream legislation that have a direct link to the hazard categories of CLP, users of substances need to continuously monitor if they fall under the scope of downstream legislation or not, regardless of the type of change in classification.

In relation to the Seveso III Directive, several situations can be distinguished regarding the impacts of classification on the applicability and types of obligations triggered by the Directive. These situations are outlined below and elaborated further in the following sub-sections:

1. Substances or mixtures which have not been classified in a relevant hazard category¹⁹ are **newly classified** for at least one of the relevant hazard categories, e.g. because new data are available. This could result in the Seveso III Directive being applicable to establishments, where the substances/mixtures are present at least in quantities at the lower threshold²⁰.
2. The classification of substances or mixtures that have been classified in at least one relevant hazard category **change** to another **classification**. This may²¹ result in a change of thresholds determining the tier of the establishment (upper-tier threshold) or the coverage of the directive in general (lower-tier threshold):
 - A stricter classification may result in an establishment being newly covered or moving from a lower-tier to an upper-tier establishment;
 - A less stringent classification may result in an establishment falling out of scope or changing from an upper-tier to a lower-tier establishment;
 - Changes in classification would also have to be considered when determining hazard types using the summation method to derive the overall risk of the establishment associated with health, physical or environmental hazards. The changes may cause changes in coverage and in the tier of the establishments or “level each other out”, i.e. if some substances are classified more stringently and others less stringently.
3. The classification criteria for a hazard class/hazard category change resulting in a number of substances changing their classification; the consequences are the same as for point 2; however, this is most likely with a clear direction towards more or less stringent classification.

¹⁷ Effect concentration.

¹⁸ No Observed Effect Concentration.

¹⁹ Relevant hazard categories are those listed in Annex I, part I of the Seveso III Directive.

²⁰ If the sum of substances / mixtures within one hazard type (human health, environment, physical chemical) is calculated, a new substance coming into the scope or changing the hazard category would also impact the result (c.f. Assessment Step 3 in Section **Error! Reference source not found.**).

²¹ An exception is classification for acute oral toxicity in cases where no information is available via the inhalation exposure route (c.f. hazard categories of acute toxicity category 2 and 3 and Note 7 of Annex I).

2.5 Existing mechanisms to minimise unintended impacts under Seveso as a result of CLP classification changes

2.5.1 Overview

This section discusses the flexibility of the mechanisms in CLP and Seveso to deal with the impact of classification changes and minimise effects if justified.

2.5.2 Consideration of downstream impacts in classification

The following text provides an example of how analysis and availability of data during the classification process can minimise unintended impacts in downstream legislation. The substance used to provide an example is nitric acid (see Box 2-1 overleaf). The intention of this example is to show the effect of classification changes on Seveso III establishments.

Background

Oxidising Liquids category 3, as nitric acid, is a category of Annex I of Seveso III with a lower-tier threshold of 50 tonnes and an upper-tier threshold of 200 tonnes. Corrosiveness is not a category of Seveso III and, therefore, is not relevant to the definition of the scope under Seveso.

Besides the classification of the pure substance, the harmonised classification includes specific concentration limits for the classification of mixtures. The concentration limit of 65% results in a situation where mixtures only need to be considered for Seveso III if they exceed this concentration.

Based only on the hazard category “Oxidising Liquid”, a change from category 3 to 2 would not result in a change in terms of nitric acid falling under the scope of Seveso because “oxidising liquids” in categories 2 and/or 3 are covered by the same Seveso category. The concentration limit would also have no effect on Seveso obligations.

Classification as acute toxic, category 1, instead of skin corrosive, however, would result in a situation where a second category of Seveso III Annex I was applicable. This category has a lower tier threshold of only 5 tonnes and an upper-tier threshold of 20 tonnes. Consequently, a lower threshold results in an establishment being considered as lower-tier. This would have the following consequences:

- Establishments that were previously lower tier plants could change their status and become higher-tier; and
- Several establishments that were not previously covered by Seveso could now fall within its scope.

Note that the classification change alone is insufficient to change the status of the establishment under Seveso III. For a change in status to occur, the classification change needs to be accompanied by a change in the lowest threshold. If a classification change in a hazard category does not lead to a change in the lowest limit, it will not affect the status of the establishment.

Since an official conclusion on this issue is still outstanding, it is impossible to assess the final impact. As the new data have shown that mixtures of nitric acid with less than a 70% concentration will most likely only be classified as acute toxic category 3a, a significantly smaller number of establishments would be affected by the change than indicated in the initial proposal. This newly added category

Box 2-1: Classification of Nitric Acid and proposed changes

1. Nitric Acid was included in Annex VI of CLP with the following classifications:

- Ox. Liq. 3
- Skin Corr. 1A

2. Original classification of Nitric acid:

- Skin Corr. 1A; H314: $C \geq 20\%$ and Skin Corr. 1B; H314: $5\% \leq C < 20\%$
- Ox. Liq. 3; H272: $C \geq 65\%$

3. In the harmonised classification and labelling process (CLH), the following classification was proposed^a:

- Ox. Liq. 2
- Acute Tox. 1
- Skin Corr. 1A

Accompanied by the following specific concentration limits:

- Ox. Liq. 2; H272: $C \geq 99\%$, Ox. Liq. 3; H272: $99\% > C \geq 65\%$
- Skin Corr. 1A; H314: $C \geq 20\%$ and Skin Corr. 1B; H314: $5\% \leq C < 20\%$

4. Following the proposal for harmonised classification described above, industry stakeholders generated and provided new data resulting in a new proposal^b:

- Nitric acid ...% ($C \leq 70\%$)
 - Ox. Liq. 3, H272: $C \geq 65\%$
 - Acute Tox. 3, H331
 - Skin Corr. 1A, H314: $C \geq 20\%$ and Skin Corr. 1B, H314: $5\% \leq C < 20\%$
 - EUH071
- Nitric acid ...% ($C > 70\%$)
 - Ox. Liq. 2, H272: $C \geq 99\%$ and Ox. Liq. 3, H272: $99\% > C$
 - Acute Tox. 1, H330
 - Skin Corr. 1A, H314
 - EUH071

Notes:

^aSee also the ECHA database of submitted harmonised classification and labelling intentions <https://echa.europa.eu/registry-of-submitted-harmonised-classification-and-labelling-intentions/-/substance-rev/12703/term>

^bCurrently under revision as submitted proposal <http://echa.europa.eu/registry-of-submitted-harmonised-classification-and-labelling-intentions/-/substance-rev/12703/term>

(acute toxic 3) has the same upper- and lower-tier thresholds as oxidising liquids which are already applicable under current classification rules. The changes in the tier threshold would therefore only affect companies that handle nitric acid with a higher concentration (i.e. $>70\%$). While nitric acid in concentrations below 70% is widely used across many industry sectors, use of highly concentrated nitric acid is less common and more likely to occur in industry sectors that are already expected to be subject to the Seveso Directive. Should the proposal for re-classification pass, the number of establishments that would newly fall under the scope of the Seveso Directive is therefore likely to be limited.

Conclusion

Under CLP, differentiation between the different “severity/severities of hazards” of a substance, e.g. as a result of concentrations or physical states, is possible if respective data are available. The nitric acid example shows that it can be useful to provide more specific data on mixtures. These can justify an allocation to different hazard categories that might result in a less stringent risk level under the downstream legislation and therefore be an approach to limit the effects of the downstream

legislation. It should be noted that this does not lead to a weakening of Seveso III but follows the stringent approach to combine hazard and tonnage to defined and agreed risk levels. The opposite outcome to that in the nitric acid example could also apply. New data can also cause more stringent classifications and therefore increase the risk level that needs to be applied.

It should be noted that the generation of new data under CLP is possible but has to be performed in accordance with Articles 7 and 8 of the CLP Regulation that restrict the performance of animal tests and allow the conducting of new tests only as last resort if no other sources can be identified.

2.5.3 Listing of substances in Annex I Part 2

With Part 2 of Annex I, the Seveso Directive already includes an instrument that considers specific risk considerations in relation to certain substances or substance groups. The following (hypothetical) example is intended to demonstrate the different uses of Parts 1 and 2 of Annex I of Seveso III. Part 2 of Annex I provides the option to be more specific for substances/groups of substances that have a higher or a lower risk potential compared to using the relevant generic category of Part 1.

Background

When a substance is listed in Part 2 of Annex I as a “*named dangerous substance*”, the relevant qualifying quantities are applied regardless of whether or not another category based on its generic hazard classification (Seveso III, Annex I Part 1) would be applicable to the named substance. For example, in the case of “petroleum products” the thresholds in the specific parts of Seveso III are 2,500 and 25,000 tonnes for the lower and the upper tier establishments respectively. This is true regardless of which qualifying quantities are higher. To show what the effect would be if no specific entry was included for petroleum substances, Table 2-1 (overleaf) demonstrates the effect of the application of the generic threshold to diesel fuel.

When CLP was introduced into Seveso, the categories in Part 1 of Annex I and the respective scope of the CLP categories remained the same. However, the qualifying quantities for environmental hazards were lowered (see Table 2-1). This generic approach would have meant that,

When the change to CLP was introduced, the respective aquatic chronic cat. 2 (H411) thresholds were lowered to 200 tonnes (representing 240 m³)²². These thresholds represent rather small tank establishments for such fuel. Applying the generic classification would thus result in a very high number of establishments falling within the scope of Seveso III. However, accidents within such small establishments are not likely to have a significant impact and so justify having a less stringent threshold. Due to such considerations, a specific entry for petroleum substances was introduced with a higher threshold. As mentioned earlier, the thresholds for the specific entry for petroleum substances including diesel are therefore 2,500 and 25 000 tonnes.

This mechanism can also be applied to substances that potentially pose a higher risk than displayed via the generic classification. Such specific entries are linked to thresholds that are below the ones that would be assigned by using the classification (e.g. arsenic pentoxide with 1 and 2 tonnes instead of 5 and 20 tonnes for a substance that is acute toxic Cat. 1).

²² Under Seveso II and DSD/DPD classification, an establishment with diesel tanks of 500 tonnes of diesel (or 600 m³)²² would have been included in the scope of Seveso II by R51/53 (lower tier).

Table 2-1: Classifications of diesel fuel under DSD and CLP and hypothetical generic connection to Seveso II and III

Hazard type	DSD category ²³	R-Phrase	Qualifying quantity [tonnage] Part 1 Annex I Seveso II (lower / upper)	CLP category ²⁴	H-Statement	Qualifying quantity [tonnage] Part 2 Annex I Seveso III (lower / upper)
Physical Hazards	None/ Flammable		- / - 5,000 / 50,000	None/ Flam. Liquid 3		- / - 5,000 / 50,000
Health Hazards	-	-	-	Acute Tox. 4	H332: Harmful if inhaled	Not included
	Irritant	R38: Irritating to skin	Not included	Skin Irrit. 2	H315: Causes skin irritation	Not included
	Harmful	R65: Harmful; may cause lung damage if swallowed	Not included	Asp. Tox. 1	H304: May be fatal if swallowed and enters airways	Not included
	-	-	-	Carc. 2	H351: Suspected of causing cancer	Not included
	-	-	-	STOT Rep. Exp. 2	H373: May cause damage to organs through prolonged or repeated exposure	Not included
Environmental hazards	Dangerous for the environment	R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment	500 / 2,000	Chronic Aquatic Toxicity Category 2	H411: Toxic to aquatic life with long lasting effects	200 / 500

²³ See CONCAWE (2012): Report no. 8/12, "Hazard classification and labelling of petroleum substances in the European Economic Area – 2012" page 75 ff. Available at: https://www.concawe.eu/uploads/files/Rpt_12-8-2012-05150-01-E.pdf

²⁴ ECHA Database of registered substances "Fuel Diesel" Registration Dossier (EC 270-676-1 <http://echa.europa.eu/registration-dossier/-/registered-dossier/15396/1>)

Conclusion

The example above shows the different tasks Parts 1 and 2 fulfil in the Seveso III context. While the generic Part 1 of Annex I ensures that substances that have relevant hazardous properties are automatically included in the scope of Seveso, a further assessment on the risk potential in Part 2 is used to adapt the specific risk level if needed and to minimise any unwanted consequences from the automated inclusion of substances by Part 1. Consequently, Part 2 of Annex I can be used to set qualifying quantities independently from the actual classification. This can be based on special risk or socio-economic considerations. The Seveso III Directive does not include criteria for addressing substances or substance groups in this part of the annex. The basis for such an entry can therefore be determined according to criteria that are more or less flexible but are based on, for example, the experiences with certain types of establishments and subject to political and stakeholder discussion. Nevertheless, sufficiently sound evidence would have to be provided for any proposed change as such amendments would be subject to an impact assessment.

Adaptation of Annex I according to Article 25²⁵ of Seveso III is not envisaged, because this might alter its scope which would require the involvement of Parliament. Hence, a formal initiative by the Commission would be needed to propose a new scope for the Seveso Directive if changes to Annex I of the Directive were envisaged. In conclusion, the process is formal but can be used to modify the unwanted impacts of classifications by including specific entries in order to be more or less restrictive on certain substances.

2.5.4 Exclusions from scope according to Article 4 of Seveso III and CLP

Background

As pointed out above, Article 4 was introduced into the Seveso III Directive in order to cope with the unintended effects of the introduction of the CLP by excluding substances from the scope of Seveso III. The stakeholders consulted for this case study (Member States and industry) thought that the Article was impractical in terms of excluding a substance within a reasonable time frame. The process was criticised for being too burdensome and time consuming. However, it should be mentioned that, up to now, no substance has actually undergone this process. Indeed, other options can be used to address the unwanted impacts of Seveso. For example, as shown by the discussion on petroleum above, Part 2 of Annex I can be used to limit the effect of an entry. It is therefore not possible to draw conclusions on the duration and effort required under Article 4. Nevertheless, the Article will be considered in more detail below.

The exclusion of substances via Article 4 of Seveso III is linked to several hazard and risk based preconditions:

[...]”a) a comprehensive list of properties necessary to assess the dangerous substance’s potential for causing physical, health or environmental harm;

(b) physical and chemical properties (for instance molecular mass, saturated vapour pressure, inherent toxicity, boiling point, reactivity, viscosity, solubility and other relevant properties);

²⁵ This Article only allows changes via delegating acts in the Annexes II to VI to adapt these to the technical progress und consideration of the process described in Article 26.

(c) health and physical hazard properties (for instance reactivity, flammability, toxicity together with additional factors such as mode of attack on the body, injury to fatality ratio, and long-term effects, and other properties as relevant);

(d) environmental hazard properties (for instance ecotoxicity, persistence, bio-accumulation, potential for long-range environmental transport, and other properties as relevant);

e) where available, the Union classification of the substance or mixture;

(f) information about substance-specific operating conditions (for instance temperature, pressure and other conditions as relevant) under which the dangerous substance is stored, used and/or may be present in the event of foreseeable abnormal operations or an accident such as fire.”

Article 4 allows the exclusion of a substance under the above mentioned conditions. The reference in Article 4 is to the substance which is subject to the assessment; specific uses of that substance cannot be excluded from the scope, even if those uses can be considered “safe” with regard to effects in a major-accident. However, Article 4 can also be used in a specific way by addressing the physical form, packaging or concentration ranges of the substance in mixtures/units. Limiting an application for exclusion to such parameters could simplify the whole assessment process.

The conditions for exclusion include the assessment of all hazardous properties, e.g. in this context Article 4 (3d):

“[...] environmental hazard properties (for instance ecotoxicity, persistence, bio accumulation, potential for long range transport, and other properties as relevant);”

It is worth noting that these properties already include issues that reach beyond the scope of the hazard assessment performed under CLP, as they are specific to the risk assessment related to major accidents. Long range transport²⁶, for example, is not a classification criterion under CLP. Therefore, it is clear that the condition for excluding a substance from the scope of Seveso III by using Article 4 does not require the absence of a classification endpoint to be demonstrated. Article 4 is additionally linked to the assessment of the operating conditions²⁷ that are applied to the substance in the processes that are performed in the respective establishments. Bearing in mind that a substance is either within or excluded from the scope as a result of Article 4, the absence of risks has to be shown for all uses under intended conditions and also under conditions that could arise upon the unintended release of the substance as a consequence of e.g. a fire (c.f. Article 4 (3f)).

To assist Member States with the application of Article 4 and to clarify the conditions necessary for the exclusion of a substance from the scope of Seveso, the Commission contracted a study (carried out by AMEC²⁸) to describe the potential ways to assess substances for the purpose of exclusion by

²⁶ Long range transport is the ability of a substance to be spread over long distances. This can be a substance property, e.g. mediated by its solubility or originate from external conditions like a major accident that has the potential make the substance become air or waterborne and thereby spread over long distances.

²⁷ This does not address one operator’s specific conditions but reflects the full range of conditions relevant for the substance.

²⁸ Corden C., Cherrier V., Calero J., Bolvin C., Lahoz A., Demeestere M., Lenoble C., Salvi O. (2014): ‘Development of an assessment methodology under Article 4 of Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (070307/2013/655473/ENV.C3), Overall project report – Final report. Available at: <https://circabc.europa.eu/w/browse/b0844827-b17d-4a1d-a1c3-34354e118de4>

Article 4. This study analysed the methods and tools available in the Member States to develop major accident scenarios, identify accident risks and model impacts from accidents. It also proposed elements of a potential assessment methodology to justify the exemption of substances from the scope of the Directive. The study concluded that the specific approaches are likely to be different for different substances and will require expert judgement. In addition, the modelling of the consequences of accidents appears complex due to the different types of environments across the Member States.

Conclusion

From a comparison of the mechanisms of CLP classification and Article 4 of Seveso, it can be concluded that the mechanism for exclusion from the scope of Seveso III based on Article 4 is completely different to CLP classification. Whereas CLP only addresses hazard, the scope of the assessment under Seveso is broader and more risk based arguments need to be considered to reflect the special task of the directive to handle major accidents. The use of CLP for declassification is possible if sufficient data are available on a certain endpoint, but declassification based on risk arguments is not appropriate and cannot be used in CLP. This is in line with the original task of CLP to classify substances and to provide information to the users of such chemicals. As described earlier, risk management measures are only a very limited part of CLP in the form of some precautionary statements. Real risk assessment is therefore left to the downstream legislation; this is very well illustrated by the Seveso Directive, which is dedicated to handling the specific risks.

When no data are available to distinguish between classifications, CLP cannot declassify forms having a lower “risk potential”. The proof of complete risk control can only be established by Article 4 of the Seveso Directive, even though there might be cases where considerable effort is needed to obtain information on the use pattern and operating conditions. No case has yet been treated under Article 4, so the actual burden and timelines associated with the process are difficult to evaluate. Nevertheless, the inclusion of such an article does provide more flexibility when compared to Seveso II where no such mechanism was foreseen.

2.5.5 Addressing substances with different risks based on their form and flexibility through proper self-classification (the metals example)

Background

Besides the possibility of addressing different risk levels under Seveso III, as described in the previous example, there are also examples showing that there are options to address the hazard of substances within the Seveso framework. If data can demonstrate that special forms of the substance do have less hazardous properties, CLP can be used to differentiate between these forms in their classification. For example, the massive forms of metals may have different properties from the powder forms and, as a result, fall outside of the scope of Seveso for e.g. environmental hazards. Examples are provided below with the aim of only demonstrating the differences in the approaches under CLP and Seveso III Article 4 that may be associated with a substance depending on its physical state. Other endpoints, and in particular human health endpoints of relevance, have not been considered and there was no assessment of all the uses of metals across the EU, so it cannot be concluded that exclusion through Article 4 is seen as justified.

Metals can be used either in powder form or as massive metals e.g. in the form of slabs, sheets or wires. Registration data for metals²⁹ (e.g. copper, zinc and lead) shows that hazardous properties may vary depending on the physical form of the substance.

For example, in the case of metals and focusing on environmental classification, the massive form often shows less leaching from the substance in the respective tests compared to other forms such as powders. Flammability may also be influenced by the physical form of metals. As long as there is no harmonised classification covering the relevant physical form, this can lead to the non-classification (through self-classification) of any of the massive forms, while the powder forms of the metals remain classified, for example as³⁰:

- Lead (powder) Aquatic Acute 1, H400; Aquatic Chronic 1 H410 (M=10)
- Zinc (stabilised, unstabilised) Aquatic Acute 1 H400; Aquatic Chronic 1 H410 (M=1)
- Copper (powder) Aquatic Acute 1 H400; Aquatic Chronic 3 H412

However, the massive forms of lead, zinc and copper may not require an environmental classification included in the scope of Seveso. As a consequence, massive forms of these metals would not trigger a tonnage assessment according to E1 of Annex I of the Seveso III Directive.

Conclusion

A necessary condition for differentiation of forms of a substance under CLP is test data that prove the different hazard potential. CLP does not include further risk considerations. There is no assessment of the subsequent use and possible changes in the hazard potential of the substance. For the assignment to Seveso III, there is no obligation to question the classification communicated along the supply chain³¹ and to perform subsequent risk assessments for processing or treatment of the substances (here the massive metals). However, in situations where the powder form and hence hazards could be present (e.g. as a result of mechanical stress or processing conditions such as grinding), this would have to be assessed separately.

The CLP classification refers only to the substance as supplied. This might lead to an underestimation of risks, when downstream legislation is triggered only by the hazard characteristic and tonnage. If there are different classifications this is not reflected in the labelling to avoid confusion³². Optional classifications of a substance based on the physical form as indicated above are not addressed in the communication triggered by CLP³³.

²⁹ See ECHA's Database of registered substances.

³⁰ Other human health or physical chemical endpoints are not shown here. See also Case study 2 which discusses original proposals for the harmonised classification of lead for reproductive toxicity, which did not distinguish between the massive and powder forms, although such a distinction was made in the final decision on the harmonised classification.

³¹ In general there is of course an obligation for the operator of an establishment to check the plausibility of the communicated information. If an operator is using hazardous substances, he should have at least a basic understanding of the hazard potential and in case of obvious mistakes be able to react.

³² But note that it would be possible to include such information in chapter 16 of the safety data sheet.

³³ It could be communicated in the safety data sheet (e.g. chapter 16) and also in other additional information included in this instrument that help the recipient of the document.

3 Information from Consultation

3.1 Overview

The following information originates from interviews and the public consultation. All information in this chapter is therefore based on the non-representative experiences and opinions of the individual consulted stakeholders.

3.2 Role of Seveso in the broader EU RMM framework

All stakeholders contacted highlighted the specific situation of major accidents that are covered under Seveso III and the preceding versions of Seveso. In their own understanding, they did not see Seveso as part of a dedicated risk assessment system for chemicals. There were no doubts on the usefulness of Seveso as it tackles unintended and unforeseeable situations that require a high level of protection not only inside an establishment but also at regional level with the public authorities. Some stakeholders highlighted the importance of the implementation of a systematic assessment of an establishment on the basis of EU-law. This would force market actors, traditionally not involved in such risk assessments, to engage in accident prevention.

The general scope of the Directive was evaluated as appropriate by the stakeholders contacted. None of the stakeholders claimed that categories included in Seveso III should be deleted. Single stakeholders claimed that the scope should even be extended to cover the effects of major accidents that do not cause immediate impacts, but could result in effects over the long term. Examples highlighted were CMR, sensitisation and endocrine disruption.

As Seveso III does not prescribe technical measures to improve the prevention of accidents, stakeholders often derive these from other processes that contribute to the safety of the standard operation. Some Stakeholders contacted stated that a main source for technical measures in some sectors was the IED³⁴ and the accompanying BREF process. This seems especially true for stakeholders that already require high safety standards during standard operations, as they handle highly flammable substances under rigid conditions (e.g. refineries). Other BREFs provide less specific measures that could be used for Seveso. In such cases, the complementarity of IED and Seveso seems to be limited. Nevertheless, some stakeholders would favour a stronger link between Seveso and IED. It was proposed that the scope should be harmonised in a way that each Seveso establishment should also be covered under the IED, and the BREF-process should additionally cover major accident prevention to a higher degree. This opinion is not shared by all stakeholders, as there are other examples where standard operation and accident prevention deviate strongly from each other. While the scope of Seveso is defined by substances and hazardous properties of substances, the IED is linked to industrial operations and emissions from these.

Another issue that was reported by an NGO is the fact that Seveso itself does not require a formal permitting procedure. This, from the NGO's perspective, would make it difficult for them to participate actively in some of the processes of Seveso like public consultation and decision making, where the processes of the IED are not already in place. In latter cases, the participation was often ensured by interaction in the IED permitting process and Seveso should be addressed there also. This was another argument to have a stronger harmonisation between the scope of Seveso and the

³⁴ Industrial Emission Directive (Directive 2010/75/EU), OJ L 334/17 - 119 (2010)

IED. However, it is clear that such an automatic linkage could itself trigger a range of significant unintended impacts, bringing facilities such as warehouses into the scope of the IED and is not necessarily an appropriate approach for addressing concerns over the lack of a national permitting procedure.

It was also highlighted that safety with regard to major accidents has to be seen in a broader perspective. Stakeholders highlighted that the safety of establishments is basically in the owners' interest, as major accidents often result in the complete loss of installations and of related investment. Safety with regard to accidents is also linked to insurance premiums that prescribe measures that minimise the risk of an incident and the obligations of the insurer to pay for the consequences. Seveso also ensures a level playing field across the EU with regard to the efforts that need to be taken for accident prevention thus avoiding distortion of competition.

A further issue that was highlighted with regard to the overall role of the Seveso III Directive and the prevention of major accidents was that it is not an issue that companies should compete on. A high level of protection should be an aim of all industry players. Therefore, exchange of best practices should be encouraged, for example, by publication of good design of installations or parts or organisational measures that reduce the risk of major accidents. In this context, it was noted that the retrospective evaluation of events could be improved and more guidance for companies could be developed from this exercise. Current practices were not seen as sufficient specifically with regard to establishing a better practice of accident prevention. On the other hand, other stakeholders stated that this practice was already reflected in publications and that there are industry activities allowing for exchanges on sector specific good practice. Research has identified examples of activities already in place at international and Member State levels, such as MARS, that aim to implement good practice with regard to accident prevention.

It was also highlighted by an NGO that transparency was needed on such issues, as well as an exchange of findings with other stakeholders. In this respect, there was criticism that neither the MAPPs nor safety reports are publically available. The reason that there is no publication relates to the fact that the MAPP and safety reports contain, for example, sensitive security and commercial information. Nevertheless, the NGO claimed that these documents should be published and this obligation should be regulated at an EU level.

There was also criticism that some establishments or sectors with similar potential to cause major accidents are excluded from Seveso, but no comparable regulation applies to such establishments to ensure the same level of protection. Differences were seen by the stakeholders but measures for these kinds of installations should still be taken. Examples that were mentioned by a few stakeholders (NGO and industry) were:

- Mining activities (large waste storage establishments with extreme pH);
- Off-shore activities; and
- Pipelines.

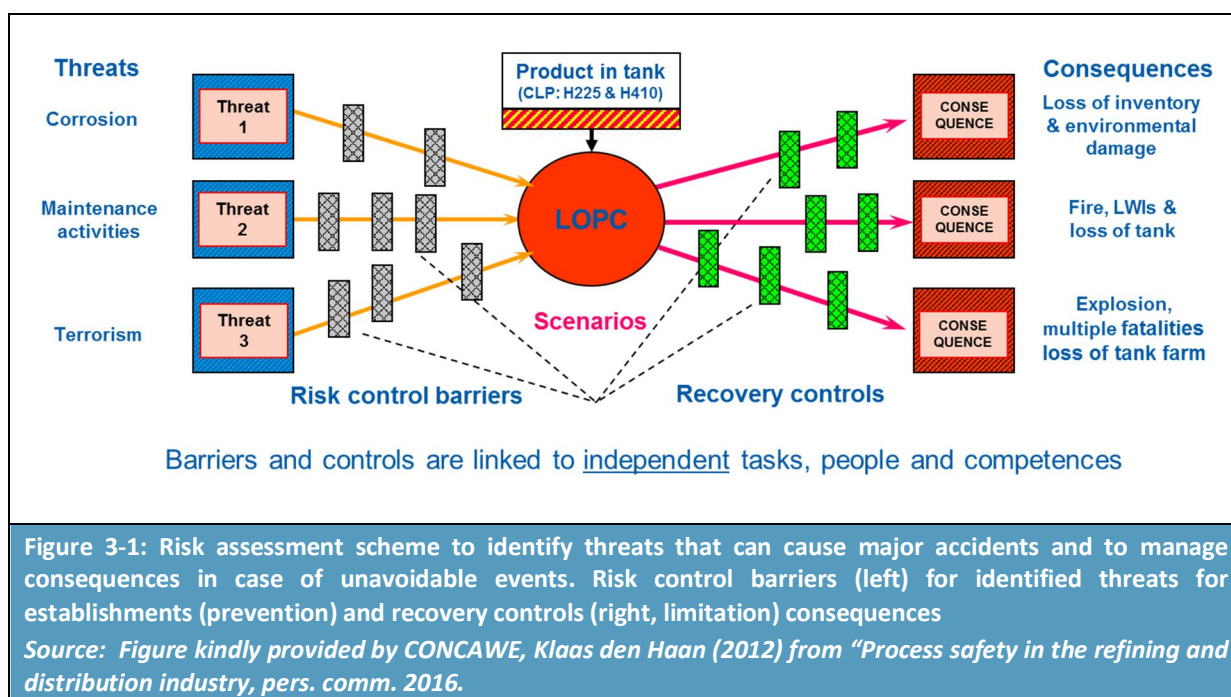
However, it needs to be pointed out that for all of the above mentioned examples, national or EU legislation is in place and previous assessments did not suggest the need for Seveso to include these activities within its scope.

3.3 Risk management measures under CLP and Seveso III

It was highlighted that CLP itself was not seen as a piece of legislation that provides risk management measures but triggers a risk assessment in downstream legislation and, in the case of

Seveso III, via the classification provided. It was also highlighted that Seveso III does not provide measures itself with regard to the technical improvement of an establishment, but operates at the organisational level (requiring a systematic assessment of the safety of the establishment with regard to major accidents through considerations of the technical measures in place to protect workers' health and safety or for emission control purposes, and the provision of information to the authorities). CLP in this regard is seen as a tool that identifies hazards in relation to the individual and smaller accidents with limited effects for the normal handling of substances.

From the perspective of some stakeholders, a high level of protection for workers in establishments is often linked to safe installations (among other measures). They consider the source of major accidents to be in many cases several little incidents in an establishment that suddenly lead to catastrophes. From their experience, the legislation is already very helpful for systematically avoiding these little incidents with regard to workers and installation defects, and thus ensuring that the overall safety of the establishment is very high. In installations covered under the IED, this may be supported by the implementation of "best available techniques (BAT)", which may include elements (depending on the sector concerned) that would lead to the reduction of hazardous substances and also to an improvement in the safety of the installations. The same is true when other provisions with regard to health and safety are implemented. These measures can also contribute to the reduction of the overall risk of an accident. Still it must be noted that further measures are needed under Seveso that not only aim to prevent an accident but also limit the effects once an accident has taken place. Where such practices are already applied in the sectors, the implementation of Seveso III is not considered to be very burdensome. For sectors that have less experience in handling risks that originate from chemicals, Seveso is seen as a good entry into "safety thinking" and a good trigger for introducing a high level of safety across industry sectors. It was further highlighted that IED indicates that the potential for accidents should be reduced³⁵ but that specific measures are often missing in the described processes. This is illustrated by Figure 3-1 below.



³⁵ See. Article 11 and Annex III.

3.4 Impacts of classification changes and listing in Annex I on Seveso establishments

3.4.1 Consideration of downstream impacts in classification

As illustrated in Section 2, changes in classification can change the status of establishments under Seveso III. Most stakeholders indicate that it is not possible, for the time being, to state if there will be a significant change in the number of installations due to the introduction of CLP into Seveso III. Some state that it is more likely that there will be an increase (rather than a decrease) due to new data on substances from REACH-registrations resulting in reclassifications of some substances. There was some criticism that, in some cases, this might lead to unnecessary burdens because there have been no changes to the establishment and the handling of chemicals; while others note that the systematic assessments performed for Seveso have increased the safety level even where establishments were previously well run.

Some stakeholders indicated that they would welcome the consideration of downstream impacts in relation to Seveso when classifications were being made. All stakeholders were aware though that there is no room to deviate from a classification if data require it, as classification is a hazard based process. It was highlighted that more differentiation between forms of substances or concentration of mixtures might be useful (as shown by the examples of nitric acid and the massive metals) even if justification might be difficult. For chemical users, this would most efficiently solve situations where the classification is considered to overestimate the real risk, especially as harmonised classifications can have an effect on other pieces of downstream legislation as well.

Downstream users involved in formulation activities (formulation of mixtures using substances or mixtures) reported that establishments have already changed their status, and that this has led to an additional administrative burden, especially when this was a change towards an upper tier establishment (i.e. for either an upgrade from a lower tier establishment or the completely new inclusion of an establishment into the scope of the Seveso III Directive). The additional burden of becoming a lower tier establishment was however viewed as being less significant. It was stated that one of the factors leading to an increased burden (in the range of €50 000 - €100 000) was the need to involve additional external expertise for setting up emergency plans.

The following observations were made:

- Some substances changed their classifications, some were classified for the first time and some were classified more strictly. The category that has the largest impact for formulators³⁶ is the classification as hazardous for the aquatic environment. Here, the very high M-factors assigned for cat. 1 substances cause problems. It should be noted that the system for how M-factors are assigned between the DPD and CLP has not been changed significantly. Only the use of the NOEC³⁷ for chronic effects has been introduced instead of the E(L)C₅₀³⁸. The application of the NOEC is rather more conservative, as it is usually somewhat lower and refers to more tests (e.g. inhibition of growth for algae). In addition, there are usually fewer NOECs available in literature than E(L)C₅₀.

³⁶ Producers of chemical products – mixtures.

³⁷ No observed effect concentrations.

³⁸ Effect (Lethal) Concentration showing effects on 50% of the test individuals.

- Many classifications changed as a result of REACH registrations. This observation is also true for endpoints not covering environmental hazards. As a result, from the classification for the environmental effects, it was observed that many substances have very high M-factors, which in turn leads to very low limit values for the classification of mixtures. The assignment of an M-factor is linked to the number of test data available. If only a few data have been included in the classification, the M-factor is very high due to the high safety factors that have to be applied to ensure a conservative assessment. This leads to situations where mixtures need to be classified as hazardous to the aquatic environment at very low substance concentrations.
- Seveso obliges the operators of establishments to assess the classification of substances and mixtures. When substances and mixtures of the same category are assessed, the tonnage of the mixture is taken into account and not the tonnage of the substance that has an inherent hazard. In combination with the above issues regarding the M-factors, there are situations where very low tonnages of a substance classified as aquatic tox. 1 (chronic or acute) are handled, but the threshold for the establishment is calculated based on the tonnage of the resulting mixture. On the other hand, it must be noted that a high volume of the mixture to be handled in case of an accident will need measures other than those required for a low volume of a pure substance. Furthermore, this could be another example where test data on the mixture might limit the effect of downstream legislation, if these show that the mixture poses less toxicity than the pure substances contained in it.

As a result of the combined effects of the three bullet points above, it was claimed that many formulators might qualify as Seveso establishments. This was often due to the effect that the mixture contributes to the threshold based on the full tonnage of the mixture that is stored in the establishment. The tonnage of the actual substances that have the Seveso relevant properties is far lower and the threshold would potentially not be exceeded if only the share of the hazardous substance was taken into account. In addition, the individual packaging units of such mixtures pose additional barriers, which, if there was an accident, could limit the uncontrolled emission of the total volume of the mixture in the store. The storage phase, in the opinion of stakeholders, poses a lower risk due to the fact that the substance is present in lower concentrations in the mixture and usually in a lower tonnage per packaging unit. It was highlighted that in road transport, lower requirements are applied if substances or mixtures are transported in smaller containers, e.g. 1 litre cans, than if the same substance or mixture was in a larger packaging unit, e.g. a barrel of a tank wagon with the same overall transport amount. However, such aspects can be considered in the MAPP and safety report and would influence the actual measures to be taken.

Some Seveso stakeholders stated that it is sometimes difficult to get trustworthy information on substances from the supply chain. It was reported that inconsistencies between classifications can lead to situations where similar establishments that handle the same substance are not covered in the same way under Seveso. One establishment could be covered because the operator has received a relevant classification, while another operator did not receive such a classification for the same substance. There may also be some difficulties for market actors to determine the correct tonnages if several substances or mixtures are handled within the establishment. Member States provide support for this situation, e.g. in the form of simple excel sheets that cover the formulas from Seveso to make calculations easier.

Even if operators do check the classifications, they may struggle to find the correct information. The main source for classification information is the CLI database established by Article 42 of CLP (see Section 6 of the Task 1 Report). Links to Seveso are only included for harmonised classifications and users do not get reliable information due to the range of notified self-classifications.

3.4.2 Listing of substances in Annex I, part II

The combination of the generic inclusion of substances into the scope of Seveso is mainly seen as adequate. It is acknowledged that in some situations in some establishments, the risk might be overestimated with some disadvantages/unnecessary burden for the specific operators. It was stated by a single stakeholder that in some rare cases risks might also be underestimated, for example, when low tonnages of substances are handled under conditions that have the potential to cause large negative effects for human health or the environment. The use of chromium in electroplating establishments was highlighted in this regard. But it was acknowledged that the specific entries in Annex I part 2 can be adapted to tackle such situations by setting a limit or lower limits for the respective substance otherwise not covered by generic entries in part 1 (as an example Nickel compounds could be mentioned).

Some stakeholders indicated that the use of Part 2 of Annex I could be more useful to define these kinds of situations, and that it might be better to include a risk based approach from the beginning. It was also clear to these stakeholders that this would potentially require a more complex process, involving a technical debate between stakeholders from the sectors and authorities (similar to the BREF process), to define the potential for a major accident within a sector and to define the qualifying quantities and update the Annex regularly. The increased complexity could on the one hand help to close potential gaps, for example, when risks are not identified by the direct linkage to CLP classifications, but result from the conditions of use even though thresholds are not exceeded (more stringent entries in Annex I Part 2). On the other hand, situations could be addressed where the generic approach in Part 1 overestimates the risk (e.g. the petroleum example with its higher threshold compared to a situation where the generic approach would have been applied). Such entries would result in a situation where fewer companies might exceed the threshold and would not need to follow the provisions of Seveso anymore or vice versa.

3.4.3 Exemptions from scope according to Article 4

Article 4 was strongly criticised by most stakeholders contacted, as it does not appear to be clear how it could be used in practice. Besides the legislative process, which was seen as too slow for effective practical use by most of the contacted stakeholders, there were doubts that substances exist that fulfil the high requirements of demonstrating no risk in any relevant use (intended and non-intended). Even if it were possible to collect all the data needed to demonstrate “no-risk”, the timelines would be too long for a new establishment to benefit from such an exclusion.

On the other hand it was highlighted that new classifications would also need some time to be implemented. There is a public process and an announcement when this process starts. If good cases were brought forward that do not trigger lots of controversial discussions regarding justification, or have data gaps, the legislative process could be rather rapid. The time lag before the announcement of the potential classification could be used for the collection of data to show no hazard (see nitric acid example) or to collect data that are needed for a justification under Article 4 (if it is clear that respective substance data do not have the potential for a lower classification.) It was highlighted that Article 4, with all its limitations, is still an improvement compared to Seveso II, which did not have such a provision. Finally, the usefulness for operators to exclude establishments from the scope of Seveso (whether old or new) was seen as rather limited, because most Seveso establishments have several hazardous substances on site and would still remain Seveso establishments if only one substance was excluded from the scope.

4 Evaluation

4.1 Effectiveness

The main contribution to the overall risk management system of chemicals is the systematic risk assessment operators of establishments need to perform. As Seveso III is not only limited to addressing the consequences of an accident but also aims to prevent such events, it contributes significantly to the protection of human health and the environment. Furthermore, it provides information to authorities and the public to organise subsequent measures, e.g. regional organisation of emergency response forces (fire brigade, police, ambulances etc.). As primarily acute effects are intended to be addressed, not all endpoints from the chemicals legislation are covered. Endocrine disruptors, nanomaterials and new toxicity endpoints are currently not foreseen in the legislation.

As there is a direct link to CLP, the data that trigger the scope of Seveso are of high quality. Seveso III can cover all the life cycle steps of a substance including waste, so there are no gaps in this regard. The safety assessments with regard to workers contribute to the development of the assessments necessary under Seveso III and vice versa. With regard to consumers, there are no effects from Seveso III, as it does not aim to ensure the safety of products. Seveso does not contribute directly to the general aim of substitution of dangerous substances from processes, as its scope concentrates on handling the ones that are in use. Nevertheless, it does not restrain such activities when they are the most favourable option of an overall assessment of an establishment. Additionally there is a tendency to avoid storage of large tonnages of hazardous substances in order to avoid that the establishment/installation in question falls under the Seveso III Directive and would therefore need to comply with its requirements; if it does fall under the Directive, this will lead to additional investment requirements which may have a significant impact on SMEs³⁹.

With regard to a harmonised single market, the definition of the scope of Seveso III does not pose any problems. Seveso-like provisions are now enshrined in multinational agreements and many countries have established similar pieces of legislation worldwide. As Seveso III contributes to an overall safety philosophy of the establishments covered, it contributes to a high level of competitiveness due to a high level of reliance on the technical installation and reduction of the risks for a supplier from a major accident, thus avoiding investment losses and ensuring business continuity. This also contributes to sustainable growth and provides a level playing field for operators. Furthermore, accident prevention leads to an improved corporate image as a trading partner/supplier, which can lead to a stronger market position.

Some stakeholders would prefer for more risk considerations (beyond tonnage and hazard) to be considered when the scope of Seveso III is defined, as can be incorporated into Part 2 of Annex I. Nevertheless, all stakeholders acknowledge that the generic link to CLP reduces the need for discussions on which substances have to be included, even if in some cases this leads to over- or underestimation of the specific risk of an establishment.

³⁹ See also Commission Staff Working Document “Summary of the Impact Assessment accompanying document to the Proposal for a Directive of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. Available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52010SC1591>

4.2 Efficiency

As only organisational measures are required under Seveso direct, the cost of Seveso III for the risk assessment process can be considered as less significant. Nevertheless Seveso's follow up measures can result in major costs. When investments for equipment need to be made, the costs are limited to those associated with its implementation. The costs are evaluated as appropriate by the stakeholders consulted, although comments from the targeted consultation did indicate that some market actors that formulate mixtures (and especially SMEs) are concerned by the potential magnitude of costs as the Directive continues to be implemented. This seems mostly to be due to the potential for new classifications under CLP⁴⁰ to be followed by a status change of the establishments. Such a status change could either be that new establishments fall into the scope of Seveso (moving to be at least a 1st tier establishment) or move from being a 1st tier to a 2nd tier establishment.

In a study that assessed the cumulative cost of the EU Chemical industry⁴¹, the capital expenditure costs (CAPEX) linked to the emissions and industrial processes legislation package (that included Seveso costs) were estimated to be in the order of 3 billion Euros per year. These CAPEX costs represented about 3.7% of the value added by the sector. It must be noted that other legal obligations are also covered in this calculation and the main costs have to be allocated to emissions reduction, including the costs of complying with best available techniques from the BREF process and CO₂ reduction requirements, as well as participation in the emission trade scheme (ETS).

Differences were described between the various subsectors of the chemicals industry (for the complete package, not exclusively Seveso). This description shows that a typical formulator, on average, only had costs of about 1% of value added, while other subsectors that are linked to the production of chemicals had costs in the range of 7% of value added.

4.3 Relevance

The Seveso III Directive covers a very specific field in the chemicals legislation framework. It ensures a high level of protection by contributing to the avoidance of major accidents. Furthermore it limits the consequences of such events when they happened. Events that led to the implementation of Seveso have decreased in frequency since its implementation in 1982 due to its strong role in accident prevention by triggering in depth risk assessments and requiring on-site risk management. Although accident prevention is in the scope of several other legal acts, Seveso and its principles integrate the role of the establishment, with those of the authorities and the public. This is unique and highly relevant to ensure safe handling of chemicals in the EU.

4.4 Coherence

Since the main principles of the Seveso Directive have not changed since its first implementation, companies are well aware of the legislation, in particular, industry sectors close to chemical manufacturers of first tier formulators.

⁴⁰ These do not necessarily follow the introduction of CLP, but new information from REACH. Therefore, this is neither an effect of CLP nor Seveso.

⁴¹ EUROPEAN COMMISSION, 2016 Cumulative Cost Assessment for the EU Chemical Industry - Final Report (Chapter 5).

CLP categories are implemented in a 1:1 way. Re-classification becomes effective right away, so no inconsistencies originate from the link between CLP and Seveso.

In cases where Seveso overlaps with the IED, the risk assessment can generate benefits from the situation. This is broadly welcomed and evaluated as positive because coverage under the IED seems to be a source of useful information for designing an establishment in a way that ensures that a high level of safety is realised. Even though this situation exists, the two legal acts do have different aims (IED to handle major emissions; Seveso to handle major accidents) so from a perspective of coherence it seems logical to define different scopes.

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