

Analysis of the Potential Effects of  
the Proposed GHS Regulation on  
Its EU Downstream Legislation

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## Foreword

The Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) was developed to overcome inconsistencies in classification and hazard communication at international level. In its Plan of Implementation, adopted in Johannesburg on 4 September 2002, the World Summit on Sustainable Development encouraged countries to implement the harmonised system as soon as possible, with a view to reach a full operational state by 2008.

The recommendations of the UN World Summit on Sustainable Development were signed up to by all EU Member States. Following this, the Member States called upon the Commission to implement the GHS. On 29 October 2003, the Commission stated in the explanatory memorandum to the amendment of Directive 67/548/EEC, adopted at the same time as REACH, that it is the intention of the Commission to propose the inclusion of the internationally agreed GHS in Community law as soon as possible.

DG Enterprise & Industry and DG Environment have developed a draft proposal for a GHS - implementing Regulation. The new legislation will replace, after a transitional period, the currently existing provisions on classification and labelling of chemicals as set out in Council Directive 67/548/EEC and Directive 1999/45/EC.

To complement the legislative proposal, the Commission Services have performed an impact assessment. In addition, the Services have prepared the attached analysis: it focuses on the potential effects of the proposed GHS Regulation on more than 20 EU Regulations and Directives which currently refer to the existing rules on classification and labelling. In this respect, these acts are considered "downstream legislation".

As a contribution to the Commission initiative "Better Regulation", this analysis will examine in detail the effects of replacing the existing rules by the GHS criteria. To ensure coherence with other policies, it was developed in cooperation with the Commission Services responsible for the respective downstream acts. The analysis explains the provisions in the GHS Regulation that ensure the transition from the old to the new system for many of the examined Regulations and Directives.

On the basis of the findings of this analysis, conclusions will be drawn with regard to minimising potential effects, if any, for particular downstream acts. The conclusions will either pertain to consequential changes of that legislation or to separate amendments which may become necessary when the adaptation to the GHS is considered more difficult. In the latter case, the specific impact of planned amendments of the respective legislation will be assessed. In turn, the impact assessment study pertaining to the proposed GHS Regulation will mainly focus on general effects which will be due to replacing the current legislation on classification and labelling as such.

# Analysis of the Potential Effects of the Proposed GHS Regulation on Its EU Downstream Legislation

## PART I – Background of the Analysis / Conclusions

### I. Introduction

For more than 30 years, information on the hazards posed by chemicals has been a worldwide issue, giving rise to the development of distinct classification systems in different jurisdictions of the world, e.g. in the EC, Australia, Japan, the US, Canada, Korea and others. Having merits at the national level, clear drawbacks were recognised at the international level: the diverse classification and labelling systems often employ not only different criteria for hazard assessment, but also give dissimilar health and safety information for the same goods which may be traded across the borders. Table I.1 below illustrates how a particular hazard is communicated on the basis of different criteria:

Table I.1: Description of the toxicity hazard of a substance with LD<sub>50</sub> = 257 mg/kg (oral) in different jurisdictions

Jurisdiction / System	Hazard Classification / Communication
GHS	signal word: “Danger”; pictogram: Skull & Crossbones
Transport	“Slightly Toxic” (liquid) for solids not classified
EU	indication of danger: “Harmful” pictogram: St. Andrew’s cross
US	Toxic
CAN	Toxic
Australia	Harmful
India	Non-toxic
Japan	Toxic
Malaysia	Harmful
Thailand	Harmful
New Zealand	Hazardous
China	Not Dangerous
Korea	Toxic

To overcome these inconsistencies at a global level, the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) was developed by various international organisations, including the “Inter-organisation Programme on the Sound Management of Chemicals” (IOMC), the Organisation for Economic Cooperation and Development (OECD), the UN Committee of Experts on the Transport of Dangerous Goods (UN CE TDG) and the International Labour Organisation (ILO). The EU Member States, other stakeholders and the Commission were strongly involved in the elaboration of the GHS in these organisations.

In December 2002, the GHS was agreed by the UN Committee of Experts on the Transport of Dangerous Goods and the Globally Harmonised System for the Classification and Labelling of Chemicals (UN CE TDG / GHS) in Geneva. The GHS was then formally adopted by UN ECOSOC in July 2003 and so became available for implementation in the so-called “Purple Book”.

In its Plan of Implementation, adopted in Johannesburg on 4 September 2002, the World Summit on Sustainable Development encouraged countries to implement the harmonised system as soon as possible, with a view to reach a full operational state by 2008. Implementation has already started with pilot countries introducing the system in their national practices in different regions of the world. To encourage all key parties’ involvement, however, the adoption of GHS is formally voluntary.

All EU Member States signed up to the recommendations of the UN World Summit on Sustainable Development. Following this, the Member States called upon the Commission to implement the GHS. The Commission itself has confirmed on several occasions that it intends to propose the implementation of the GHS into EU legislation.

The preparations of implementing the GHS at Community level comprise two main elements:

1. One element is the preparation of a proposal for a Regulation of the European Parliament and of the Council on classification and labelling of substances and mixtures based on the Globally Harmonised System (GHS Regulation). The proposal will specify the rules, principles and criteria for the classification and labelling of substances and mixtures according to the GHS;
2. In parallel with the above, the responsible Commission Services have considered the effects of the proposed Regulation. This work in turn comprises two tasks: The first is an impact assessment of the general effects which are due to the introduction of the GHS as such. The second task, being the focus of this analysis, is a detailed examination of potential effects of the GHS Regulation on those pieces of Community legislation which make use of classification and labelling criteria. The analysis takes account of the fact that at the end of the transitional period set out in the GHS Regulation, Directives 67/548/EEC and 1999/45/EC will be repealed. In particular, this analysis aims to clarify whether
  - it is sufficient to replace the references to the current classification and labelling criteria as set out in Directives 67/548/EEC and 1999/45/EC by references to the GHS Regulation. This would include to make use of a reference table for certain endpoints;
  - additional changes to the respective downstream acts are possible to adapt to the GHS criteria. If so, it has to be decided whether these changes can be made in the GHS Regulation or whether a more substantial revision of a particular downstream act would be a better solution. In this connection, Articles 37 to 38 of the GHS Regulation sum up the results of this study as far as it concludes that it is either sufficient to replace the references or that additional changes can be made in the GHS Regulation.

## **II. Scope of the Analysis**

The current EU classification and labelling system is set out in Council Directive 67/548/EEC and Directive 1999/45/EC. These acts define hazard criteria for the classification and labelling of substances and preparations placed on the market.

Many other Regulations and Directives addressing specific sectors or products refer to the classification criteria as conditions for obligations in these Community acts. Therefore, these acts are considered “downstream legislation”. They either refer to the “classification as dangerous” in general, thus including all categories of danger, or to selected hazards or R - phrases. Whereas some obligations rely on the classification (hazard) alone, others are based on risk, i.e. they also include exposure elements as trigger for obligations.

The specific legal obligations based on the classification and labelling of substances or preparations are the primary focus of this analysis.

Table II.1 provides for an overview of the respective acts of Community legislation and the type of reference made:

**Table II.1:** Overview of EU legislation employing the classification and labelling criteria of Council Directive 67/548/EEC and / or Directive 1999/45/EC (“downstream legislation”)

<b>EU Legislation</b>	<b>Reference to EU System of Classification &amp; Labelling</b>
<b>I. Consumer products</b>	
Regulation (EC) No 648/2004/EC of the European Parliament and of the Council of 31 March 2004 on detergents	§ Classification & labelling acc. to Directives 67/548/EEC and 1999/45/EC
Regulation (EC) No 1980/2000 of the European Parliament and of the Council on a revised Community eco-label award scheme  § Commission Decision 2001/523/EC of 27 June 2001 establishing the ecological criteria for the award of the Community eco-label to all-purpose cleaners and cleaners for sanitary facilities  § Commission Decision 2001/607/EC of 19 July 2001 establishing the ecological criteria for the award of the Community eco-label to hand dishwashing detergents  § Commission Decision 2002/739/EC of 3 September 2002 establishing revised ecological criteria for the award of the Community eco-label to indoor paints and varnishes and amending Decision 1999/10/EC  § Commission Decision 2003/31/EC of 29 November 2002 establishing revised ecological criteria for the award of the Community eco-label	§ R-phrases and categories of danger: R23, R24, R25, R26, R27, R28, R31, R39, R40, R42, R43, R45, R46, R48, R49, R60, R61, R62, R63, R64, R68, R50-53, R59

to detergents for dishwashers and amending Decision 1999/427/EC § Commission Decision 2003/200/EC of 14 February 2003 establishing revised ecological criteria for the award of the Community eco-label to laundry detergents and amending Decision 1999/476/EC	
Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products	§ Reference to the categories of danger as set out in Directive 67/548/EEC § Reference to CMR cat. 1, 2 and 3
Council Directive 88/378/EEC on the approximation of laws of the Member States concerning the safety of toys	§ Classification & labelling acc. to Directives 67/548/EEC and 1999/45/EC § Reference to CMR cat. 1 and 2
Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers	§ Reference to the categories of danger Extremely Flammable, Highly Flammable and Flammable as defined in Dir 67/548/EEC
<b>II. Handling chemicals for particular uses</b>	
Directive 1998/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market	§ Classification and labelling acc. to Directives 67/548/EEC and 1999/45/EC § Reference to CMR, Very Toxic, Toxic and sensitising properties
Council Directive 91/414/EEC concerning the placing of plant protection products on the market	§ Classification of active substances and PPP acc. to Directive 67/548/EEC and 1999/45/EC § Packaging and Labelling of PPP acc. to Directive 1999/45/EC § Testing of metabolites triggered by T+, T and CMR
<b>III. Control of dangerous / hazardous chemicals</b>	
Draft REACH Regulation, in the version as agreed by the Council on 13 December 2005	§ Reference to selected categories of danger: CMR, N/R50-53, respiratory sensitisers for registration deadlines, substances that might be subjected to authorisation and for harmonised classifications § Notification to the classification and labelling inventory 3 years after entry - into-force of REACH § Information on classification and labelling needed at the time of

	<p>substance registration</p> <p>§ Chemical Safety Report: documents the classification of substances; the exposure part is triggered by the classification as dangerous acc. to Directive 67/548/EEC</p> <p>§ Prioritisation of substance evaluation triggered by substances which are likely to be dangerous acc. to the criteria set out in Dir 67/548/EEC</p> <p>§ Exemptions of naturally occurring substances in Annex III to the REACH Regulation do not apply if substances are classified as dangerous</p>
<p>Council Directive 1996/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances, as amended by Directive 2003/105/EC of the European Parliament and of the Council of 16 December 2003</p>	<p>§ Annex I, Part 2: reference to numerous categories of danger and R-phrases as set out in Directive 67/548/EEC</p> <p>§ Reference to the „explosive“ categories of UN/ADR, as transposed by Directive 1994/55/EC</p>
<p>Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals</p>	<p>§ Classification &amp; labelling acc. to Directives 67/548/EEC and 1999/45/EC</p> <p>§ Reference to the introduction of a new system of classification and labelling in the EU</p> <p>§ Reference to changes of labelling</p>
<p>Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations</p> <p>§ Directive 2004/42/EC of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in decorative paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC</p>	<p>§ Reference to R40, R45, R46, R49, R60, R61</p> <p>§ Reference to labelling acc. to Directives 67/548/EEC and 1999/45/EC</p>
<p>Council Directive 1996/62/EC of 27 September 1996 on ambient air quality assessment and management</p>	<p>§ Reference to the categories of danger as set out in Dir 67/548/EEC</p>
<p>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</p> <p>§ Decision No 2455/2001/EC of the European</p>	<p>§ <u>No</u> explicit reference to the categories of danger as set out in Dir 67/548/EEC</p> <p>§ Reference to substances with toxic, carcinogenic and mutagenic</p>

Parliament and of the Council of 20 November 2001 establishing the list of priority substances	properties
IV. Occupational health and safety	
Council Directive 1998/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work	§ Reference to substances and mixtures meeting the criteria for classification as set out in Directives 67/548/EEC and 1999/45/EC
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	§ Reference to the categories of danger carcinogen and mutagen, cat. 1 and 2
Council Directive 1994/33/EC of 22 June 1994 on the protection of young people at work	§ Reference to numerous categories of danger and R-phrases in the Annex: Very Toxic, Toxic, Corrosive, Irritant, Harmful, R39, R40, R42, R43, R45, R46, R48, R60, R61, R12
Council Directive 1992/85/EEC of 19 October 1992 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	§ Reference to substances labelled as R40, R45, R46, R47 according to Directive 67/548/EEC
Council Directive 1992/58/EEC of 24 June 1992 on the minimum requirements for the provisions of safety and/or health signs at work	§ Reference to classification and labelling acc. to Directives 67/548/EEC and 1999/45/EC
V. Waste and end-of-life products	
Council Directive 91/689/EEC of 12 December 1991 on hazardous waste § Council Directive 75/442/EEC of 15 July 1975 on waste § Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste	§ Reference to the classification criteria of Directive 67/548/EEC § Reference to the generic concentration limits as defined in Directive 1999/45/EC § Further references are disputed
Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of-life vehicles	§ Reference to substances which are considered dangerous according to Directive 67/548/EEC
Directive 2002/95/EC of the European Parliament and the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment	§ Reference to substances which are considered dangerous according to Directive 67/548/EEC § Reference to mixtures which are

	considered dangerous according to Directive 67/548/EEC
Council Directive 91/157/EEC of 18 March 1991 on batteries and accumulators containing certain dangerous substances	§ Term “dangerous” only used in the title of the Directive; no reference identified in the Articles

This analysis does not address the consequences the GHS -Regulation might have on Member State legislation. Also, the focus of this analysis has to be differentiated from the impact assessment which is to accompany legislative drafting. This means that statements on the costs and benefits related to introducing the GHS as such are not derived in this document. The impact assessment referring to general aspects of the introduction of the GHS in the Community, e.g. costs which will be due to reclassification, is prepared in a separate study.

### **III. Principles Underlying the Development of the Draft Proposal for a GHS Regulation**

Some principles underlying the development of the GHS Regulation shall be highlighted here that were also taken into account in the examination of Community downstream legislation.

The draft proposal for a GHS Regulation is based inter alia upon the following four principles:

- § Building Block Approach, cf. GHS ST/SG/AC.10/30/Rev.1, 2005, 1.1.3.1.5;
- § No-reduction-in-protection principle, cf. GHS 1.1.1.6(a);
- § “As close as possible to the existing EU scheme”, cf. Commission Status Paper (Helsinki 2005);
- § Consistency with the implementation into Transport legislation: the GHS will be implemented in the Directives on the Transport of Dangerous Goods (to be updated in 2007 and 2009) so that the GHS will be available for both supply & use and for transport.

In line with these principles, the draft proposal for a GHS Regulation

- § takes up the principles of application and implementation as stated in the GHS Purple Book,
- § takes up all hazards which are today in the EU system and converts them as far as possible to the equivalent / closest corresponding GHS classification(s) ;
- § provides for mechanisms to convert EU “left-overs” into a GHS classification as soon as criteria are adopted at UN level, e.g. R59,
- § takes up all what will be taken up by the Transport legislation, e.g. *Gases under Pressure* or *Corrosive to Metals*, for reasons of consistency;
- § provides for mechanisms to take up all additional R-phrases (physico-chemical and health hazards) which will be converted into a GHS classification as soon as criteria are adopted at UN level, e.g. R29;
- § takes up the labelling requirements of the GHS and provides for a mechanism to include precautionary statements that may not be ready at UN level when the Commission proposal for the GHS Regulation is adopted;

§ retains the current scope of the REACH Regulation and of other downstream acts as far as feasible.

Furthermore, the principles for the harmonisation of the substance classifications will be changed by the adoption of the REACH Regulation.

Both the current EU system and the GHS are self-classification systems for enterprises to apply.

To achieve harmonised self-classifications for substances from 3 years after the adoption of the REACH Regulation, suppliers of substances will have to notify their self-classifications to the Agency or submit them to the Agency as part of a registration dossier. The Agency will then include these classifications in a classification & labelling inventory. Suppliers of the same substance shall make every effort to come to an agreed entry for any classification of that substance.

For that reason harmonised classifications in an annex to the legislation are normally only required for CMRs and respiratory sensitisers; other endpoints may be harmonised on a case-by-case basis, cf. Council Agreement of 13 December 2005. Such harmonised classifications will be introduced in Annex VI to the GHS Regulation. It is intended to include in the annex for the internet consultation CMRs and respiratory sensitisers with harmonised classifications converted from entries in Annex I to Directive 67/548/EEC on the basis of equivalent criteria. As to other substances for which harmonised entries exist, it is also intended to include them in the annex as soon as resources permit.

It should be noted that Annex V of Directive 67/548/EEC will be repealed already as a consequence of the REACH Regulation. The deletion of this Annex will apply 12 months from the entry into force of the REACH Regulation; the testing methods will then be specified on the basis of Article 12 of the REACH Regulation in a further Commission Regulation or by recognition of other international test methods by the Commission or the Agency.

Finally, a smooth transition to the new system shall be ensured. To this end, when the GHS Regulation comes into force, the current system will not be repealed immediately, but both systems will coexist for some years. There will be at least two deadlines to ensure that the reclassification of substances takes place before the reclassification of mixtures. During the transitional period, a supplier may choose to classify and label according to the EU system or according to the GHS. Annex I to Directive 67/548/EEC will be legally binding during the transitional period for those substances classified according to the criteria of Council Directive 67/548/EEC.

#### **IV. Approach for Assessing Potential Effects of the GHS on EU Downstream Legislation**

The assessment of the potential consequences of the introduction of the GHS on the various EU downstream acts will be based on the draft proposal for the GHS Regulation. Each analysis will include the following steps:

1. Identification of the provisions which use classification and labelling;
2. Assessment of the role of classification and labelling in a particular downstream act. The legislation will be checked for legal obligations which contain references to classification and labelling. Beyond it will be examined whether obligations are based on hazard alone or if exposure considerations are also relevant.

3. Assessment of the changes induced by shifting reference to the criteria or the classification scheme of the GHS Regulation in a particular downstream act. The assessment will be based on available documents and studies which focus on the similarities (equivalences) and differences between the current EU classification & labelling system and the GHS, cf. Chapter V below. In order to have a common ground for assessing potential effects, it will be assumed that the legal text of the relevant legislation stays the same, apart from shifting reference to the GHS.
4. On the basis of the findings, proposals will be made to minimise potential consequences, if any, for a particular downstream act. The conclusions will either pertain to consequential changes of that legislation or to separate amendments which may become necessary when the adaptation to the GHS is considered more difficult.

## **V. Comparison of the Current EU System and the GHS**

When the GHS Regulation repeals Council Directive 67/548/EEC and Directive 1999/45/EC after a transitional period, the GHS hazard classes and categories will replace the existing classification scheme. While the EU and GHS criteria match completely for some hazard classifications, differing criteria may apply to others. Table V.3 below gives an overview of those EU classifications and their closest corresponding GHS classifications which are included in the proposed GHS Regulation. Further explanations related to the criteria are given in Annex I to this study.

With regard to the similarities and differences between the current system for classification and labelling which is represented by Council Directive 67/548/EEC and Directive 1999/45/EC and the GHS, various Commission and Member State Working Groups have produced a wide range of analysis documents, cf. Annex I. Numerous results are compiled and evaluated in a comprehensive report that the Commission has prepared in 2004 (Ökopoll study); it can be found at the Commission website [http://europa.eu.int/comm/enterprise/reach/docs/ghs/ghs\\_impl\\_final\\_report.pdf](http://europa.eu.int/comm/enterprise/reach/docs/ghs/ghs_impl_final_report.pdf)

In general, the GHS Purple Book presents a classification system that is structurally similar to the EU system; differences can be identified at the level of individual elements, i.e. hazard classes and categories and some labelling elements. Note that the current “categories of danger” correspond to the “hazard classes” under GHS which may comprise further sub-classifications.

The most important similarities are:

- § Both systems provide for one single system for hazard classification and labelling;
- § The GHS covers nearly all hazards which are currently covered by the EU system;
- § The GHS mostly uses similar or equal classification criteria;
- § The GHS sets up a system of hazard communication that is equivalent to the EU system of hazard communication, both consisting of labels and safety data sheets.

The differences can be summarised as follows:

- § The GHS defines additional hazard classes: Whereas the EU system comprises 15 categories of danger, the GHS comprises 27 hazard classes. 16 hazard classes relate to the physical properties (EU: 5 categories of danger) or the physical state of a chemical, 10

hazard classes relate to health hazards (EU: 9 categories of danger) and 1 class relates to environmental hazard (EU: 1 category of danger);

- § Overall, main differences relate to physico-chemical properties, the existing transport classification system providing the basis for the hazard classifications under GHS;
- § The GHS comprises more hazard categories under one hazard class, e.g. GHS hazard class *Organic Peroxides* comprises seven subclassifications (Type A -G) whereas the EU classifies organic peroxides as *Oxidising O, R7* only;
- § The GHS classifies some EU hazards in more than one GHS hazard class (“cross - classification” of EU hazards). The most prominent example is EU Explosive E, R2 and E, R3 where the corresponding substances and mixtures would have to be classified in the GHS hazard classes *Explosives, Self-Reactives Type A -B and Organic Peroxides Type A-B*;
- § The GHS partially uses other criteria and other cut-offs, e.g. for explosive substances and mixtures (other criteria) and for *acute toxicity* (different LD<sub>50</sub> cut-offs), cf. Annex I to this study;
- § The GHS uses a different approach for the evaluation of the classification of a mixture, especially with regard to the health hazards CMR, acute toxicity, skin corrosion / irritation and serious eye damage / eye irritation:
  - Testing: With regard to CMRs, available data may be used if they fulfil specific conditions. With regard to the other hazards, a tiered approach will have to be followed, comprising the application of so-called bridging principles, calculations based on the hazardous properties of the ingredients and the use of test data for the mixtures itself, if available.
  - Calculations: For the classification of mixtures, the GHS often provides for formulas which deviate from the corresponding EU method, e.g. for *acute toxicity* and for *corrosion / irritation* hazards. The implications of the different formulas used under the EU system and the GHS are discussed in various documents prepared by industry and ECB. Important results are also presented in Annex I to this study.
  - Concentration limits: For the derivation of the hazard of a mixture based on the ingredient concentration, lower concentration limits apply under GHS, e.g. for *irritation / corrosion* hazards and for *reproductive toxicity*. This is shown in Table V.1 below. The lower limits may generally lead to an increased number of classified mixtures, cf. Annex I to this study.

Table V.1: Health hazard-related concentration limits for the classification of mixtures

EU category of danger, R-phrases	EU concentration limit	Most closely corresponding GHS hazard classification	GHS concentration limit
Corrosive C, R34	10%	Skin corrosion, cat. 1B and 1C	5%
Corrosive C, R35	5%	Skin corrosion, cat. 1A	3%
Irritant Xi, R38	20%	Skin irritation, cat. 2	10%
Irritant Xi, R36	20%	Eye irritation, cat. 2A	10%
Irritant Xi, R41	10%	Serious eye damage, cat. 1	3%
Reproductive toxicity, R60 or R61	0.5%	Reproductive toxicity, cat. 1	0.3%
Reproductive toxicity, R62 or R63	5%	Reproductive toxicity, cat. 2	3%

§ The GHS changes some labelling elements. In particular, some new pictograms applying to health hazards are defined:



Health hazard, attributed to the higher hazard categories of various health hazard classes



Exclamation mark, often attributed to the lower hazard categories of various health hazards classes where it will replace the St. Andrew's cross

Moreover, the GHS will introduce the signal words “Danger” for the more severe hazard categories of a hazard class, and “Warning” for the less severe hazard categories.

A comprehensive description of the GHS labelling elements is set out in Annexes III-V to the draft proposal for the GHS Regulation. Table V.2 below presents the EU / GHS health hazard classifications as well as various elements of the corresponding EU / GHS label. It should be noted that the GHS allocates more expressive labelling elements to some hazard categories compared to the current EU system. The respective hazard categories are highlighted in red in the table.

**Table V.2:** Overview of health hazard classifications and related labelling elements according to current EU legislation / the GHS. It should be noted that the classifications given in each row reflect the most closely corresponding EU and GHS classifications.

<b>EU category of danger, risk phrase</b>	<b>EU symbol and indication of danger</b>	<b>GHS hazard class or category</b>	<b>GHS symbol</b>	<b>GHS signal word</b>
Very toxic (T+), R26	Skull and crossbones, "very toxic"	Acute toxicity (inhalation), cat. 1 and 2	Skull and crossbones	Danger
Very toxic (T+), R27	Skull and crossbones, "very toxic"	Acute toxicity (dermal), cat. 1 and 2	Skull and crossbones	Danger
Very toxic (T+), R28	Skull and crossbones, "very toxic"	Acute toxicity (oral), category 1 and 2	Skull and crossbones	Danger
Toxic (T), R23	Skull and crossbones, "toxic"	Acute toxicity (inhalation), cat. 2 and 3	Skull and crossbones	Danger
Toxic (T), R24	Skull and crossbones, "toxic"	Acute toxicity (dermal), category 2 and 3	Skull and crossbones	Danger
Toxic (T), R25	Skull and crossbones, "toxic"	Acute toxicity (oral), category 2 and 3	Skull and crossbones	Danger
Harmful (Xn), R20	St. Andrew's cross, "harmful"	Acute toxicity (inhalation), category 3 and 4	Skull and crossbones (cat. 3) or Exclamation mark (cat. 4)	Danger (cat. 3) or Warning (cat. 4)
Harmful (Xn), R21	St. Andrew's cross, "harmful"	Acute toxicity (dermal), category 3 and 4	Skull and crossbones (cat. 3) or Exclamation mark (cat. 4)	Danger (cat. 3) or Warning (cat. 4)
Harmful (Xn), R22	St. Andrew's cross, "harmful"	Acute toxicity (oral), category 3 and 4	Skull and crossbones (cat. 3) or Exclamation mark (cat. 4)	Danger (cat. 3) or Warning (cat. 4)
		Acute toxicity, category 5	No symbol	Warning
Corrosive (C), R34	Corrosion symbol, "corrosive"	Skin corrosion / irritation, category 1B and 1C	Corrosion symbol	Danger
Corrosive (C), R35	Corrosion symbol, "corrosive"	Skin corrosion / irritation, category 1A	Corrosion symbol	Danger
Irritant (Xi), R38	St. Andrew's cross, "irritant"	Skin corrosion / irritation, category 2	Exclamation mark	Warning
Irritant (Xi), R36	St. Andrew's cross, "irritant"	Serious eye damage / Eye irritation, category 2A	Exclamation mark (cat. 2A)	Warning
Irritant (Xi), R41	St. Andrew's cross, "irritant"	Serious eye damage / Eye irritation,	Corrosion symbol	Danger

		category 1		
Harmful (Xn), R42	St. Andrew's cross, "harmful"	Respiratory sensitisation, category 1	Health hazard ("Exploding man")	Danger
Irritant (Xi), R43	St. Andrew's cross, "irritant"	Skin sensitisation, category 1	Exclamation mark	Warning
Very Toxic (T+), R39 and Toxic (T), R39	Skull and crossbones, "very toxic" or "toxic"	STOT (single exposure), category 1	Health hazard ("Exploding man")	Danger
Toxic (T), R48	Skull and crossbones, "toxic"	STOT (repeated exposure), category 1	Health hazard ("Exploding man")	Danger
Harmful (Xn), R48	St. Andrew's cross, "harmful"	STOT (repeated exposure), category 2	Health hazard ("Exploding man")	Warning
Harmful (Xn), R68	St. Andrew's cross, "harmful"	STOT (single exposure), category 2	Health hazard ("Exploding man")	Warning
Harmful (Xn), R65	St. Andrew's cross, "harmful"	Aspiration hazard, cat. 1 and 2	Health hazard ("Exploding man") (cat. 1 and 2)	Danger (cat. 1) or Warning (cat. 2)
Carcinogen cat. 1 (T), R45 or R49	Skull and crossbones, "toxic"	Carcinogen category 1 A	Health hazard ("Exploding man")	Danger
Carcinogen cat. 2 (T), R45 or R49	Skull and crossbones, "toxic"	Carcinogen category 1 B	Health hazard ("Exploding man")	Danger
Carcinogen cat. 3 (Xn), R40	St. Andrew's cross, "harmful"	Carcinogen category 2	Health hazard ("Exploding man")	Warning
Mutagen cat. 1 (T), R46	Skull and crossbones, "toxic"	Mutagen category 1 A	Health hazard ("Exploding man")	Danger
Mutagen cat. 2 (T), R46	Skull and crossbones, "toxic"	Mutagen category 1 B	Health hazard ("Exploding man")	Danger
Mutagen cat. 3 (Xn), R68	St. Andrew's cross, "harmful"	Mutagen category 2	Health hazard ("Exploding man")	Warning
Toxic to reproduction cat. 1 (T), R60 or R61	Skull and crossbones, "toxic"	Reproductive toxicant, category 1A	Health hazard ("Exploding man")	Danger
Toxic to reproduction cat. 2 (T), R60 or R61	Skull and crossbones, "toxic"	Reproductive toxicant, category 1B	Health hazard ("Exploding man")	Danger
Toxic to reproduction cat. 3 (Xn), R62 or R63	St. Andrew's cross, "harmful"	Reproductive toxicant, category 2	Health hazard ("Exploding man")	Warning
R64	No symbol, no indication of danger	Reproductive toxicant, effects on or via lactation	No symbol	No signal word

Table V.3 gives a brief overview of the general hazard-specific conclusions which can be drawn from the available documents and studies mentioned in Annex I to this study. It reflects those hazards which will be included in the GHS Regulation. While the first column represents a current EU hazard classification, the second column gives an indication of which GHS hazard class and / or category would most closely correspond to the EU classification. The third and fourth columns show what potential effects may be expected in general, when the reference to the EU classification as shown in column 1 will be replaced by the reference to the GHS classification as shown in column 2 in a particular downstream act:

**Table V.3:** Potential effects related to those endpoints which will be included in the GHS Regulation. Statements related to potential effects are derived from a comparison of the current EU and GHS classification criteria.

EU category of danger / risk phrase acc. to Directive 67/548/EEC	Most closely corresponding GHS classification(s)	Potential effect(s) on classified substances	Potential effect(s) on classified mixtures
Physical Hazards			
Explosives (E), R2 and R3	<ul style="list-style-type: none"> <li>§ Explosives, Division 1.1-1.6</li> <li>§ Explosives, unstable explosives</li> <li>§ Self-Reactives, Type A or B</li> <li>§ Organic Peroxides, Type A or B</li> </ul>	<ul style="list-style-type: none"> <li>§ Different substances</li> <li>§ Additional substances</li> <li>§ Some unintentional explosives are not covered by the GHS (work ongoing at UN level)</li> </ul>	<ul style="list-style-type: none"> <li>§ Different mixtures</li> <li>§ Additional mixtures</li> <li>§ Some unintentional explosives are not covered by the GHS (work ongoing at UN level)</li> </ul>
Oxidising (O), R7	<ul style="list-style-type: none"> <li>§ Organic Peroxides, Type C-F</li> </ul>	<ul style="list-style-type: none"> <li>§ Some fewer substances</li> </ul>	<ul style="list-style-type: none"> <li>§ Some fewer mixtures</li> </ul>
	<ul style="list-style-type: none"> <li>§ Organic Peroxides, Type G</li> </ul>	<ul style="list-style-type: none"> <li>§ Additional substances</li> </ul>	<ul style="list-style-type: none"> <li>§ Additional mixtures</li> </ul>
Oxidising (O), R8	<ul style="list-style-type: none"> <li>§ Oxidising Gases, category 1</li> <li>§ Oxidising Liquids, category 1, 2 or 3</li> <li>§ Oxidising Solids, category 1, 2 or 3</li> </ul>	<ul style="list-style-type: none"> <li>§ None</li> <li>§ None</li> <li>§ Additional substances</li> </ul>	<ul style="list-style-type: none"> <li>§ None</li> <li>§ None</li> <li>§ Additional mixtures</li> </ul>
Oxidising (O), R9	<ul style="list-style-type: none"> <li>§ Oxidising Liquids, category 1</li> <li>§ Oxidising Solids, category 1</li> </ul>	<ul style="list-style-type: none"> <li>§ None</li> <li>§ None</li> </ul>	<ul style="list-style-type: none"> <li>§ None</li> <li>§ None</li> </ul>
Extremely Flammable (F+), R12	<ul style="list-style-type: none"> <li>§ Flammable Liquids, category 1</li> </ul>	<ul style="list-style-type: none"> <li>§ None</li> </ul>	<ul style="list-style-type: none"> <li>§ None</li> </ul>

	§ Flammable Gases, category 1 § Self-Reactives, Type C-F (liquids)	§ None § Additional substances	§ None § Additional mixtures
Highly Flammable (F), R11	§ Flammable Liquids, category 2 § Flammable Solids, category 1 or 2 § Self-Reactives, Type C-F (solids)	§ None § None § Additional substances	§ None § None § Additional mixtures
Flammable, R10	§ Flammable Liquids, category 3	§ Some fewer substances	§ Some fewer mixtures
Highly Flammable (F), R15	§ S&M which, in contact with water, emit flammable gases, category 1, 2 or 3	§ None	§ None
Highly Flammable (F), R17	§ Pyrophoric Liquids, category 1 § Pyrophoric Solids, Category 1	§ None § None	§ None § None
	§ Self-Heating S&M, category 1 or 2	§ New, therefore additional substances	§ New, therefore additional mixtures
Cf. Directive 75/324/EEC (to be revised)	§ Flammable Aerosols, category 1 or 2	§ New	§ New
	§ Gases under Pressure	§ New, therefore additional substances	§ New, therefore additional mixtures
	§ Corrosive to Metals	§ New, therefore additional substances	§ New, therefore additional mixtures
<b>Health Hazards</b>			
Very Toxic (T+), R28	§ Acute Toxicity, category 1 (oral)	§ Fewer substances if replaced by GHS category 1	§ Statement not possible
Toxic (T), R25	§ Acute Toxicity, category 2 or 3 (oral)	§ Additional substances if replaced by GHS category 2 and 3	§ Statement not possible

Harmful (Xn), R22	§ Acute Toxicity, category 4 (oral)	§ Fewer substances if replaced by GHS category 4	§ Statement not possible
Very Toxic (T+), R27	§ Acute Toxicity, category 1 (dermal)	§ None	§ Statement not possible
Toxic (T), R24	§ Acute Toxicity, category 2 (dermal)	§ Fewer substances if replaced by GHS category 2	§ Statement not possible
Harmful (Xn), R21	§ Acute Toxicity, category 3 or 4 (dermal)	§ Additional substances if replaced by GHS category and 4	§ Statement not possible
Very Toxic (T+), R26 (inhalation of gases)	§ Acute Toxicity, category 1 (inhalation of gases)	§ None	§ Statement not possible; discussions at OECD / UN level
Toxic (T), R23 (inhalation of gases)	§ Acute Toxicity, category 2 (inhalation of gases)	§ None	§ Statement not possible; discussions at OECD / UN level
Harmful (Xn), R20 (inhalation of gases)	§ Acute Toxicity, category 3 or 4 (inhalation of gases)	§ None	§ Statement not possible; discussions at OECD / UN level
Very Toxic (T+), R26 (inhalation of vapours)	§ Acute Toxicity, category 1 (inhalation of vapours)	§ None	§ Statement not possible
Toxic (T), R23 (inhalation of vapours)	§ Acute Toxicity, category 2 (inhalation of vapours)	§ None	§ Statement not possible
Harmful (Xn), R20 (inhalation of vapours)	§ Acute Toxicity, category 3 or 4 (inhalation of vapours)	§ None	§ Statement not possible
Very Toxic (T+), R26 (aerosols & particulates)	§ Acute Toxicity, category 1 (inhalation of dust / mist / fume)	§ Fewer substances if replaced by GHS category 1 only	§ Statement not possible
Toxic (T), R23 (aerosols & particulates)	§ Acute Toxicity, category 2 or 3 (inhalation of dust /	§ Additional substances if replaced by GHS	§ Statement not possible

	mist / fume)	category 2 and 3	
Harmful (Xn), R20 (aerosols & particulates)	§ Acute Toxicity, category 4 (inhalation of dust / mist / fume)	§ None	§ Statement not possible
	§ Acute Toxicity, category 5 (all routes of uptake)	§ Would have comprised additional substances (new classification)	§ Would have comprised significantly more mixtures (new classification)
Corrosive (C), R35	§ Skin corrosion / irritation, cat. 1A	§ None	§ Additional mixtures
Corrosive (C), R34	§ Skin corrosion / irritation, category 1B or 1C	§ None	§ Additional mixtures
Irritant (Xi), R38	§ Skin corrosion / irritation, category 2	§ None	§ Additional mixtures
Irritant (Xi), R41	§ Serious eye damage / eye irritation, category 1	§ None	§ Additional mixtures
Irritant (Xi), R36	§ Serious eye damage / eye irritation, category 2 (A / B)	§ None	§ Additional mixtures
Harmful (Xn), R42	§ Respiratory sensitisation, cat. 1	§ None	§ None
Irritant (Xi), R43	§ Skin sensitisation, category 1	§ None	§ None
Very Toxic (T+), R39/28	§ STOT (single exposure), cat. 1	§ Additional substances	§ Additional mixtures
Very Toxic (T+), R39/27	§ STOT (single exposure), cat. 1	§ Additional substances	§ Additional mixtures
Very Toxic (T+), R39/26	§ STOT (single exposure), cat. 1	§ Additional substances	§ Additional mixtures
Toxic (T), R39/25	§ STOT (single exposure), cat. 1	§ Additional substances	§ Additional mixtures
Toxic (T), R39/24	§ STOT (single exposure), cat. 1	§ Additional substances	§ Additional mixtures
Toxic (T), R39/23	§ STOT (single	§ Additional	§ Additional

	exposure), cat. 1	substances	mixtures
Harmful (Xn), R68/22	§ STOT (single exposure), cat. 2	§ None	§ None
Harmful (Xn), R68/21	§ STOT (single exposure), cat. 2	§ None	§ None
Harmful (Xn), R68/20	§ STOT (single exposure), cat. 2	§ None	§ None
Irritant (Xi), R37	§ STOT (single exposure), cat. 3	§ None	§ None
[R67] – additional R-phrase	§ STOT (single exposure), cat. 3	§ New, therefore additional substances (converted EU “left-over”)	§ New, therefore additional mixtures
Toxic (T), R48/25	§ STOT (repeated exposure), cat. 1	§ Additional substances	§ Additional mixtures
Toxic (T), R48/24	§ STOT (repeated exposure), cat. 1	§ Additional substances	§ Additional mixtures
Toxic (T), R48/23	§ STOT (repeated exposure), cat. 1	§ No statement available	§ No statement available
Harmful (Xn), R48/22	§ STOT (repeated exposure), cat. 2	§ Additional substances	§ Additional mixtures
Harmful (Xn), R48/21	§ STOT (repeated exposure), cat. 2	§ Additional substances	§ Additional mixtures
Harmful (Xn), R48/20	§ STOT (repeated exposure), cat. 2	§ No statement available	§ No statement available
Harmful (Xn), R65	§ Aspiration Hazard, category 1	§ Additional substances	§ Additional mixtures
Mutagen category 1 (T), R46	§ Germ Cell Mutagenicity, category 1A	§ None	§ None
Mutagen category 2 (T), R46	§ Germ Cell Mutagenicity, category 1B	§ None	§ None
Mutagen category 3 (Xn), R68	§ Germ Cell Mutagenicity, category 2	§ None	§ None
Carcinogen category 1	§ Carcinogenicity,	§ None	§ None

(T), R45 or R49	category 1A		
Carcinogen category 2 (T), R45 or R49	§ Carcinogenicity, category 1B	§ None	§ None
Carcinogen category 3 (Xn), R40	§ Carcinogenicity, category 2	§ None	§ None
Toxic to Reproduction (T), R60 or R61	§ Reproductive Toxicity, cat. 1A	§ None	§ Possibly some more mixtures
Toxic to Reproduction (T), R60 or R61	§ Reproductive Toxicity, cat. 1B	§ None	§ Possibly some more mixtures
Toxic to Reproduction (Xn), R62 or R63	§ Reproductive Toxicity, cat. 2	§ None	§ Possibly some more mixtures
[R64] – additional R-phrase	§ Reproductive toxicity, effects on or via lactation	§ New, therefore additional substances (converted EU “left-over”)	§ New, therefore additional mixtures
<b>Environmental Hazards</b>			
(N), R50	§ Hazardous to the aquatic environment, acute I	§ Equivalent number of substances	§ No statement available
(N), R50/53	§ Hazardous to the aquatic environment, chronic I	§ Equivalent number of substances	§ Possibly different / additional mixtures
(N), R51/R53	§ Hazardous to the aquatic environment, chronic II	§ Equivalent number of substances	§ Possibly different / additional mixtures
R52/53	§ Hazardous to the aquatic environment, chronic III	§ Equivalent number of substances	§ No statement available
R53	§ Hazardous to the aquatic environment, chronic IV	§ Equivalent number of substances	§ No statement available
R59	§ Criteria under development at UN level	§ No statement possible	§ No statement possible

Some comments on the terminology used in the table:

- § “additional substances / mixtures” does not reflect the relative amount of additional substances or mixtures classified under GHS. One reason is that the significance of differences in the criteria can not always be assessed. An estimate of how many substances might be affected is given by an evaluation of the current Annex I to Directive 67/548/EEC with regard to existing and new chemicals, cf. Annex II to this study;
- § “new” either means that the GHS defines a completely new hazard classification for supply & use, e.g. Gases Under Pressure, or that the GHS classifies where there is only an additional labelling requirement today, e.g. in case of R64 and R67;
- § “possibly” means that there are indications only which point in this direction;
- § “Statement not possible” is used where the scientific evidence does not permit final conclusions to be drawn;
- § “None” means no effect expected

It should be noted that the statements in Table V.3 are indicative. They rely on theoretical considerations based on the comparison of the EU and the GHS classification criteria.

## **VI. Characterisation of Potential Effects of the Introduction of the GHS and Solutions**

### **1. Characterisation**

In case a particular downstream act shifts reference from the current EU classification scheme to the GHS, particular aspects become relevant:

- The degree of similarity between the EU and the GHS classification criteria determines a particular effect: The less the EU and the GHS criteria deviate from each other, the less pronounced the effect will be. Effects are characterised as minimal if a particular downstream act will cover about the same kind and number of classified substances and mixtures (preparations) as currently because the criteria are considered to be equivalent. In these cases, no further adaptations of the legislation at issue are deemed necessary.
- It is relevant whether the hazard classification is the main trigger for obligations in a downstream act or whether the obligations depend also on the outcome of risk or exposure assessment.
- If hazard classification is the main trigger for obligations, potential effects for the downstream act will then follow from differences in the classification criteria, either due to the introduction of new hazard classifications or due to changes of the criteria for hazards that are already addressed in the current system;

**Such effects may be minimised by limited changes to the “downstream” act. This can be addressed in two ways:**

1. **Exemption from the reference** to classified substances and preparations of those hazard classifications (classes and categories) which are newly introduced by the GHS. This means to refer to “substances and mixtures classified as hazardous in accordance with [GHS Regulation]”, but to exempt those additional hazard classifications, cf. Table VI.1 below, that will be newly introduced into the supply and use system by the GHS;
2. **Adaptation of the references** to certain classification criteria in a particular downstream act. For that purpose the references would be shifted to the most closely corresponding GHS criteria; in addition, the cut-off limits or concentration thresholds

as specified in the current classification system would be maintained. The latter would then need to be specified for the respective “downstream” act.

Both approaches can be proposed as consequential changes in the GHS -Regulation itself or in separate amendments of the respective downstream acts.

It should be noted that further changes to certain downstream acts may be necessary, e.g. in case a marginal effect due to applying the GHS criteria is adversely reinforced by provisions inherent to the legislation at issue, e.g. for the Seveso II Directive.

- If the outcome of risk or exposure assessment is the main trigger for obligations, any effect due to the differences in the classification criteria has only indirect implications. The need for additional risk assessments may have to be checked whereas the results and conclusions of any examination or assessments may not necessitate further action. Accordingly, potential effects may either be characterised as minimal or may be minimised by changes to the hazard - or risk-related conditions of any obligation.

## 2. Solutions

In all cases the references to the criteria for classification according to Directives 67/548/EEC or 1999/45/EC will be replaced by references to the criteria in the GHS -Regulation. A reference table in Annex VIII to the GHS draft Regulation will provide for the appropriate hazard classes and categories / types / divisions.

- Where effects of the introduction of the GHS -Regulation on a respective “downstream” act are considered to be absent or minimal, no specific adaptations are suggested.
- Where effects of the introduction of the GHS -Regulation on a respective “downstream” act need to be minimised, one of the two following solutions is proposed:

### Solution 1

The following hazard classes and categories, which are more or less additional hazard classes or categories compared to the current system, shall be exempt from the reference to the GHS Regulation in the respective “downstream” act:

Table VI.1: GHS hazard classifications proposed for exemption from the scope of particular “downstream” acts (Solution 1) because they are additional hazard classes or categories compared to the current system

<i>Gases under pressure</i> , in accordance with Annex I Chapter 2.5
<i>Self-reactive substances and mixtures, Type C to G</i> , in accordance with Annex I Chapter 2.8
<i>Self-heating substances and mixtures</i> , in accordance with Annex I Chapter 2.11
<i>Oxidising liquids, category 3</i> , in accordance with Annex I Chapter 2.13
<i>Oxidising solids, category 3</i> , in accordance with Annex I Chapter 2.14
<i>Organic peroxides, Type G</i> , in accordance with Annex I Chapter 2.15
<i>Corrosive to metals</i> , in accordance with Annex I Chapter 2.16
<i>Reproductive toxicity, effects on or via lactation</i> , in accordance with Annex I Chapter 3.7
<i>STOT, single exposure, category 3 (narcotic effects)</i> , in accordance with Annex I Chapter 3.8

## **Solution 2**

Where references are made to specific hazard criteria for substances and preparations as defined in Directives 67/548/EEC and 1999/45/EC, and for the most closely corresponding hazard in the GHS Regulation the cut-off levels or concentration thresholds are different, the current levels or thresholds shall be maintained for this specific reference in any specified downstream act.

Where this solution is proposed, the cut-off level or concentration threshold is specified in Table VI.2 for the respective hazard. These values shall only apply in the specified cases, and not in cases of general reference to the classification.

All suggested solutions are included Table VI.2 below.

Table VI.2: Overview over hazard-specific options for those endpoints which will be included in the GHS-Regulation

EU category of danger / risk phrase acc. to Directive 67/548/EEC	Most closely corresponding GHS classification(s) (2 <sup>nd</sup> column)	Proposed adaptations for substances and mixtures to minimise effects
Physical Hazards		
Explosives (E), R2 and R3	§ Explosives, Division 1.1-1.6 § Explosives, unstable explosives § Self-Reactives, Type A and B § Organic Peroxides, Type A and B	§ Refer to the GHS classifications <i>Explosives, Division 1.1-1.6</i> and <i>Explosives, unstable explosives</i> as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Include in reference substances and mixtures for which test series A.14 according to Dir 67/548/EEC gives a positive test result
Oxidising (O), R7	§ Organic Peroxides, Type C-F	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Oxidising (O), R8	§ Oxidising Gases, category 1 § Oxidising Liquids, category 1, 2 and 3 § Oxidising Solids, category 1, 2 and 3	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 1:</u> Exempt from reference substances and mixtures

		classified in category 3 of the hazards <i>Oxidising Liquids and Oxidising Solids</i>
Oxidising (O), R9	§ Oxidising Liquids, category 1 § Oxidising Solids, category 1	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Extremely Flammable (F+), R12	§ Flammable Liquids, category 1 § Flammable Gases, category 1 § Self-Reactives, Type C-F (liquids)	§ Refer to the category 1 of the GHS classifications <i>Flammable Liquids</i> and <i>Flammable Gases</i> as specified in the 2 <sup>nd</sup> column § <u>Solution 1:</u> Exempt from reference liquid substances and mixtures classified in GHS hazard class <i>Self-Reactives, Type C-F</i>
Highly Flammable (F), R11	§ Flammable Liquids, category 2 § Flammable Solids, category 1 and 2 § Self-Reactives, Type C-F (solids)	§ Refer to the GHS classification <i>Flammable Liquids, category 2</i> and <i>Flammable Solids, category 1 and 2</i> as specified in the 2 <sup>nd</sup> column § <u>Solution 1:</u> Exempt from reference solid substances and mixtures classified in GHS hazard class <i>Self-Reactives, Type C-F</i>
Flammable, R10	§ Flammable Liquids, category 3	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified substances and mixtures with an upper flash point limit > 55°C
Highly Flammable (F), R15	§ S&M which, in contact with water, emit flammable gases, category 1, 2 and 3	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Highly Flammable (F), R17	§ Pyrophoric Liquids, category 1 § Pyrophoric Solids, category 1	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column

	§ Self-Heating S&M, category 1 and 2	§ <u>Solution 1:</u> Exempt from reference substances and mixtures classified in this hazard class
Cf. Directive 75/324/EEC (to be revised)	§ Flammable Aerosols, category 1 and 2	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
	§ Gases under Pressure	§ <u>Solution 1:</u> Exempt from reference substances and mixtures classified in this hazard class
	§ Corrosive to Metals	§ <u>Solution 1:</u> Exempt from reference substances and mixtures classified in this hazard class
<b>Health Hazards</b>		
Very Toxic (T+), R28	§ Acute Toxicity, category 1 (oral)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Include in reference substances and mixtures classified in GHS category 2 up to LD <sub>50</sub> • 25 mg/kg bw
Toxic (T), R25	§ Acute Toxicity, category 2 and 3 (oral)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified substances and mixtures in the ranges 5 • LD <sub>50</sub> • 25 mg/kg bw and 200 • LD <sub>50</sub> • 300 mg/kg bw
Harmful (Xn), R22	§ Acute Toxicity, category 4 (oral)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u>

		Include in reference substances and mixtures classified in GHS category 3 from LD <sub>50</sub> • 200 mg/kg bw
Very Toxic (T+), R27	§ Acute Toxicity, category 1 (dermal)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Toxic (T), R24	§ Acute Toxicity, category 2 (dermal)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Include in reference substances and mixtures classified in GHS category 3 up to LD <sub>50</sub> • 400 mg/kg bw
Harmful (Xn), R21	§ Acute Toxicity, category 3 and 4 (dermal)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified substances and mixtures in the range 200 • LD <sub>50</sub> • 400 mg/kg bw
Very Toxic (T+), R26 (gases)	§ Acute Toxicity, category 1 (inhalation of gases)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Toxic (T), R23 (gases)	§ Acute Toxicity, category 2 (inhalation of gases)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Harmful (Xn), R20 (gases)	§ Acute Toxicity, category 3 and 4 (inhalation of gases)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Very Toxic (T+), R26 (vapours)	§ Acute Toxicity, category 1 (inhalation of vapours)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Toxic (T), R23 (vapours)	§ Acute Toxicity, category 2 (inhalation of vapours)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Harmful (Xn), R20 (vapours)	§ Acute Toxicity, category 3 and 4	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column

	(inhalation of vapours)	column
Very Toxic (T+), R26 (aerosols & particulates)	§ Acute Toxicity, category 1 (inhalation of dust / mist / fume)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Include in reference substances and mixtures classified in GHS category 2 up to LC <sub>50</sub> • 0.25 mg/l/4h
Toxic (T), R23 (aerosols & particulates)	§ Acute Toxicity, category 2 and 3 (inhalation of dust / mist / fume)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified substances and mixtures in the range 0.05 • LC <sub>50</sub> • 0.25 mg/l/4h
Harmful (Xn), R20 (aerosols & particulates)	§ Acute Toxicity, category 4 (inhalation of dust / mist / fume)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Corrosive (C), R35	§ Skin corrosion / irritation, category 1A	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified mixtures below 5% concentration of substances classified for this hazard
Corrosive (C), R34	§ Skin corrosion / irritation, category 1B and 1C	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified mixtures below 10% concentration of substances classified for this hazard
Irritant (Xi), R38	§ Skin corrosion / irritation, category 2	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified mixtures below 20%

		concentration of substances classified for this hazard
Irritant (Xi), R41	§ Serious eye damage / eye irritation, category 1	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified mixtures below 10% concentration of substances classified for this hazard
Irritant (Xi), R36	§ Serious eye damage / eye irritation, category 2 (A / B)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified mixtures below 20% concentration of substances classified for this hazard
Harmful (Xn), R42	§ Respiratory sensitisation, category 1	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Irritant (Xi), R43	§ Skin sensitisation, category 1	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Very Toxic (T+), R39/28	§ STOT (single exposure), category 1	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified substances with LD <sub>50</sub> • 25 mg/kg bw; do not take account of such substances in mixture classification
Very Toxic (T+), R39/27	§ STOT (single exposure), category 1	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified substances with LD <sub>50</sub> • 50 mg/kg bw; do not take account of such substances in mixture classification

Very Toxic (T+), R39/26 (gas, vapour)	§ STOT (single exposure), category 1	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified substances with LC <sub>50</sub> • 0.5 mg/l/4h; do not take account of such substances in mixture classification
Very Toxic (T+), R39/26 (aerosols & particulates)	§ STOT (single exposure), category 1 (dust / mist / fume)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified substances with LC <sub>50</sub> • 0.25 mg/l/4h; do not take account of such substances in mixture classification
Toxic (T), R39/25	§ STOT (single exposure), category 1	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified substances with LD <sub>50</sub> • 200 mg/kg bw; do not take account of such substances in mixture classification
Toxic (T), R39/24	§ STOT (single exposure), category 1	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified substances with LD <sub>50</sub> • 400 mg/kg bw; do not take account of such substances in mixture classification
Toxic (T), R39/23 (gas, vapour)	§ STOT (single exposure), category 1	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified substances with LC <sub>50</sub> •

		2 mg/l/4h; do not take account of such substances in mixture classification
Toxic (T), R39/23 (aerosols & particulates)	§ STOT (single exposure), category 1 (dust / mist / fume)	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Harmful (Xn), R68/22	§ STOT (single exposure), category 2	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Harmful (Xn), R68/21	§ STOT (single exposure), category 2	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Harmful (Xn), R68/20	§ STOT (single exposure), category 2	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Irritant (Xi), R37	§ STOT (single exposure), category 3	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
[R67] – additional R-phrase	§ STOT (single exposure), category 3 (narcotic effects)	§ <u>Solution 1:</u> Exempt from reference substances and mixtures classified in <i>STOT (single exposure)</i> , category 3
Toxic (T), R48/25	§ STOT (repeated exposure), category 1	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column  § <u>Solution 2:</u> Exempt from reference classified substances with LD <sub>50</sub> • 5 mg/kg bw; do not take account of such substances in mixture classification
Toxic (T), R48/24	§ STOT (repeated exposure), category 1	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column  § <u>Solution 2:</u> Exempt from reference classified substances with LD <sub>50</sub> • 10 mg/kg bw; do not take account of such substances in

		mixture classification
Toxic (T), R48/23 (gas, vapour)	§ STOT (repeated exposure), category 1	<p>§ Refer to the GHS classifications as specified in the 2<sup>nd</sup> column</p> <p>§ <u>Solution 2:</u> Exempt from reference classified substances with LC<sub>50</sub> • 0.025 mg/l/6hr/d; do not take account of such substances in mixture classification</p>
Harmful (Xn), R48/22	§ STOT (repeated exposure), category 2	<p>§ Refer to the GHS classifications as specified in the 2<sup>nd</sup> column</p> <p>§ <u>Solution 2:</u> Exempt from reference classified substances with LD<sub>50</sub> • 50 mg/kg bw; do not take account of such substances in mixture classification</p>
Harmful (Xn), R48/21	§ STOT (repeated exposure), category 2	<p>§ Refer to the GHS classifications as specified in the 2<sup>nd</sup> column</p> <p>§ <u>Solution 2:</u> Exempt from reference classified substances with LD<sub>50</sub> • 100 mg/kg bw; do not take account of such substances in mixture classification</p>
Harmful (Xn), R48/20 (gas, vapour)	§ STOT (repeated exposure), category 2	<p>§ Refer to the GHS classifications as specified in the 2<sup>nd</sup> column</p> <p>§ <u>Solution 2:</u> Exempt from reference classified substances with LC<sub>50</sub> • 0.25 mg/l/6h/d; do not take account of such substances in mixture classification</p>
Harmful (Xn), R65	§ Aspiration Hazard, category 1	<p>§ Refer to the GHS classifications as specified in the 2<sup>nd</sup> column</p> <p>§ <u>Solution 2:</u></p>

		Exempt from reference classified substances and mixtures with a kinematic viscosity above 7 mm <sup>2</sup> /s
Mutagen category 1 (T), R46	§ Germ Cell Mutagenicity, category 1A	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Mutagen category 2 (T), R46	§ Germ Cell Mutagenicity, category 1B	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Mutagen category 1 (Xn), R68	§ Germ Cell Mutagenicity, category 2	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Carcinogen category 1 (T), R45 or R49	§ Carcinogenicity, category 1A	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Carcinogen category 2 (T), R45 or R49	§ Carcinogenicity, category 1B	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Carcinogen category 2 (Xn), R40	§ Carcinogenicity, category 2	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
Toxic to Reproduction category 1 (T), R60 or R61	§ Reproductive Toxicity, category 1A	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified mixtures below 0.5% concentration of substances classified for this hazard
Toxic to Reproduction category 2 (T), R60 or R61	§ Reproductive Toxicity, category 1B	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column § <u>Solution 2:</u> Exempt from reference classified mixtures below 0.5% concentration of substances classified for this hazard
Toxic to Reproduction category 3 (Xn),	§ Reproductive Toxicity, category 2	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column

R62 or R63		§ <u>Solution 2:</u> Exempt from reference classified mixtures below 5% concentration of substances classified for this hazard
[R64] – additional R-phrase	§ Reproductive toxicity, effects on or via lactation	§ <u>Solution 1:</u> Exempt from reference substances and mixtures classified in hazard category <i>effects on or via lactation</i>  § <u>Solution 2:</u> Exempt from reference classified mixtures below 0.5% concentration of substances classified for this hazard
Environmental Hazards		
(N), R50	§ Hazardous to the aquatic environment, acute I	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
(N), R50/53	§ Hazardous to the aquatic environment, chronic I	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
(N), R51/R3	§ Hazardous to the aquatic environment, chronic II	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
R52/53	§ Hazardous to the aquatic environment, chronic III	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
R53	§ Hazardous to the aquatic environment, chronic IV	§ Refer to the GHS classifications as specified in the 2 <sup>nd</sup> column
R59	§ Criteria under development at UN level	§ Classify as soon as criteria are adopted at UN level and taken over in the GHS Regulation

Comment: For STOT (single / repeated exposure), the GHS may employ different units for the criteria compared to the EU classifications R39, R48 or R68. In such cases, the adaptation of the cut-off values according to Solution 2 may have to be reviewed.

## **VII. Summary of the Conclusions**

This analysis concludes that the implementation of the GHS Purple Book in the GHS Regulation will entail effects on EU downstream legislation which are mostly minimal or can be minimised through limited consequential adaptations of the respective acts. For 22 of the examined pieces of legislation it is concluded that either no change is necessary or that adaptations based on Solution 1 and / or Solution 2, cf. Chapter VI, are appropriate. Only for a few acts also other ways of simple adaptation are suggested. Most of the respective adaptations can be performed in the GHS Regulation itself. Only for the Seveso II Directive, a separate amendment seems more appropriate.

It should be emphasised that this analysis does not intend to pre-empt particular changes to any of the downstream acts, because this is seen to remain in the competence of the responsible Commission Service. Nor does it require such changes to be implemented through provisions in the GHS Regulation itself or through specific amendments to downstream legislation prepared by the responsible Service. The decision on the appropriate approach will be taken only after individual consultation with the responsible Service.

### 1. Downstream legislation with GHS effects characterised as minimal if any; changes to the legislation are not deemed necessary (neither Solution 1 nor Solution 2):

- § Regulation (EC) No 648/2004/EC of the European Parliament and of the Council of 31 March 2004 on detergents
- § Directive 2004/42/EC of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in decorative paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC
- § 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
  - Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 establishing the list of priority substances
- § 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
- § Council Directive 1992/85/EEC of 19 October 1992 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
- § Council Directive 1992/58/EEC of 24 June 1992 on the minimum requirements for the provisions of safety and/or health signs at work

- § Council Directive 91/157/EEC of 18 March 1991 on batteries and accumulators containing certain dangerous substances
- 2. Downstream legislation with GHS effects that can be minimised through Solution 1 and / or Solution 2:
  - § Regulation (EC) No 1980/2000 of the European Parliament and of the Council on a revised Community eco-label award scheme
    - Commission Decision 2001/523/EC of 27 June 2001 establishing the ecological criteria for the award of the Community eco-label to all-purpose cleaners and cleaners for sanitary facilities
    - Commission Decision 2001/607/EC of 19 July 2001 establishing the ecological criteria for the award of the Community eco-label to hand dishwashing detergents
    - Commission Decision 2002/739/EC of 3 September 2002 establishing revised ecological criteria for the award of the Community eco-label to indoor paints and varnishes and amending Decision 1999/10/EC
    - Commission Decision 2003/31/EC of 29 November 2002 establishing revised ecological criteria for the award of the Community eco-label to detergents for dishwashers and amending Decision 1999/427/EC
    - Commission Decision 2003/200/EC of 14 February 2003 establishing revised ecological criteria for the award of the Community eco-label to laundry detergents and amending Decision 1999/476/EC
  - § Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products
  - § Council Directive 88/378/EEC on the approximation of laws of the Member States concerning the safety of toys
  - § Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers
  - § Directive 1998/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market
  - § Council Directive 91/414/EEC concerning the placing of plant protection products on the market
  - § Draft REACH Regulation, in the version as agreed by the Council on 13 December 2005
  - § Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals
  - § Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations

- § Council Directive 1996/62/EC of 27 September 1996 on ambient air quality assessment and management
  - § Council Directive 1998/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work
  - § Council Directive 1994/33/EC of 22 June 1994 on the protection of young people at work
  - § Council Directive 91/689/EC of 12 December 1991 on hazardous waste
    - Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste
  - § Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of-life vehicles
  - § Directive 2002/95/EC of the European Parliament and the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
3. Downstream legislation which may be adapted by a separate amendment:
- § Council Directive 1996/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances, as amended by Directive 2003/105/EC of the European Parliament and of the Council of 16 December 2003

On the following pages, the solutions proposed for the different pieces of downstream legislation are tabled. It is assumed that these options apply as consequential change to the shift of reference to the GHS criteria.

**Table VII.1:** Solutions to minimise potential effects of the GHS Regulation on “downstream” legislation. It is assumed that reference is shifted to the GHS Regulation or to the respective GHS criteria, where appropriate.

<b>EU Legislation</b>	<b>Reference to EU System of Classification &amp; Labelling</b>	<b>General Assessment of Effects</b>	<b>Solutions to minimise potential effects of the GHS Regulation</b>
Regulation (EC) No 648/2004/EC of the European Parliament and of the Council of 31 March 2004 on detergents	§ Classification & labelling acc. to Directives 67/548/EEC and 1999/45/EC	§ Minimal / No effects	§ <b>No specific adaptation needed</b>
<p>Regulation (EC) No 1980/2000 of the European Parliament and of the Council on a revised Community eco-label award scheme</p> <p>§ Commission Decision 2001/523/EC of 27 June 2001 establishing the ecological criteria for the award of the Community eco-label to all-purpose cleaners and cleaners for sanitary facilities</p> <p>§ Commission Decision 2001/607/EC of 19 July 2001 establishing the ecological criteria for the award of the Community eco-label to hand dishwashing detergents</p> <p>§ Commission Decision 2002/739/EC of 3 September 2002 establishing revised ecological criteria for the award of the Community eco-label to indoor paints and varnishes and amending Decision 1999/10/EC</p> <p>§ Commission Decision 2003/31/EC of</p>	§ R-phrases and categories of danger: R23, R24, R25, R26, R27, R28, R31, R39, R40, R42, R43, R45, R46, R48, R49, R60, R61, R62, R63, R64, R68, R50-53, R59	§ Effects to be minimised	<p>§ <b>Solution 2 acc. to Table VI.2 for the following endpoints:</b></p> <ul style="list-style-type: none"> <li>- <u>Acute Toxicity, category 2 and 3 (inhalation of dust / mist / fume):</u> Exempt from reference classified substances and mixtures in the range 0.05 • LC<sub>50</sub> • 0.25 mg/l/4h</li> <li>- <u>Acute Toxicity, category 2 (dermal):</u> Include in reference substances and mixtures classified in GHS category 3 up to LD<sub>50</sub> • 400 mg/kg bw</li> <li>- <u>Acute Toxicity, category 2 and 3 (oral):</u> Exempt from reference classified substances and mixtures in the ranges 5 • LD<sub>50</sub> • 25 mg/kg bw and 200 • LD<sub>50</sub> • 300 mg/kg bw</li> <li>- <u>Acute Toxicity, category 1 (inhalation of dust / mist / fume):</u> Include in reference substances and mixtures classified in GHS category 2 up to LC<sub>50</sub> • 0.25 mg/l/4h</li> </ul>

<p>29 November 2002 establishing revised ecological criteria for the award of the Community eco-label to detergents for dishwashers and amending Decision 1999/427/EC</p> <p>§ Commission Decision 2003/200/EC of 14 February 2003 establishing revised ecological criteria for the award of the Community eco-label to laundry detergents and amending Decision 1999/476/EC</p>			<ul style="list-style-type: none"> <li>- <u>Acute Toxicity, category 1 (oral)</u>: Include in reference substances and mixtures classified in GHS category 2 up to LD<sub>50</sub> • 25 mg/kg bw</li> <li>- <u>STOT (single exposure), cat. 1 (oral)</u>: Exempt from reference classified substances with LD<sub>50</sub> • 25 mg/kg bw; do not take account of such substances in mixture classification</li> <li>- <u>STOT (single exposure), cat. 1 (dermal)</u>: Exempt from reference classified substances with LD<sub>50</sub> • 50 mg/kg bw; do not take account of such substances in mixture classification</li> <li>- <u>STOT (single exposure), cat. 1 (gas, vapour)</u>: Exempt from reference classified substances with LC<sub>50</sub> • 0.5 mg/l/4h; do not take account of such substances in mixture classification</li> <li>- <u>STOT (single exposure), cat. 1 (dust / mist / fume)</u>: Exempt from reference classified substances with LC<sub>50</sub> • 0.25 mg/l/4h; do not take account of such substances in mixture classification</li> <li>- <u>STOT (repeated exposure), cat. 1 (oral)</u>: Exempt from reference classified substances with LD<sub>50</sub> • 5 mg/kg bw; do not take account of such substances in mixture</li> </ul>
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			<p>classification</p> <ul style="list-style-type: none"> <li>- <u>STOT (repeated exposure), cat. 1 (dermal)</u>: Exempt from reference classified substances with <math>LD_{50} \cdot 10</math> mg/kg bw; do not take account of such substances in mixture classification</li> <li>- <u>STOST (repeated exposure), category 1 (gas, vapour)</u>: Exempt from reference classified substances with <math>LC_{50} \cdot 0.025</math> mg/l/6h/d; do not take account of such substances in mixture classification</li> <li>- <u>STOT (repeated exposure), cat. 2 (oral)</u>: Exempt from reference classified substances with <math>LD_{50} \cdot 50</math> mg/kg bw; do not take account of such substances in mixture classification</li> <li>- <u>STOT (repeated exposure), cat. 2 (dermal)</u>: Exempt from reference classified substances with <math>LD_{50} \cdot 100</math> mg/kg bw; do not take account of such substances in mixture classification</li> <li>- <u>STOT (repeated exposure), cat. 2 (gas, vapour)</u>: Exempt from reference classified substances with <math>LC_{50} \cdot 0.25</math> mg/l/6h/d; do not take account of such substances in mixture classification</li> <li>- <u>Reproductive Toxicity, cat. 1A and</u></li> </ul>
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			<p><u>1B</u>: Exempt from reference classified mixtures below 0.5% concentration of substances classified for this hazard</p> <ul style="list-style-type: none"> <li>- <u>Reproductive Toxicity, cat. 2</u>: Exempt from reference classified mixtures below 5% concentration of substances classified for this hazard</li> <li>- <u>Reproductive Toxicity, effects on or via lactation</u>: Exempt from reference classified mixtures below 0.5% concentration of substances classified for this hazard</li> </ul>
Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products	<p>§ Reference to the categories of danger as set out in Directive 67/548/EEC</p> <p>§ Reference to CMR category 1, 2 and 3</p>	§ Minimal / No effects	§ <b>Solution 1 acc. to Table VI.1</b>
Council Directive 88/378/EEC on the approximation of laws of the Member States concerning the safety of toys	<p>§ Classification &amp; labelling acc. to Directives 67/548/EEC and 1999/45/EC</p> <p>§ Reference to CMR category 1 and 2</p>	§ Effects to be minimised	§ <b>Solution 1 acc. to Table VI.1</b>
Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers	§ Reference to the categories of danger Extremely Flammable, Highly Flammable and Flammable as defined in Dir 67/548/EEC	§ Effects to be minimised	<p>§ <b>Solution 2 acc. to Table VI.2 for endpoints related to flammable properties</b></p> <ul style="list-style-type: none"> <li>- <u>Flammable Liquids, category 3</u>: Exempt from reference classified substances and mixtures with an upper flash point limit &gt; 55°C</li> </ul>

<p>Directive 1998/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market</p>	<p>§ Classification and labelling acc. to Directives 67/548/EEC and 1999/45/EC</p> <p>§ Reference to <i>CMR, Very Toxic, Toxic</i> and sensitising properties</p>	<p>§ Effects to be minimised</p>	<p>§ <b>Solution 1 acc. to Table VI.1</b></p> <p>§ <b>Solution 2 acc. to Table VI.2 for endpoints related to acute toxicity and reprotoxicity:</b></p> <ul style="list-style-type: none"> <li>- <u>Acute Toxicity, category 1-3 (oral)</u>: Exempt from reference classified substances and mixtures in the range 200 • LD<sub>50</sub> • 300 mg/kg bw</li> <li>- <u>Acute Toxicity, category 1-2 (dermal)</u>: Include in reference substances and mixtures classified in GHS category 3 up to LD<sub>50</sub> • 400 mg/kg bw</li> <li>- <u>Reproductive Toxicity, cat. 1A and 1B</u>: Exempt from reference classified mixtures below 0.5% concentration of substances classified for this hazard</li> <li>- If STOT (single / repeated exposure), category 1: adaptations cf. Table VI.2 above</li> </ul>
<p>Council Directive 91/414/EEC concerning the placing of plant protection products on the market</p>	<p>§ Classification of active substances and PPP acc. to Dir 67/548/EEC and 1999/45/EC</p> <p>§ Reference to <i>Very Toxic</i></p> <p>§ Packaging and labelling of PPP acc. to Directive 1999/45/EC</p> <p>§ Testing of metabolites triggered by T+, T and CMR (non-binding Guidance Document)</p>	<p>§ Effects to be minimised</p>	<p>§ <b>Solution 2 acc. to Table VI.2 for acute toxicity:</b></p> <ul style="list-style-type: none"> <li>- <u>Acute Toxicity, category 1 (oral)</u>: Include in reference substances and mixtures classified in GHS category 2 up to LD<sub>50</sub> • 25 mg/kg bw</li> <li>- <u>Acute Toxicity, category 1 (dust / mist / fume)</u>: Include in reference substances and mixtures classified in</li> </ul>

			GHS category 2 up to LC <sub>50</sub> • 0.25 mg/l/4h - If STOT (single exposure), category 1: adaptations cf. Table VI.2 above
Draft REACH Regulation, in the version as agreed by the Council on 13 December 2005	<ul style="list-style-type: none"> <li>§ Reference to selected categories of danger (CMR, respiratory sensitisers)</li> <li>§ Notification to the classification and labelling inventory 3 years after entry-into-force of REACH</li> <li>§ Information on classification and labelling needed at the time of substance registration</li> <li>§ Chemical Safety Report: documents the classification of substances; the exposure part is triggered by the classification as dangerous acc. to Directive 67/548/EEC</li> <li>§ Prioritisation of substance evaluation triggered by substances which are likely to be dangerous acc. to the criteria set out in Dir 67/548/EEC</li> <li>§ Exemptions of naturally occurring substances in Annex III to the REACH Regulation do not apply if substances are classified as dangerous</li> </ul>	§ Effects to be minimised	§ <b>Solution 1 acc. to Table VI.1</b>
Council Directive 1996/82/EC of 9 December 1996 on the control of major -	§ Annex I, Part 2: reference to numerous categories of danger and	§ Separate amendment necessary which	§ <b>Solution 1 acc. to Table VI.1 for the following GHS classifications:</b>

<p>accident hazards involving dangerous substances, as amended by Directive 2003/105/EC of the European Parliament and of the Council of 16 December 2003</p>	<p>R-phrases as set out in Directive 67/548/EEC</p> <p>§ Reference to the „explosive“ categories of UN/ADR, as transposed by Directive 1994/55/EC</p>	<p>includes minimising of classification effects</p>	<ul style="list-style-type: none"> <li>- <u>Oxidising Liquids and Solids:</u> Exempt from reference substances and mixtures classified in category 3 of the hazard classes <i>Oxidising Liquids and Oxidising Solids</i></li> <li>- <u>Organic Peroxides:</u> Exempt from reference substances and mixtures classified as <i>Type G</i>  <u>And</u> exempt from reference substances and mixtures classified as <i>Type A and B</i></li> <li>§ <b>Solution 2 acc. to Table VI.2 for all relevant classifications referred to in the Table of Annex I, Part 2 of the Seveso II Directive:</b></li> <li>- <u>Acute Toxicity, category 2 and 3 (inhalation of dust / mist / fume):</u> Exempt from reference classified substances and mixtures in the range 0.05 • LC<sub>50</sub> • 0.25 mg/l/4h</li> <li>- <u>Acute Toxicity, category 2 (dermal):</u> Include in reference substances and mixtures classified in GHS category 3 up to LD<sub>50</sub> • 400 mg/kg bw</li> <li>- <u>Acute Toxicity, category 2 and 3 (oral):</u> Exempt from reference classified substances and mixtures in the ranges 5 • LD<sub>50</sub> • 25 mg/kg bw and 200 • LD<sub>50</sub> • 300 mg/kg bw</li> <li>- <u>Acute Toxicity, category 1 (inhalation of dust / mist / fume):</u></li> </ul>
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			<p>Include in reference substances and mixtures classified in GHS category 2 up to LC<sub>50</sub> • 0.25 mg/l/4h</p> <ul style="list-style-type: none"> <li>- <u>Acute Toxicity, category 1 (oral)</u>: Include in reference substances and mixtures classified in GHS category 2 up to LD<sub>50</sub> • 25 mg/kg bw</li> <li>- <u>STOT (single exposure), cat. 1 (oral)</u>: Exempt from reference classified substances with LD<sub>50</sub> • 25 mg/kg bw; do not take account of such substances in mixture classification</li> <li>- <u>STOT (single exposure), cat. 1 (dermal)</u>: Exempt from reference classified substances with LD<sub>50</sub> • 50 mg/kg bw; do not take account of such substances in mixture classification</li> <li>- <u>STOT (single exposure), cat. 1 (gas, vapour)</u>: Exempt from reference classified substances with LC<sub>50</sub> • 0.5 mg/l/4h; do not take account of such substances in mixture classification</li> <li>- <u>STOT (single exposure), cat. 1 (dust / mist / fume)</u>: Exempt from reference classified substances with LC<sub>50</sub> • 0.25 mg/l/4h; do not take account of such substances in mixture classification</li> <li>- <u>STOT (repeated exposure), cat. 1 (oral)</u>: Exempt from reference</li> </ul>
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			<p>classified substances with LD<sub>50</sub> • 5 mg/kg bw; do not take account of such substances in mixture classification</p> <ul style="list-style-type: none"> <li>- <u>STOT (repeated exposure), cat. 1 (dermal)</u>: Exempt from reference classified substances with LD<sub>50</sub> • 10 mg/kg bw; do not take account of such substances in mixture classification</li> <li>- <u>STOT (repeated exposure), cat. 1 (gas, vapour)</u>: Exempt from reference classified substances with LC<sub>50</sub> • 0.025 mg/l/6h/d; do not take account of such substances in mixture classification</li> <li>- <u>Explosives</u>: Include in reference substances and mixtures for which test series A.14 according to Dir 67/548/EEC gives a positive test result</li> <li>- <u>Flammable Liquids, category 3</u>: Exempt from reference classified substances and mixtures with an upper flash point limit &gt; 55°C</li> </ul>
<p>Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals</p>	<p>§ Classification &amp; labelling acc. to Directives 67/548/EEC and 1999/45/EC</p> <p>§ Reference to the introduction of a new system of classification and labelling in the EU</p>	<p>§ Effects to be minimised</p>	<p>§ <b>Introduction of the fixed concentration limit 0.1% for mixtures containing substances from Annex I, Part 1, 2 and 3 to Regulation (EC) No 304/2003</b></p>

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	§ Reference to changes of labelling		
Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations	§ Reference to R40, R45, R46, R49, R60, R61	§ Minimal / No effects	§ <b>Solution 2 acc. to Table VI.2 for reprotoxicity:</b> - <u>Reproductive Toxicity, cat. 1A and 1B</u> : Exempt from reference classified mixtures below 0.5% concentration of substances classified for this hazard
Directive 2004/42/EC of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in decorative paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC	§ Reference to labelling acc. to Directive 67/548/EEC	§ Minimal / No effects	§ <b>No specific adaptation needed</b>
Council Directive 1996/62/EC of 27 September 1996 on ambient air quality assessment and management	§ Reference to the categories of danger as set out in Dir 67/548/EEC	§ Minimal / No effects	§ <b>Solution 1 acc. to Table VI.1</b>
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  § Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 establishing the list of priority substances	§ <u>No</u> explicit reference to the categories of danger as set out in Directive 67/548/EEC  § Reference to substances with toxic, carcinogenic and mutagenic properties	§ Minimal / No effects	§ <b>No specific adaptation needed</b>

<p>Council Directive 1998/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work</p>	<p>§ Reference to substances and preparations meeting the criteria for classification as set out in Dir 67/548/EEC and 1999/45/EC</p>	<p>§ Minimal / No effects</p>	<p>§ <b>Solution 1 acc. to Table VI.1</b></p>
<p>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</p>	<p>§ Reference to the categories of danger carcinogen and mutagen, cat. 1 and 2</p>	<p>§ Minimal / No effects</p>	<p>§ <b>No specific adaptation needed</b></p>
<p>Council Directive 1994/33/EC of 22 June 1994 on the protection of young people at work</p>	<p>§ Reference to numerous categories of danger and R-phrases in the Annex: Very Toxic, Toxic, Corrosive, Irritant, Harmful, R39, R40, R42, R43, R45, R46, R48, R60, R61, R12</p>	<p>§ Minimal / No effects</p>	<p>§ <b>Solution 2 acc. to Table VI.2 for the following endpoints:</b></p> <ul style="list-style-type: none"> <li>- <u>Acute Toxicity, category 4 (oral):</u> Include in reference substances and mixtures classified in GHS category 3 from LD<sub>50</sub> • 200 mg/kg bw</li> <li>- <u>Acute Toxicity, category 3 and 4 (dermal):</u> Exempt from reference classified substances and mixtures in the range 200 • LD<sub>50</sub> • 400 mg/kg bw</li> <li>- <u>Acute Toxicity, category 2 and 3 (inhalation of dust / mist / fume):</u> Exempt from reference classified substances and mixtures in the range 0.05 • LC<sub>50</sub> • 0.25 mg/l/4h</li> <li>- <u>Acute Toxicity, category 2 (dermal):</u> Include in reference substances and mixtures classified in GHS category 3 up to LD<sub>50</sub> • 400 mg/kg bw</li> <li>- <u>Acute Toxicity, category 2 and 3 (oral):</u> Exempt from reference</li> </ul>

			<p>classified substances and mixtures in the ranges <math>5 \cdot LD_{50} \cdot 25 \text{ mg/kg bw}</math> and <math>200 \cdot LD_{50} \cdot 300 \text{ mg/kg bw}</math></p> <ul style="list-style-type: none"> <li>- <u>Acute Toxicity, category 1 (inhalation of dust / mist / fume)</u>: Include in reference substances and mixtures classified in GHS category 2 up to <math>LC_{50} \cdot 0.25 \text{ mg/l/4h}</math></li> <li>- <u>Acute Toxicity, category 1 (oral)</u>: Include in reference substances and mixtures classified in GHS category 2 up to <math>LD_{50} \cdot 25 \text{ mg/kg bw}</math></li> <li>- <u>STOT (single exposure), cat. 1 (oral)</u>: Exempt from reference classified substances <math>LD_{50} \cdot 25 \text{ mg/kg bw}</math>; do not take account of such substances in mixture classification</li> <li>- <u>STOT (single exposure), cat. 1 (dermal)</u>: Exempt from reference classified substances with <math>LD_{50} \cdot 50 \text{ mg/kg bw}</math>; do not take account of such substances in mixture classification</li> <li>- <u>STOT (single exposure), cat. 1 (gas, vapour)</u>: Exempt from reference substances with <math>LC_{50} \cdot 0.5 \text{ mg/l/4h}</math>; do not take account of such substances in mixture classification</li> <li>- <u>STOT (single exposure), cat. 1 (dust / mist / fume)</u>: Exempt from reference substances with <math>LC_{50} \cdot</math></li> </ul>
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			<p>0.25 mg/l/4h; do not take account of such substances in mixture classification</p> <ul style="list-style-type: none"> <li>- <u>STOT (repeated exposure), cat. 1 (oral)</u>: Exempt from reference substances with LD<sub>50</sub> • 5 mg/kg bw; do not take account of such substances in mixture classification</li> <li>- <u>STOT (repeated exposure), cat. 1 (dermal)</u>: Exempt from reference substances with LD<sub>50</sub> • 10 mg/kg bw; do not take account of such substances in mixture classification</li> <li>- <u>STOT (repeated exposure), cat. 1 (gas, vapour)</u>: Exempt from reference substances with LC<sub>50</sub> • 0.025 mg/l/6h/d; do not take account of such substances in mixture classification</li> <li>- <u>STOT (repeated exposure), cat. 2 (oral)</u>: Exempt from reference substances with LD<sub>50</sub> • 50 mg/kg bw; do not take account of such substances in mixture classification</li> <li>- <u>STOT (repeated exposure), cat. 2 (dermal)</u>: Exempt from reference substances with LD<sub>50</sub> • 100 mg/kg bw; do not take account of such substances in mixture classification</li> <li>- <u>STOT (repeated exposure), cat. 2 (gas, vapour)</u>: Exempt from reference substances with LC<sub>50</sub> •</li> </ul>
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			<p>0.25 mg/l/6h/d; do not take account of such substances in mixture classification</p> <ul style="list-style-type: none"> <li>- <u>Reproductive Toxicity, cat. 1A and 1B</u>: Exempt from reference classified mixtures below 0.5% substance concentration</li> <li>- <u>Skin corrosion / irritation, cat. 1A</u>: Exempt from reference classified mixtures below 5% concentration of substances classified for this hazard</li> <li>- <u>Skin corrosion / irritation, cat. 1B and 1C</u>: Exempt from reference classified mixtures below 10% concentration of substances classified for this hazard</li> <li>- <u>Skin corrosion / irritation, cat. 2</u>: Exempt from reference classified mixtures below 20% concentration of substances classified for this hazard</li> <li>- <u>Serious eye damage / eye irritation, category 1</u>: Exempt from reference classified mixtures below 10% concentration of substances classified for this hazard</li> <li>- <u>Serious eye damage / eye irritation, category 2 (A/B)</u>: Exempt from reference classified mixtures below 20% concentration of substances classified for this hazard</li> <li>- <u>Explosives</u>: Include in reference</li> </ul>
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			substances and mixtures for which test series A.14 according to Dir 67/548/EEC gives a positive test result
Council Directive 1992/85/EEC of 19 October 1992 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	§ Reference to substances labelled as R40, R45, R46, R47 according to Directive 67/548/EEC	§ Minimal / No effects	§ <b>No specific adaptation needed</b>
Council Directive 1992/58/EEC of 24 June 1992 on the minimum requirements for the provisions of safety and/or health signs at work	§ Reference to classification and labelling acc. to Directives 67/548/EEC and 1999/45/EC	§ Minimal / No effects	§ <b>No specific adaptation needed</b>
Council Directive 91/689/EC of 12 December 1991 on hazardous waste  Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste	§ Reference to the classification criteria of Directive 67/548/EEC  § Reference to the generic concentration limits as defined in Directive 1999/45/EC  § Further references are disputed	§ Effects to be minimised	§ <b>Solution 2 acc. to Table VI.2 for the following endpoints:</b>  - <u>Acute Toxicity, category 4 (oral)</u> : Include in reference substances and mixtures classified in GHS category 3 from LD <sub>50</sub> • 200 mg/kg bw  - <u>Acute Toxicity, category 3 and 4 (dermal)</u> : Exempt from reference classified substances and mixtures in the range 200 • LD <sub>50</sub> • 400 mg/kg bw  - <u>Acute Toxicity, category 2 and 3 (inhalation of dust / mist / fume)</u> : Exempt from reference classified substances and mixtures in the range 0.05 • LC <sub>50</sub> • 0.25 mg/l/4h

			<ul style="list-style-type: none"> <li>- <u>Acute Toxicity, category 2 (dermal)</u>: Include in reference substances and mixtures classified in GHS category 3 up to LD<sub>50</sub> • 400 mg/kg bw</li> <li>- <u>Acute Toxicity, category 2 and 3 (oral)</u>: Exempt from reference classified substances and mixtures in the ranges 5 • LD<sub>50</sub> • 25 mg/kg bw and 200 • LD<sub>50</sub> • 300 mg/kg bw</li> <li>- <u>Acute Toxicity, category 1 (inhalation of dust / mist / fume)</u>: Include in reference substances and mixtures classified in GHS category 2 up to LC<sub>50</sub> • 0.25 mg/l/4h</li> <li>- <u>Acute Toxicity, category 1 (oral)</u>: Include in reference substances and mixtures classified in GHS category 2 up to LD<sub>50</sub> • 25 mg/kg bw</li> </ul> <p>§ <b>Retain the current concentration limits as defined in Decision 2000/532/EC (similar to Solution 2); repeal the corresponding phrase in footnote 7 of Decision 2000/532/EC</b></p>
Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of-life vehicles	§ Reference to substances which are considered dangerous according to Directive 67/548/EEC	§ Effects to be minimised	§ <b>Solution 1 acc. to Table VI.1</b>
Directive 2002/95/EC of the European Parliament and the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and	§ Reference to substances which are considered dangerous according to Directive 67/548/EEC	§ Effects to be minimised	§ <b>Solution 1 acc. to Table VI.1</b>

electronic equipment	§ Reference to preparations which are considered dangerous according to Directive 1999/45/EC		
Council Directive 91/157/EEC of 18 March 1991 on batteries and accumulators containing certain dangerous substances	§ Term “dangerous” only used in the title of the Directive; no reference identified in the Articles	§ Minimal / No effects	§ <b>No specific adaptation needed</b>

## PART II – Analysis of Downstream Legislation

### I. Consumer Products

#### I.1. Regulation (EC) No 648/2004/EC of the European Parliament and of the Council of 31 March 2004 on detergents

[http://europa.eu.int/smartapi/cgi/sga\\_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32004R0648&model=guichett](http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32004R0648&model=guichett)

Regulation No. 648/2004/EC (“Detergents Regulation”) establishes rules designed to achieve the free movement of detergents and surfactants for detergents in the internal market. To this end, the Regulation harmonises the following rules for the placing on the market of detergents and surfactants for detergents: the biodegradability of surfactants in detergents, restrictions or bans on surfactants on grounds of biodegradability, the additional labelling of detergents, including fragrance allergens and the information that manufacturers must hold at the disposal of the Member States’ competent authorities and medical personnel.

The classification of substances and mixtures in detergents would follow directly from the proposed GHS Regulation. The Detergents Regulation does not base any additional obligation on the classification of substances and mixtures. Accordingly, the introduction of the GHS will have no direct effect on the Detergents Regulation.

##### I.1.1. Abstract of the legislation

Regulation No. 648/2004/EC (“Detergents Regulation”) is based on Article 95 of the Treaty. It entered into force on 8 October 2005. It establishes rules designed to achieve the free movement of detergents and surfactants for detergents in the internal market. A detergent means any substance or preparation containing soaps and/or other surfactants intended for washing and cleaning processes. A surfactant means any organic substance and/or preparation used in detergents, which has surface-active properties and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of reducing the surface tension of water, and of forming spreading or adsorption monolayers at the water-air interface, and of forming emulsions and/or micro-emulsions and/or micelles, and of adsorption at water-solid interfaces.

Detergents may be in any form (liquid, powder, paste, bar, cake, moulded piece, shape, etc.) and marketed for or use in households or for institutional or industrial purposes. To achieve the free movement of detergents and surfactants in the internal market, the Regulation harmonises the following rules for the placing on the market of detergents and of surfactants for detergents:

- the biodegradability of surfactants in detergents;
- restrictions or bans on surfactants on grounds of biodegradability;
- the additional labelling of detergents, including fragrance allergens; and
- the information that manufacturers must hold at the disposal of the Member States’ competent authorities and medical personnel.

When placed on the market, detergents and surfactants for detergents shall conform with the conditions, characteristics and limits laid down in this Regulation and its Annexes and, where relevant, with Directive 1998/8/EC and with any other relevant Community legislation. Surfactants that are also active substances within the meaning of Directive 1998/8/EC and that are used as disinfectants are exempt from the provisions of Annexes II, III, IV and VIII of this Regulation, but have to comply with the provisions of Directive 1998/8/EC. As such surfactants are deemed to be disinfectants, the detergents of which they are ingredients are subject to the labelling provisions for disinfectants of Annex VII A.

If surfactants and detergents containing surfactants comply with the criteria for ultimate aerobic biodegradation as laid down in Annex III, they may be placed on the market without further limitations relating to biodegradability. If they do not comply with the aforementioned criteria, the manufacturer may still apply for a derogation. However, if the level of primary biodegradability is lower than that stipulated in Annex II, the detergent / surfactant shall not be granted a derogation.

Applications for derogation shall comprise a technical file supplying all the information and justifications necessary for evaluating the safety aspects related to the specific use of surfactants in detergents failing to comply with the biodegradability limits as set out in Annex III. In addition to the results of tests stipulated in Annex III, the technical file which is to be provided by the manufacturer shall include information and results of tests as stipulated in Annexes II (primary biodegradability) and IV (complementary risk assessment). On the basis of, in particular, the evaluation carried out by the Member State, the Commission may grant a derogation in accordance with the procedure referred to in Article 12(2) (comitology) and applying the following criteria:

- use in low-dispersive applications, rather than in wide-dispersive applications;
- use in specific industrial and/or institutional applications only;
- the risk to the environment or to health posed by the volume of sales and the pattern of use throughout the Community is small compared to the socio-economic benefits, including food safety and hygiene standards.

The derogations may allow, limit or severely restrict the placing on the market and the use of surfactants as ingredients in detergents, depending on the results of the complementary risk assessment as defined in Annex IV. The Commission shall publish the list of surfactants that have obtained derogation, with the corresponding conditions or limitations of use, as provided in Annex V. Similarly, the Commission shall publish in Annex VI the list of surfactants that have been identified as not complying with this Regulation.

Where a Member State has justifiable grounds for believing that a specific detergent, although complying with the requirements of this Regulation, constitutes a risk to safety or health of humans or of animals or a risk to the environment, it may temporarily prohibit the placing on the market of that detergent in its territory or make it temporarily subject to special conditions. It shall immediately inform the other Member States and the Commission. After consultation of the Member States, or of the relevant technical or scientific committee of the Commission, a decision shall be taken on the matter within ninety days in accordance with the procedure referred to in Article 12(2).

All tests referred to in Articles 3 and 4 and in Annexes II, III, IV and VIII shall be conducted in compliance with the standards mentioned in Annex I.1 and in accordance with testing requirements under Article 10(5) of Regulation (EEC) No 793/93. With regard to testing itself, Annexes II and III of the Detergents Regulation refer to the methods as set out in Annex V to Council Directive 67/548/EEC.

Manufacturers placing on the market the preparations covered by this Regulation shall, upon request, make available without delay and free of charge, to any medical personnel, an ingredient datasheet as stipulated in Annex VII C. The information contained in the datasheet shall be kept confidential and used only for medical purposes.

Member States' competent authorities may apply all necessary control measures to detergents placed on the market which ensure the compliance of the product with the provisions of the Detergents Regulation. The reference method shall be the test and analytical methods referred to in Annex VIII.

As far as the labelling of detergent products is concerned, the provisions relating to the classification, packaging and labelling of dangerous substances and preparations in Directives 67/548/EEC and 1999/45/EC apply. In addition, other provisions require inter alia that the packaging of detergents indicate the content in accordance with the specifications provided for in Annex VII A. It shall also indicate instructions for use and special precautions, if necessary. Furthermore, the packaging of detergents sold to the general public intended to be used as laundry detergents shall bear the information provided for in Annex VII B. Laundry detergents which, according to Annex III, Part 1 of Directive 76/768/EEC, contain known allergic ingredients, many of which are perfumes, must be labelled so that consumers can make an informed choice.

The amendments necessary for adapting the Annexes shall be adopted in comitology. The Detergents Regulation repeals the Community Directives 73/404/EEC, 73/405/EEC, 82/242/EEC, 82/243/EEC and 86/94/EEC as well as Recommendation 89/542/EEC.

### **I.1.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS**

- Generally, detergents are preparations (GHS terminology: mixtures) which are regulated by Directive 1999/45/EC. Regulation No. 648/2004 mainly serves the purpose to control or restrict those ingredients which are not readily biodegradable. Currently, there are 26 such detergent ingredients which are restricted because of insufficient biodegradability.
- Annex II and III of the Detergents Regulation refer to numerous test methods as set out in Annex V to Directive 67/548/EEC. Annex V of Directive 67/548/EEC will be repealed as a consequence of the REACH Regulation. The deletion of this Annex will apply 12 months from the entry into force of the REACH Regulation; the testing methods will then be specified on the basis of Article 12 of the REACH Regulation in a further Commission Regulation or by recognition of other international test methods by the Commission or the Agency.
- Surfactants that are also active substances within the meaning of Directive 1998/8/EC and that are used as disinfectants are exempt from the provisions of Annexes II, III, IV and VIII of this Regulation, but have to comply with the provisions of Directive 1998/8/EC. This implies that classified surfactants which are contained in detergent products may lead to a corresponding labelling of the latter.
- Being preparations (GHS terminology: "mixtures"), detergents are subject to the labelling provisions of Directives 67/548/EEC and 1999/45/EC. Consequently, the labelling would have to follow the rules of the GHS in future, cf. Table V.2 of Part I of this study.

**The classification of substances and mixtures in detergents would follow directly from the proposed GHS Regulation. The Detergents Regulation does not base any additional obligation on the classification of substances and mixtures. Accordingly, the introduction of the GHS will have no direct effect on the Detergents Regulation.**

### **I.1.3. Suggestions how to minimise potential effects of the GHS**

On the basis of the conclusions drawn above, no specific suggestions need to be made.

## **I.2. Regulation (EC) No 1980/2000 of the European Parliament and of the Council on a revised Community eco-label award scheme**

- § Commission Decision 2001/523/EC of 27 June 2001 establishing the ecological criteria for the award of the Community eco-label to all-purpose cleaners and cleaners for sanitary facilities
- § Commission Decision 2001/607/EC of 19 July 2001 establishing the ecological criteria for the award of the Community eco-label to hand dishwashing detergents
- § Commission Decision 2002/739/EC of 3 September 2002 establishing revised ecological criteria for the award of the Community eco-label to indoor paints and varnishes and amending Decision 1999/10/EC
- § Commission Decision 2003/31/EC of 29 November 2002 establishing revised ecological criteria for the award of the Community eco-label to detergents for dishwashers and amending Decision 1999/427/EC
- § Commission Decision 2003/200/EC of 14 February 2003 establishing revised ecological criteria for the award of the Community eco-label to laundry detergents and amending Decision 1999/476/EC

[http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l\\_189/l\\_18920010711en00250037.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_189/l_18920010711en00250037.pdf)  
[http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l\\_214/l\\_21420010808en00300042.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_214/l_21420010808en00300042.pdf)  
[http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l\\_236/l\\_23620020904en00040009.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_236/l_23620020904en00040009.pdf)  
[http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l\\_009/l\\_00920030115en00110025.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_009/l_00920030115en00110025.pdf)  
[http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l\\_076/l\\_07620030322en00250039.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_076/l_07620030322en00250039.pdf)

The Community legislation on eco-labelling establishes detailed criteria for the award of the eco-label to various product groups. In the case of the eco-labelling legislation referring to detergents and indoor paints and varnishes, explicit reference to classification criteria and R-phrases as established in the Directives 67/548/EEC and 1999/45/EC is made in the respective Annex: Those substances and mixtures classified for particular hazards and being present above a defined threshold concentration should not be contained in the final product if it is to be awarded the Community eco-label. Also, in some cases the final product is subject to corresponding provisions.

Potential effects of the GHS on the award of the eco-label would be due to additional substances and mixtures which could be classified for some hazards. The respective substances and mixtures would lead to a disqualification of the final product for the Community eco-label and other national eco-labels as far as the latter require the absence of product or ingredient classification. These effects can be minimised by adapting the range of certain hazards referred to in a particular downstream act. This would imply to make use of the GHS classification criteria while at the same time extending or limiting the scope of the respective reference to the current cut-off limits or concentration thresholds.

### **I.2.1. Abstract of the legislation**

**Regulation (EC) No. 1980/2000** is based on Article 175 (1) of the Treaty. It sets out rules for the award of the Community eco -label.

The Community eco -label award scheme is designed to

- promote products which have a reduced environmental impact compared with other products in the same product group;
- provide consumers with accurate and scientifically based information and guidance on products.

The eco-label may be awarded to products available in the Community which meet certain environmental requirements and specific eco-label criteria. Several product categories are excluded from the Regulation, e.g. foodstuffs, drinks, pharmaceutical products, medical devices, products manufactured by processes likely to significantly harm human being and/or the environment, and substances or preparations classified as dangerous within the meaning of Directives 67/548/EEC and 1999/45/EC.

The environmental requirements are defined with reference to the assessment matrix given in Annex I to the Regulation and must meet the methodological requirements set out in Annex II. The label may be awarded to products which contribute significantly to improvements in relation to key environmental aspects.

Eco-label criteria must be established by product group and be based on:

- the product's prospects of market penetration;
- the technical and economic feasibility of the necessary adaptations;
- the potential for environmental improvement.

The criteria are set and reviewed by the European Union Eco -Labelling Board (EUEB), which is also responsible for the assessment and verification requirements relating to them. They are published in the Official Journal of the European Union.

Product groups must fulfil the following conditions:

- they must represent a significant volume of sales and trade in the internal market;
- they must have a significant environmental impact;
- they must present a significant potential for effecting environmental improvements through consumer choice;
- a significant part of the sales volume must be sold for final consumption or use.

Applying for the award of a European eco -label:

- manufacturers, importers, service providers, traders or retailers apply to the competent body designated by the Member State in which the product has been manufactured, first marketed or imported from a non-member country;
- the competent body assesses whether the product conforms to the criteria of the eco -label and decides whether to award the label;
- the competent body concludes a standard contract with the applicant, covering the terms of use of the label.

Applications for the award of an eco -label are subject to payment of a fee. The use of the label is also subject to the payment of an annual fee by the user.

Any product to which the eco -label is awarded is recognisable by the 'daisy' logo, as described in Annex III to the Regulation.

The Commission and the Member States must promote the use of the eco -label by means of awareness-raising actions and information campaigns. They must ensure coordination between the Community eco -label scheme and existing national schemes.

The Commission must examine before 24 September 2005 how this Regulation is applied and must propose any appropriate amendments.

Numerous Commission Decisions were taken pursuant to the present Regulation, establishing revised ecological criteria for the award of a Community eco -label. Pertaining to detergent products and paints, the following acts were adopted:

- Decision **2001/523/EC** (all-purpose cleaners and cleaners for sanitary facilities)
- Decision **2001/607/EC** (hand dishwashing detergents)
- Decision **2002/739/EC** (indoor paints and varnishes)
- Decision **2003/31/EC** (detergents for dishwashers)
- Decision **2003/200/EC** (laundry detergents)

Apart from these acts, there are various other Decisions relating to articles, including Decision 2002/272/EC (hard floor coverings), Decision 2002/740/EC (bed mattresses) which refers to 2002/371/EC (textiles), Decision 2002/741/EC (copying paper), Decision 2002/747/EC (light bulbs) and Decision 2003 /121/EC (vacuum cleaners).

### **1.2.2. Analysis of the links to classification and labelling provisions**

Only those eco-labelled products are examined which are substances or preparations.

#### **Regulation (EC) No 1980/2000 of the European Parliament and of the Council on a revised Community eco -label award scheme**

##### Article 2, Scope

4. The eco-label may not be awarded to substances or preparations classified as *Very Toxic, Toxic, Dangerous to the environment, Carcinogenic, Toxic for reproduction or Mutagenic* in accordance with Council Directive 67/548/EEC(9) or Directive 1999/45/EC of the European Parliament and of the Council(10) nor to goods manufactured by processes which are likely to significantly harm man and/or the environment, or in their normal application could be harmful to the consumer.

The aforementioned provisions are modified for particular product groups:

## A. Decision 2001/523/EC (all-purpose cleaners and cleaners for sanitary facilities)

Article 1: "The product group 'all-purpose cleaners and cleaners for sanitary facilities' (hereinafter referred to as 'the product group') shall be subdivided into two subgroups, which are defined as follows: *all-purpose cleaners*: detergent products intended for the routine cleaning of floors, walls, ceilings and other fixed surfaces, and which are dissolved or diluted in water prior to use, *cleaners for sanitary facilities*: detergent products intended for the routine removal (including by scouring) of dirt and/or deposits in sanitary facilities, such as laundry rooms, bathrooms, showers, toilets and kitchens. Products which are automatically used when a toilet is flushed, for example 'self-dosing-products' such as toilet blocks, or products for use in a toilet's cistern, are not included. Products which have no cleaning effects other than calcium carbonate (scale) removal are not included. Disinfectants are not included. Products for more specific cleaning uses, such as oven or window cleaners, floor-strippers, polishes, drain cleaners, etc. are not included. The product group includes not only products which can be used by private consumers but also those products which can be used professionally."

Article 2: The environmental performance and the fitness for use of the product group shall be assessed by reference to the criteria set out in the Annex and its appendix.

### Annex, Framework

In order to qualify for the eco-label, an all purpose cleaner or a cleaner for sanitary facilities (hereinafter referred to as "the product") must fall within the product group as defined in Article 1, and must comply with the criteria of this Annex, with tests carried out on application as indicated in the criteria and the technical appendix. ...

These criteria aim at promoting:

- the reduction of environmental impact by limiting the quantity of harmful ingredients, by reducing the quantity of detergent used and by reducing packaging waste,
- the reduction or prevention of risks for the environment and for human health related to the use of hazardous substances,
- information that will enable the consumer to use the product in the way that is efficient and minimises environmental impact.

The criteria are set at levels that promote the labelling of all-purpose cleaners and sanitary cleaners that have a low environmental impact.

### Annex, Ecological Criteria

#### 4. Dangerous, hazardous or toxic substances or preparations

(b) No ingredient shall be included in the product that is classified as:

R31 (contact with acid liberates toxic gas), R40 (limited evidence of a carcinogenic effect), R45 (may cause cancer), R46 (may cause heritable genetic damage), R49 (may cause cancer by inhalation), R68 (possible risks of irreversible effects), R50+53 (very toxic to aquatic organisms and may cause long term adverse effects in the aquatic environment), R51+53 (toxic to aquatic organisms and may cause long term adverse effects in the aquatic environment), R59 (dangerous to the ozone layer), R60 (may impair fertility), R61 (may cause harm to the unborn child), R62 (possible risk of impaired fertility), R63 (possible risk of harm to the unborn child), R64 (may cause harm to breastfed babies), or any combination thereof, according to 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, and its subsequent amendments, or according to 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, and its subsequent amendments.

Each ingredient of any preparation used in the formulation that exceeds 0,1 % by weight of the preparation shall also meet the above requirement.

## **B. Decision 2001/607/EC (hand dishwashing detergents)**

Article 1: The product group 'hand dishwashing detergents' (hereinafter referred to as 'the product group') shall mean: All detergents intended to be used to wash by hand dishes, crockery, cutlery, pots, pans and other kitchen utensils, etc.

### Annex, Framework

In order to qualify for the eco-label, a hand dishwashing detergent (hereinafter referred to as 'the product' must fall within the product group as defined in Article 1, and must comply with the criteria of this Annex, with tests carried out on application as indicated in the criteria and the technical appendix. ...

### Annex, Ecological Criteria

#### 3. Dangerous, hazardous or toxic substances or preparations

... (b) No ingredient shall be included in the product that is classified as:

R40 (limited evidence of a carcinogenic effect), R45 (may cause cancer), R46 (may cause heritable genetic damage), R49 (may cause cancer by inhalation), R68 (possible risks of irreversible effects), R50+53 (very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment), R51+53 (toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment), R59 (dangerous to the ozone layer), R60 (may impair fertility), R61 (may cause harm to the unborn child), R62 (possible risk of impaired fertility), R63 (possible risk of harm to the unborn child), R64 (may cause harm to breastfed babies), or any combination thereof, according to Directive 67/548/EEC and its subsequent amendments, or according to 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), and its subsequent amendments.

Each ingredient of any preparation used in the formulation that exceeds 0,1 % by weight of the preparation shall also meet the above requirement.

Biocides that are used to preserve the product (as allowed under the criterion on biocides below), and are classified as R50+53 or R51+53 are nevertheless permitted, but only if they are not potentially bio-accumulative. In this context, a biocide is considered to be potentially bio-accumulative if the  $\log P_{ow}$  (log octanol/water partition coefficient)  $\bullet$  3,0 (unless the experimentally determined BCF  $\bullet$  100).

The exact formulation of the product shall be provided to the competent body, together with copies of the material safety data sheets of each ingredient which shall indicate the classification or lack thereof of each ingredient, as well as a declaration that none of the above substances have been included in the product. Similarly the suppliers of any preparation used in the formulation shall provide a declaration that their preparation complies with the above requirements.

#### 7. Sensitising substances

The product shall not be classified as R42 (may cause sensitisation by inhalation) and/or R43 (may cause sensitisation by skin contact) according to Directive 1999/45/EC concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

The exact formulation of the product shall be provided to the competent body, together, with copies of the material safety data sheets of each ingredient which shall indicate the relevant classification or lack thereof of each ingredient, and also a declaration of compliance with this criterion.

## **C. Decision 2002/739/EC (indoor paints and varnishes)**

In order to be awarded the Community eco-label under Regulation (EC) No 1980/2000, paints and varnishes must fall within the product group 'indoor paints and varnishes' as defined in Article 2, and must comply with the ecological criteria set out in the Annex to this Decision. The productgroup 'indoor paints and varnishes' shall comprise indoor decorative paints and varnishes, woodstains and related products, in accordance with paragraph 2, for use by do-it-yourself and professional users; and that are primarily developed for indoor use and marketed as such. This includes, *inter alia*, floor coatings and floor paints; products which are tinted by distributors at the request of amateur or professional decorators; decorative paints in liquid or paste formulas which may have been pre-conditioned, tinted or prepared by the manufacturer to meet consumers needs, including primers (and undercoats) of such product systems. 'Paint' means a pigmented coating material, in liquid or in paste or powder

form, which when applied to a substrate, forms an opaque film having protective, decorative or specific technical properties. 'Varnish' means a clear coating material which when applied to a substrate forms a solid transparent film having protective, decorative or specific technical properties. After application, the paint or varnish dries to a solid, adherent and protective coating. Decorative paints and varnishes are paints and varnishes that are applied to buildings, their trim and fittings, for decorative and protective purposes. They are applied *in situ*. While their main function is decorative in nature, they also have a protective role. Woodstains (lasures) are coatings producing a transparent or semi-transparent film for decoration and protection of wood against weathering, which enables maintenance to be carried out easily.

In order to be awarded the Community eco-label under Regulation (EC) No 1980/2000, paints and varnishes must fall within the product group 'indoor paints and varnishes' as defined in Article 2, and must comply with the ecological criteria set out in the Annex to this Decision.

#### Annex. Criteria

##### 5. Dangerous substances

(a) The product: The product shall not be classified as very toxic, toxic, dangerous to the environment, carcinogenic, toxic for reproduction or mutagenic in accordance with Directive 1999/45/EC.

Assessment and verification: The applicant shall provide a declaration of compliance with this criterion, together with a list of ingredients and related documentation (such as material and safety data sheets).

(b) Ingredients (very toxic, toxic, carcinogenic, mutagenic, toxic for reproduction): No ingredient (substance or preparation) shall be used that is assigned or may be assigned at the time of application any of the following risk phrases (or combinations thereof):

R23 (toxic by inhalation), R24 (toxic in contact with skin), R25 (toxic if swallowed), R26 (very toxic by inhalation), R27 (very toxic in contact with skin), R28 (very toxic if swallowed), R39 (danger of very serious irreversible effects), R45 (may cause cancer), R46 (may cause heritable genetic damage), R48 (danger of serious damage to health by prolonged exposure), R60 (may impair fertility), R61 (may cause harm to the unborn child), as laid down in Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, and its subsequent amendments, or in 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), and its subsequent amendments.

Active ingredients used as preservatives in the formula and that are assigned any of the risk phrases R23, R24, R25, R26, R27, R28, R39 or R48 (or combinations thereof) may nevertheless be used up to a limit of 0,1 % (m/m) of the total paint formulation.

Assessment and verification: The applicant shall provide a declaration of compliance with this criterion, together with a list of ingredients and related documentation (such as material and safety data sheets).

(c) Ingredients (dangerous for the environment): No ingredient (substance or preparation) that is assigned or may be assigned at the time of application any of the following risk phrases (or combinations thereof):

R50 (very toxic to aquatic organisms), R51 (toxic to aquatic organisms), R52 (harmful to aquatic organisms), R53 (may cause long-term adverse effects in the aquatic environment), as laid down in Directive 67/548/EEC or Directive 1999/45/EC, shall exceed 2,5 % by mass of the product. The sum total of all ingredients that are assigned or may be assigned at the time of application any of these risk phrases (or combinations thereof) shall not exceed 5 % by mass of the product. This requirement does not apply to ammonia, alkyl ammonia or alkylamine. This requirement does not affect the obligation to fulfil the requirement set out in criterion 5(a) above.

Assessment and verification: The applicant shall provide a declaration of compliance with this with a list of ingredients and related documentation (such as material and safety data sheets).

## **D. Decision 2003/31/EC (detergents for dishwashers)**

**Article 1:** In order to be awarded the Community eco-label under Regulation (EC) No 1980/2000, a detergent for dishwashers must fall within the product group 'detergents for dishwashers' as defined in Article 2, and must comply with the ecological criteria set out in the Annex to this Decision.

**Article 2:** The product group 'detergents for dishwashers' shall comprise all detergents intended for use exclusively in automatic domestic dishwashers and all detergents intended for use in automatic dishwashers operated by professional users but similar to automatic domestic dishwashers in terms of machine size and usage.

### Annex. Criteria

#### 1. Environmental scoring matrix

(d) reference to test methods as set out on Directive 67/548/EEC:

"... The tests for ready biodegradability shall be as referred to in 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 (1), and its subsequent amendments, in particular the methods detailed in Annex V.C4, or their equivalent OECD 301 A-F test methods, or their equivalent ISO tests. The 10 days window principle shall not apply. The pass levels shall be 70 % for the tests referred to in Annex V.C4-A and C4-B of Directive 67/548/EEC (and their equivalent OECD 301 A and E tests and ISO equivalents), and shall be 60 % for tests C4-C, D, E and F (and their equivalent OECD 301 B, C, D and F tests and ISO equivalents)." and

#### 2. Biodegradability of surfactants

(a) reference to test methods as set out on Directive 67/548/EEC:

"... The tests for ready biodegradability shall be as referred to in Directive 67/548/EEC, and its subsequent amendments, in particular the methods detailed in Annex V.C4, or their equivalent OECD 301 A-F test methods, or their equivalent ISO tests. The 10 days window principle shall not apply. The pass levels shall be 70 % for the tests referred to in Annex V.C4-A and C4-B of Directive 67/548/EEC (and their equivalent OECD 301 A and E tests and ISO equivalents), and shall be 60 % for tests C4-C, D, E and F (and their equivalent OECD 301 B, C, D and F tests and ISO equivalents)." and

#### 3. Dangerous, hazardous or toxic substances or preparations

(a) No ingredient shall be included in the product that, at the time of application, is or may be assigned any of the following risk phrases (or combinations thereof):

R40 (limited evidence of a carcinogenic effect), R45 (may cause cancer), R46 (may cause heritable genetic damage), R49 (may cause cancer by inhalation), R50-53 (very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment), R51-53 (toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment), R60 (may impair fertility), R61 (may cause harm to the unborn child), R62 (possible risk of impaired fertility), R63 (possible risk of harm to the unborn child), R64 (may cause harm to breastfed babies), R68 (possible risks of irreversible effects), as laid down in Directive 67/548/EEC and its subsequent amendments, or in 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(2), and its subsequent amendments.

Each ingredient of any preparation used in the formulation that exceeds 0,01 % by weight of the final product shall also meet this requirement.

Assessment and verification: The exact formulation of the product shall be provided to the competent body, together with copies of the material safety data sheets of each ingredient and a declaration of compliance with this criterion. Test results or references to published data shall be given.

(b) No preservatives shall be used that are or may be classified as R50-53, as laid down in Council Directive 67/548/EEC and its subsequent amendments or Directive 1999/45/EC and its subsequent amendments, whatever their amount.

Assessment and verification: The exact formulation of the product shall be provided to the competent body, together with copies of the material safety data for such ingredients (whether substances or preparations) and a declaration of compliance with this criterion. Test results or references to published data shall be given.

## E. Decision 2003/200/EC (laundry detergents)

Article 1: In order to be awarded the Community eco-label under Regulation (EC) No 1980/2000, a laundry detergent must fall within the product group 'laundry detergents' as defined in Article 2, and must comply with the ecological criteria set out in the Annex to this Decision.

Article 2: The product group 'laundry detergents' shall comprise all laundry detergents, in powder, liquid or any other form, for the washing of textiles, and which are intended to be used principally in household machines, but not excluding the use in laundrettes and common laundries.

### Annex, Criteria

#### 3. Biodegradability of surfactants

(a) reference to test methods as set out on Directive 67/548/EEC:

"... The tests for ready biodegradability shall be as referred to in 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, and its subsequent amendments, in particular the methods detailed in Annex V.C4, or their equivalent OECD 301 A-F test methods, or their equivalent ISO tests. The 10 days window principle shall not apply. The pass levels shall be 70 % for the tests referred to in Annex V.C4(A) and C4(B) of Directive 67/548/EEC (and their equivalent OECD 301 A and E tests and ISO equivalents), and shall be 60 % for tests C4-C, D, E and F (and their equivalent OECD 301 B, C, D and F tests and ISO equivalents)."

#### 6. Dangerous, hazardous or toxic substances or preparations

d) No ingredient shall be included in the product that is classified or may be classified as:

R40 (limited evidence of a carcinogenic effect), R45 (may cause cancer), R46 (may cause heritable genetic damage), R49 (may cause cancer by inhalation), R50-53 (very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment), R51-53 (toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment), R59 (dangerous to the ozone layer), R60 (may impair fertility), R61 (may cause harm to the unborn child), R62 (possible risk of impaired fertility), R63 (possible risk of harm to the unborn child), R64 (may cause harm to breastfed babies), R68 (possible risks of irreversible effects) or any combination thereof, according to Directive 67/548/EEC and its subsequent amendments, or according to 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, and its subsequent amendments.

Each substance or ingredient of any preparation used in the formulation that exceeds 0,01 % of the final product shall also meet the above requirements. No preservatives shall be used that are or may be classified as R50-53, whatever their amount.

Assessment and verification: the exact formulation of the product shall be provided to the Competent Body. Copies of the material safety data sheets shall be provided for all ingredients (whether substances or preparations). A declaration of compliance with this criterion shall be provided by the applicant.

(e) The product shall not be classified as R43 (may cause sensitisation by skin contact) according to 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.

Assessment and verification: the exact formulation of the product shall be provided to the Competent Body, together with copies of the material safety data sheets of each ingredient which shall indicate the relevant classification or lack thereof of each ingredient, and also a declaration of compliance with this criterion.

**As can be seen from the extracts above, hazard plays a decisive role for the criteria for the award of the Community eco-label.** With regard to ingredients (substances and preparations, including preservatives), reference to R-phrases and to defined maximum concentrations is made. With regard to products or formulations (mixtures!), reference both to R-phrases and categories of danger is made. The classifications and R-phrases are applied to three different levels of compounds, i.e. to the final product itself, to direct ingredients (substances and preparations) and to sub-ingredients of the direct ingredients:

**Table I.2.2.1:** Level of application of classification criteria / R -phrases in various eco-labelling acts

<b>Legislation / Level of application of classification</b>	<b>Decision 2001/523/EC</b>	<b>Decision 2001/607/EC</b>	<b>Decision 2002/739/EC</b>	<b>Decision 2003/31/EC</b>	<b>Decision 2003/200/EC</b>
<b>product</b>		X	X		X
<b>ingredients</b>	X	X	X	X	X
<b>ingredients up to x% or under particular conditions</b>		X	X		
<b>ingredients of an ingredient preparation up to x% of the final product</b>	X	X		X	X

Table I.2.2.2 below gives an overview over the R -phrases which trigger a ban or the strictly limited use up to a maximum concentration of a particular (sub -)ingredient to be used in the respective products:

**Table I.2.2.2:** Criteria referring to ingredients (I = substances and preparations, including preservatives) and products (P) in Community eco -labelling legislation

<b>Legislation / R-phrase</b>	<b>Decision 2001/523/EC</b>	<b>Decision 2001/607/EC</b>	<b>Decision 2002/739/EC</b>	<b>Decision 2003/31/EC</b>	<b>Decision 2003/200/EC</b>
<b>R23</b>			I, P		
<b>R24</b>			I, P		
<b>R25</b>			I, P		
<b>R26</b>			I, P		
<b>R27</b>			I, P		
<b>R28</b>			I, P		
<b>R31</b>	I				
<b>R39</b>			I, P		
<b>R40</b>	I	I		I	I

R42		P			
R43		P			P
R45	I	I	I, P	I	I
R46	I	I	I, P	I	I
R48			I, P		
R49	I	I	P	I	I
R60	I	I	I, P	I	I
R61	I	I	I, P	I	I
R62	I	I	P	I	I
R63	I	I	P	I	I
R64	I	I		I	I
R68	I	I	P	I	I
R50			I, P	I	I
R51			I, P	I	I
R52			I, P	I	I
R53			I, P	I	I
R50/53	I	I	I, P	I	I
R51/53	I	I	I, P	I	I
R52/53			I, P	I	I
R59	I	I			I

With regard to the other eco -labelling acts, cf. I.2.1., reference to selected R -phrases can be found in the respective Annex. These R -phrases are already included in the list above.

### I.2.3. Anticipation of the potential effects of the GHS

The Annexes to Decision 2003/31/EC and 2003/200/EC refer to selected test methods as set out in Annex V to Directive 67/548/EEC. Annex V of Directive 67/548/EEC will be repealed as a consequence of the REACH Regulation. The deletion of this Annex will apply 12 months from the entry into force of the REACH Regulation; the testing methods will then be specified on the basis of Article 12 of the REACH Regulation in a further Commission Regulation or by recognition of other international test methods by the Commission or the Agency.

With regard to the EU categories of danger or R -phrases which are relevant in the above - mentioned eco-labelling acts, Table V.3 of Part I of this study shows the most closely corresponding GHS hazard classes and categories. When the reference is shifted to these GHS classifications, the diverse eco-labelling acts might apply to additional substances and / or mixtures, due to the classification for *acute toxicity, STOT (single / repeated exposure)*,

*reproductive toxicity* and *hazardous to the aquatic environment*, cf. Table V.3 and Annex I to this study. In general, the following statements can be derived from a comparison of the EU and GHS criteria:

- For *acute toxicity*, the concentration limits of the individual GHS categories do not always coincide with the concentration limits of the corresponding EU categories of danger. For this reason, it has to be checked which GHS classification interval is to replace the EU category *Toxic (R25, R24, R23)* in the eco-labelling legislation – depending on the respective concentration limits, the number of classified substances might change. For example, *GHS acute toxicity category 3* would probably comprise more substances than the EU category of danger *Toxic* does for the oral and dermal routes of uptake, cf. the figure below:

<b>EU</b>	T+ R28		T R25		
<b>LD<sub>50</sub>(*)</b>	≤ 5	5-25	25-50	50-200	200-300
<b>GHS</b>	Cat. 1		Category 2		Category 3

**Figure 1:** Cut-off limits for the higher toxicity range of the acute toxicity hazard (oral pathway) under EU legislation and the GHS

- For detergent products (preparations / mixtures!), no final statement on a potential effect of the GHS can be made. However, depending on the calculation method applied under GHS, cf. Annex I, it can not be excluded that fewer detergent products will be eligible for the award of the EU eco-label under GHS.
- For *STOT (single exposure)*, the GHS will probably classify additional substances and mixtures. This would be due to higher cut-off values for substance classification for all routes of uptake.
- For *STOT (repeated exposure)*, the GHS criteria are twice as stringent as the current EU criteria for *R48* so that the number of substances and mixtures classified for this hazard will probably increase.
- For CMR, the situation will not change substantially under GHS. The scope of classified substances will probably stay the same as under the current EU legislation. With regard to mixtures, a slight change might occur: The GHS will lower the concentration limits from 0.5% to 0.3% for EU category 1 and 2 / GHS category 1A and 1B and from 5% to 3% for EU category 3 / GHS category 2 for the classification of mixtures which contain reprotoxic ingredients. This means that some more detergents and other products could be classified for *reproductive toxicity* and disqualify the respective product for the eco-label.
- With regard to *hazardous to the aquatic environment*, it is sometimes stated that the introduction of M-factors under GHS would result in some mixtures either being classified or more severely classified than they are currently, cf. Annex I to this study. Also in this case, the additional classification would disqualify the affected product for the eco-label.

Currently, detergents as well as other consumer products are also subject to particular eco - labels which are applicable in some Member States, e.g. the Nordic Swan (awarded in the Nordic countries). One of the criteria to get the respective eco -labelling is based on the absence of product or ingredient classifications. For example, the Nordic Swan labelling would not be granted if the products were classified under EU legislation. This means that the GHS might disqualify a product also for the award of further eco -labels.

**Concluding, potential effects of the GHS could be due to additional substances and / or mixtures classified under GHS. The corresponding final products would consequently disqualify for the Community eco -label and other national eco -labels as far as the latter require the absence of product or ingredient classification.**

#### **I.2.4. Suggestions how to minimise potential effects of the GHS**

In order to minimise effects related to additional classification under GHS, it is proposed to adapt the range of certain references mentioned in the eco-labelling acts in accordance with **Solution 2**, cf. Table VI.2 of Part I of this study. This would imply to make use of the GHS classification criteria while at the same time extending or limiting the scope of the respective reference to the current cut-off limits or concentration thresholds.

With regard to the reclassification of current entries in Annex I to Directive 67/548/EEC, the GHS Regulation will provide for conversions for CMR and respiratory sensitisers on the basis of equivalent criteria. It is planned to carry them over to Annex VI to the GHS Regulation. Non-harmonised, but classified CMRs can easily be reclassified by using the conversion table in Annex VII.

### **I.3. Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products**

- **Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (7th amendment)**
- **Commission Directive 2004/94/EC of 15 September 2004 amending Council Directive 76/768/EEC as regard Annex IX**

[http://ec.europa.eu/enterprise/cosmetics/html/consolidated\\_dir.htm](http://ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm)

Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (“Cosmetics Directive”) constitutes the main regulatory framework for cosmetic products. It regulates the ingredients of cosmetic products, their labelling and issues of animal testing.

The Cosmetics Directive refers to Council Directive 67/548/EEC in its Articles 4(b) and 7a(1)(h).

Article 4(b) prohibits the use in cosmetic products of substances which are classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, and which are listed in Annex I to Directive 67/548/EEC. These substances have to be listed in Annex II to the Cosmetics Directive. As to substances classified in category 3, these may be used in cosmetic products if they have been evaluated by the SCCNFP and found acceptable for use in cosmetic products. Due to equivalent criteria for CMR hazards, the GHS will classify the same substances as Council Directive 67/548/EEC.

Article 7a(1)(h) states that quantitative information on dangerous substances contained in cosmetic products shall be made easily accessible to the public and to the competent authorities of the Member States. The extent of information to be provided for according to Article 7a(1)(h) will depend on the number of substances to be classified according to the GHS criteria.

### **I.3.1. Abstract of the legislation**

Council Directive 76/768/EEC (“Cosmetics Directive”) constitutes the main regulatory framework for cosmetic products and contains provisions related to their composition, particular ingredients, labelling and animal testing.

A ‘cosmetic product’ shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.

The Cosmetics Directive is based on the principle of manufacturer responsibility. The manufacturer / importer is responsible for the safety of the cosmetic product. Member States’ supervision is restricted to in-market controls.

In terms of regulation of ingredients, the Cosmetics Directive contains various lists of ingredients which are prohibited, restricted or authorised: In particular, Annex II contains those substances which cannot be included in cosmetic products.

Article 4(b) Cosmetics Directive prohibits the use in cosmetic products of substances which are classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, and which are listed in Annex I to Directive 67/548/EEC. These substances have also to be listed in Annex II to the Cosmetics Directive (“prohibited substances”). As to substances classified in category 3, these may be used in cosmetic products if they have been evaluated by the SCCNFP and found acceptable for use in cosmetic products.

Article 7a(1)(h) Cosmetics Directive states that quantitative information on dangerous substances contained in cosmetic products shall be made easily accessible to the public and to the competent authorities of the Member States.

With regard to labelling, the Cosmetics Directive defines its own rules. Therefore, cosmetic products, i.e. mixtures in the finished state intended for the final user, are excluded from the scope of EU legislation on classification and labelling, cf. Article 1(2)(b) of Directive 67/548/EEC and Article 1(5) of Directive 1999/45/EC.

Cosmetic products are important consumer products. The European cosmetics industry is a world leader, with a value of output of more than 35 billion €. It is highly innovative: on average, major cosmetic companies replace or reformulate around 25% of their products every year. Beyond, it is a significant employer: over 150.000 Europeans are employed directly; a further 350.000 jobs are created indirectly in retail, distribution and transport.

### **I.3.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS**

#### **A. Article 4(b) of the Cosmetics Directive – listing of CMRs in Annex II**

Article 4(b) prohibits the use in cosmetic products of substances which are classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, and which are listed in Annex I to Directive 67/548/EEC. These substances have to be listed in Annex II to the Cosmetics Directive (“prohibited substances”). As to substances classified in category 3, these may be used in cosmetic products if they have been evaluated by the SCCNFP and found acceptable for use in cosmetic products.

With respect to the listing of CMR substances in Annex II to the Cosmetics Directive, it will be of relevance if the GHS classifies the same substances for CMR hazards as Directive 67/548/EEC does. Whereas the criteria for CMR classification are equivalent, cf. Annex I to this study, guidance on how to interpret the data for potentially carcinogenic and reprotoxic substances and derive a particular classification is still under development at UN level.

The overall conclusion to be drawn for CMR hazards is that the number of classified substances will stay the same as under the current EU legislation.

As to *effects on or via lactation*, the GHS allocates this hazard to a separate subcategory within the hazard class *reproductive toxicity*. This means that corresponding effects constitute an independent classification under GHS, whereas EU risk phrase “R64, may cause harm to breastfed babies” can only be allocated to substances already classified otherwise. Currently, this hazard is not covered by the Cosmetics Directive. It might be considered if reference to the classification *effects on or via lactation* in Directive 76/768/EEC is appropriate.

The GHS Regulation will provide for an annex where harmonised classifications of CMR substances will be listed (Annex VI to the draft Regulation). It is the intention to transfer the CMR substance classifications which are currently in Annex I to Directive 67/548/EEC directly to the new annex. The current EU and the future GHS classifications are re tabled below:

**Table I.3.2.1:** Conversion of CMR EU classifications to the GHS classifications

EU Classification	GHS Classification
Carcinogen category 1	Carcinogen category 1A
Carcinogen category 2	Carcinogen category 1B
Carcinogen category 3	Carcinogen category 2
Mutagen category 1	Mutagen category 1A
Mutagen category 2	Mutagen category 1B
Mutagen category 3	Mutagen category 2
Toxic to reproduction category 1	Reproductive toxicant category 1A
Toxic to reproduction category 2	Reproductive toxicant category 1B
Toxic to reproduction category 3	Reproductive toxicant category 2
[R64]	Reproductive toxicity, effects on or via lactation

**B. Article 7a(1)(h) of the Cosmetics Directive – public information to be provided on dangerous substances covered by Directive 67/548/EEC**

Article 7a(1)(h) states that quantitative information on dangerous substances contained in cosmetic products shall be made easily accessible to the public and to the competent authorities of the Member States. Dangerous substances are those covered by Directive

67/548/EEC. When reference is shifted to the GHS Regulation, the extent of information to be made available will depend on the number of substances classified under GHS. With regard to human health hazards, the GHS will probably classify more substances in the hazard classes *STOT (single / repeated exposure)* and *aspiration hazard*. More substances would certainly be classified in case *acute toxicity category 5* were included in the GHS Regulation. The additional substances will be regulated by Article 7a(1)(h) of the Cosmetics Directive. For further information confer Table V.3 of Part I and Annex I to this study.

### C. Should GHS labelling apply to products used for professional use?

The question was raised whether the GHS labelling should apply to cosmetic products when used by professionals.

If such an approach was adopted, one of the basic principles of the current legislation would be deviated from: Cosmetic products in the finished state intended for the final user (consumer and professional) are excluded from the scope of EU legislation on classification and labelling, cf. Article 1.2(b) of Directive 67/548/EEC and Article 1.5) of Directive 1999/45/EC. With regard to hazard labelling, it is the Cosmetics Directive itself which provides for the rules on labelling of cosmetic products. The underlying policy is that Community rules for labelling of cosmetic products pertaining to ingredients and warnings should be dealt with in one single piece of legislation.

This argument would also be valid with regard to the GHS. Actually, the GHS rules confirm this approach in 1.1.2.5(iii) GHS: "At the point of intentional intake ... such requirements would not normally be applied to these products as a result of the GHS". However, the GHS rules on labelling would apply to the production of the product at the workplace as is discussed in 1.1.2.5(ii) GHS.

### I.3.3. Suggestions how to minimise potential effects of the GHS

It is not expected that the current scope of CMR substances regulated by the Cosmetics Directive will change. With regard to *effects on or via lactation*, it has to be decided if reference to this hazard should be taken up in the Cosmetics Directive.

With regard to the reclassification of current entries in Annex I to Directive 67/548/EEC, the GHS Regulation will provide for conversions for CMR and respiratory sensitizers on the basis of equivalent criteria. It is planned to carry them over to Annex VI to the GHS Regulation. Non-harmonised, but classified CMRs can easily be reclassified by using the conversion table in Annex VII.

With regard to Article 7a(1)(h), additional quantitative information on further classified substances could be necessary. In order to minimise potential effects related to additional classification under GHS, it is proposed to exempt from the reference to classified substances and mixtures those hazard classifications (classes and categories / types / divisions) which are newly introduced by the GHS, in accordance with **Solution 1**, cf. Part I of this study. The respective classifications are listed in Table VI.1 of Part I of this study.

#### **I.4. Council Directive 88/378/EEC on the approximation of laws of the Member States concerning the safety of toys**

[http://europe.eu.int/eur-lex/en/consleg/pdf/1988/en\\_1988L0378\\_do\\_001.pdf](http://europe.eu.int/eur-lex/en/consleg/pdf/1988/en_1988L0378_do_001.pdf)

Council Directive 88/378/EC (“Toy Safety Directive”) is to ensure the free movement of toys in the Community market and to protect the health and safety of children using toys and of third parties by completely harmonising the essential safety and health requirements toys must conform with. A toy is defined as any product or material designed or clearly intended for use in play by children of less than 14 years of age; any toy put on the market would have to comply with the essential safety requirements set out in Annex II, including requirements pertaining to dangerous substances and preparations.

The safety of toys is mainly evaluated according to the so-called “New Approach”, i.e. harmonised standards applying to substances or preparations contained in toys which are not restricted by Directive 76/769/EEC, but which are dangerous in the meaning of Directives 67/548/EEC and 1999/45/EC. Since the New Approach is risk-based – it focuses on exposure due to migration and release of hazardous chemical compounds – hazard classification as such is not relevant. Consequently, the GHS will have no direct effect, either.

The only provision where classification as such becomes relevant relates to dangerous substances or preparations which are banned for inclusion in a toy if they are intended to be used as such while the toy is being used. The GHS could have an effect in so far as it could classify additional substances and mixtures (preparations) compared to the current situation. It is proposed to exempt from the reference to classified substances and mixtures those hazard classifications (classes and categories / types / divisions) which are newly introduced by the GHS. The respective classifications are listed in Table VI.1 of Part I of this study.

Further effects of the GHS will largely depend on the degree to which hazard-based provisions will be introduced in a revised Directive.

##### **I.4.1. Abstract of the legislation**

Council Directive 88/378/EEC (“Toy Safety Directive”) is based on Article 95 of the Treaty. Its objective is to ensure the free movement of toys in the Community market and to protect the health and safety of children using toys and of third parties by completely harmonising the essential safety and health requirements toys must conform with. A toy is defined as any product or material designed or clearly intended for use in play by children of less than 14 years of age.

The Toy Safety Directive (TSD) is based on the so-called “New Approach”. The New Approach was introduced to remove the technical barriers to trade in the internal market due to the use of national standards through the active encouragement of a system of European Standards. The TSD includes mandatory essential safety requirements, conformity assessment procedures, provisions on CE marking, notification procedures and market surveillance. More specific requirements are given in the harmonised standards under the TSD (EN 71). All toys marketed in the EU are expected to have a CE mark, by which the manufacturer declares that the toys are in conformity with the provisions of the TSD.

The Toy Safety Directive requests Member States to take all steps necessary to ensure that toys cannot be placed on the market unless they meet the essential safety requirements set out

in Annex II. With regard to hazardous physico-chemical properties, the following provisions are made:

## “II.2. Flammability

(a) Toys must not constitute a dangerous flammable element in the child’s environment. They must therefore be composed of materials which:

1. do not burn if directly exposed to a flame or spark or other potential seat of fire; or
  2. are not readily flammable (the flame goes out as soon as the fire cause disappears); or
  3. if they do ignite, burn slowly and present a low rate of spread of the flame; or
  4. irrespective of the toy’s chemical composition, are treated so as to delay the combustion process.
- Such combustible materials must not constitute a risk of ignition for other materials used in the toy.

(b) Toys which, for reasons essential to their functioning, contain dangerous substances or preparations as defined in Council Directive 67/548/EEC(1), in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, must not contain, as such, substances or preparations which may become flammable due to the loss of non-flammable volatile components.

(c) Toys must not be explosive or contain elements or substances likely to explode when used as specified in Article 2 (1) of the Directive. This provision does not apply to toy percussion caps, for which reference should be made to point 10 of Annex I and the related footnote.

(d) Toys and, in particular, chemical games and toys, must not contain as such substances or preparations:

Ø which, when mixed, may explode:

- through chemical reaction, or through heating,
- when mixed with oxidizing substances,

Ø which contain volatile components which are flammable in air and liable to form flammable or explosive vapour/air mixture.

## II.3. Chemical properties

1. Toys must be so designed and constructed that, when used as specified in Article 2(1) of the Directive, they do not present health hazards or risks of physical injury by ingestion, inhalation or contact with the skin, mucous tissues or eyes. They must in all cases comply with the relevant Community legislation relating to certain categories of products or to the prohibition, restriction of use or labelling of certain dangerous substances and preparations.

2. In particular, for the protection of children’s health, bioavailability resulting from the use of toys must not, as an objective, exceed the following levels per day: 0,2 • g for antimony, 0,1 • g for arsenic, 25,0 • g for barium, 0,6 • g for cadmium, 0,3 • g for chromium, 0,7 • g for lead, 0,5 • g for mercury, 5,0 • g for selenium, or such other values as may be laid down for these or other substances in Community legislation based on scientific evidence. The bioavailability of these substances means the soluble extract having toxicological significance.

3. Toys must not contain dangerous substances or preparations within the meaning of Directives 67/548/EEC and 88/379/EEC (1) in amounts which may harm the health of children using them. At all events it is strictly forbidden to include, in a toy, dangerous substances or preparations if they are intended to be used as such while the toy is being used. However, where a limited number of substances or preparations are essential to the functioning of certain toys, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, they are permitted up to a maximum concentration level to be defined for each substance or preparation by mandate to the European Committee for Standardization (CEN) according to the procedure of the committee set up by Directive 83/189/EEC, provided the permitted substances and preparations comply with the Community classification rules in respect of labelling, without prejudice to point 4 of Annex IV.”

The procedures for assessing the conformity of toys with the essential requirements are based on the modular approach set out in Council Decision 93/465/EEC. Accordingly, manufacturers have two ways of carrying out their conformity assessment regarding the essential requirements for toys:

a) self-verification: the manufacturer applies a “referenced standard”, draws up a design dossier and describes the means whereby he ensures conformity of the planned production

with the referenced standard. A “referenced standard” is a European standard drafted by a European standardisation body (CEN or CENELEC), following a mandate from the Commission, and for which the reference has been published in the Official Journal. Any toy manufactured in conformity with the harmonised standards is presumed to conform with the essential requirements;

b) EC Type examination: the manufacturer submits the model of the toy as well as a design dossier to one of the laboratories recognised by the Member States (“Notified Bodies”). The Notified Body assesses if the model meets the essential requirements of the Toy Safety Directive as set out in Article 3. If possible, it bases the assessment on available harmonised standards. If the result is positive, it issues an EC Type examination certificate. The manufacturer has to ensure that his production conforms to the approved model.

Before being marketed, toys must be provided with a CE conformity marking which

- symbolises their conformity with the provisions of this Directive ;
- consists of a unique seal or design, namely the CE seal;
- is affixed by the manufacturer or his authorized representative established in the Community.

When a toy falls within the purview of other Directives that stipulate the CE marking, the marking must also indicate that the toy conforms with the requirements of these Directives. Any other mark may be affixed to the toy, provided there is no risk of confusion with the conformity marking. Penalties may be adopted by the Member States if they ascertain that the EC marking has been improperly used.

The Toy Safety Directive is currently under revision. An impact assessment on important issues for the revision was prepared in 2004, cf. above. With regard to flammability, it is probable that the corresponding provisions as set out in Annex II.II.2. will remain unchanged, cf. document ENTR/TOYS/2005/50. With regard to the chemical part, diverging views, in particular referring to CMRs, have been exchanged between the Commission and the Member States while a preliminary agreement has not been achieved yet, cf. the meeting report from 23 May 2005. To clarify open points pertaining to the content of certain chemicals which are used in toys, the Commission Services have launched a study, cf. page 3 below of the meeting report. The study will be available during the second half of 2006.

The European toy industry is innovative and makes a significant contribution to the creation of employment and wealth. The total toy market is estimated in 17.3 billion € at retail prices in 2002, which total imports amounting to over 9 billion €. The European toy industry employs over 100,000 people directly and there are over 2000 companies operating in the toy and games sector. Most of them are small and medium sized enterprises. Some of the European regions in which toy companies are concentrated are the Jura in France, the province of Alicante in Spain and the Black Forest in Germany. There are toy industries also in some regions in the enlargement candidate countries.

The EU toy market has grown 1.4% in 2002. The most important trading partners remain USA, 22% of exports, and the Far East, 88% of imports. One of the main opportunities for the European toy industry is the tremendous export potential of high quality European products. In this field, the European Commission actively support the industry by improving market access conditions in third countries.

#### **I.4.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS**

The interaction between the Community legislation on chemicals and the Toy Safety Directive is manifold. The main link is given by Annex II to the TSD and by a number of European Standards focussing on various aspects of toy safety, e.g. EN 71 -2 which focuses on flammable properties of substances or materials used in toys. In general, the Toy Safety Directive contains four different approaches with regard to chemical substances in toys, cf. below. These approaches will be evaluated in the light of the relevance of the legislation on classification and labelling and of potential effects of the GHS:

**1. Respect of Directive 76/769/EEC on the restriction of the marketing and use of certain dangerous substances and preparations**, cf. Annex II.II.3.1. It is not possible for European Standards or Notified Bodies to allow toys in the market that do not respect the chemical legislation.

In the context of the Toy Safety Directive, respect of Directive 76/769/EEC means that substances which are classified as CMR category 1 or 2 may not be used in substances or preparations (GHS: mixtures) on the market for sale to the general public. However, the corresponding restrictions do not all refer explicitly to the use in toys. Moreover and most important, there is no corresponding restriction relating to articles in Directive 76/769/EEC, except for certain specific CMRs (e.g. wood preservatives). This means that the gross amount of articles is excluded from the restrictions relating to CMRs. This issue is currently discussed in the context of a revision of the TSD.

Evaluation of approach 1: Reference to Directive 76/769/EEC implies that the use of CMR category 1 or 2 substances in substances or mixtures which are used as toys is prohibited. Thus approach 1 is based on (CMR -) hazard. The GHS will have no effect because the classification criteria will not change under GHS.

**2. Specific restrictions for certain chemicals set by the Toys Directive itself.** These are limit values for the bioavailability resulting from the use of toys for the following substances: antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium.

Evaluation of approach 2: Setting limit values has no link to classification and labelling provisions. The GHS will have no effect.

**3. The so-called “New Approach” for substances and preparations which are not restricted by Directive 76/769/EEC, but which are dangerous in the meaning of Directives 67/548/EEC and 1999/45/EC.** The Toy Safety Directive requires:

“Toys must not contain dangerous substances or preparations within the meaning of Directives 67/548/EEC and 88/379/EEC (repealed by Dir 1999/45/EC) in amounts which may harm the health of children using them.”

This sentence is the legal basis for the use of the New Approach for chemicals in toys. The New Approach is to complement the chemical legislation: European Standards and Notified Bodies have to respect the restrictions imposed by Directive 76/769/EEC, but they can impose further restrictions on the use of chemicals classified as dangerous by Directives 67/548/EEC and 1999/45/EC. Recent as well as ongoing standardisation work aims at introducing restrictions related to the use of certain organic chemicals in toys. This work follows a mandate from the Commission to CEN given in 1996. The mandate requested CEN to “prepare one or several European standards concerning the risks associated with the presence of organic chemical compounds in toys ... CEN will have to identify the substances that come

within the remit of Directive 67/548/EEC, with the exception of those banned by Directive 76/769/EEC, within the groups of organic chemical products recommended by the Toxicology Section of the Scientific Advisory Committee, as well as those of paints and colouring agents.” In the following, CEN elaborated the draft European Standard prEN 71 -Y “Safety of toys – Organic chemical compounds – Requirements”. Draft standard prEN -Y addresses the risks by in particular taking into account the potential exposure to and toxicological effects of those substances which are considered to represent the greatest health hazards. It specifies requirements for the most hazardous organic compounds concerning their migration from, or content in, toys and parts of toys which (when used in a foreseeable fashion by children, or as intended) are likely to be mouthed, or which might be ingested; which come into prolonged contact with the skin or into contact with the eyes or which contain organic compounds which might be inhaled.

Draft Standard prEN-Y sets out a table listing the toys and toy components, made from specific listed materials, which may not contain or release the organic compounds associated with them beyond the stipulated amounts. The amounts are also expressed in tables.

On the whole, CEN considered the risks associated with more than 650 organic compounds. The draft European Standard prEN 71 -Y contains restrictions for the use of 90 chemical substances in toys. These restrictions are not the same for all toys, but are linked to at least one of the 18 categories of toys. The organic compounds covered by the draft Standard can be assigned to the following categories: solvents, preservatives, wood preservatives, plasticisers, flame retardants, monomers, primary aromatic amines, processing aids and colouring agents. However, CEN realised that not all potentially hazardous substances could be addressed. The draft therefore explicitly reiterates that the limitation of the scope to only some hazardous compounds should not reduce the responsibility of toy manufacturers, importers and suppliers to ensure that the use of other substances will not endanger the health of children whilst playing with toys as intended or in a reasonable manner.

Evaluation of approach 3: The approach is risk -based – it focuses on exposure due to migration and release of hazardous chemical compounds. The GHS will have indirect effects only because potentially additional chemicals may become eligible for the application of the New Approach. The effects are deemed minimal.

#### **4. Prohibition to include dangerous substances and preparations (mixtures) in a toy if they are intended to be used as such while the toy is being used**, cf. Annex I.I.3.3.

Evaluation of approach 4: Classification is relevant because it triggers the ban of the respective chemical. The GHS may have direct effects because it could classify additional chemicals compared to the current situation.

The potentially affected hazard classifications are listed in Table V.3 of Part I of this study.

The latter provision has an escape clause:

“Where a limited number of substances or preparations are essential to the functioning of the toy, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, they are permitted up to a maximum concentration level to be defined for each substance or preparation by mandate to the European Committee for Standardization (CEN) according to the procedure of the committee set up by Directive 83/189/EEC, provided the permitted substances and preparations comply with the Community classification rules in respect of labelling, without prejudice to point 4 of Annex IV.”

The two standards which exist in this field are EN 71 -4:1990 “Safety of toys – Part 4: Experimental sets for chemistry and related activities” and EN 71 -5:1993 “Safety of toys – Part 5: Chemical toys (sets) other than experimental sets”.

The approach taken in the escape-clause is the New Approach, focussing on exposure due to migration and release of hazardous chemical compounds. The GHS will have indirect effects only which are deemed minimal, cf. above.

#### **I.4.3. Suggestions how to minimise potential effects of the GHS**

In order to minimise potential effects related to additional classification under GHS, it is proposed to exempt from the reference to classified substances and mixtures those hazard classifications (classes and categories / types / divisions) which are newly introduced by the GHS, in accordance with **Solution 1**, cf. Part I of this study. The respective classifications are listed in Table VI.1 of Part I of this study.

#### **I.4.4. Member State Issues**

As mentioned above, only selected chemicals, i.e. 90 organic chemicals from Annex I to Council Directive 67/548/EEC, have been subject to the New Approach. The selection was made according to the toxicological relevance of the chemical and the availability of appropriate analytical methods. Thus, the standards can only be interpreted as a first step to a comprehensive ruling – it is the manufacturer who has to comply with the safety requirements of Article 3 of Directive 88/378/EEC for all the other dangerous substances and mixtures used in toys.

In this connection, there seems to be no clarity about the interpretation of the phrase “Toys must not contain dangerous substances or preparations within the meaning of Directives 67/548/EEC and 88/379/EEC (repealed by Dir 1999/45/EC) in amounts which may harm the health of children using them” when it is used outside the harmonised standards. In one Member State, this provision has been interpreted to mean that toys may not contain a classified substance above the limit where it needs to be taken into account for general classification purposes, e.g. 1% for substances classified as carcinogen category 3 (interpretation 1). However, it seems that at some other Member States are interpreting the provision in a different manner, cf. document ENTR/TOYS/2005/49: they make a case-by-case evaluation of the specific substance in order to decide if the substance may harm the child due to migration (interpretation 2).

1. If the first interpretation is supported, cut-off values for dangerous substances and mixtures become relevant. They are defined either in Annex I to Directive 67/548/EEC, in Annex II to Directive 1999/45/EC or, by default, in Article 3.3 of the latter act. Under GHS, these values will change partly, depending on the endpoint considered:

**Table I.4.3.1:** Cut-off values for classified substances which have to be taken into account for classification purposes

GHS Hazard Class	Cut-off Values from the GHS Regulation	Comparable EU Cut-off Value, cf. Dir 1999/45/EC (w/w)
Acute toxicity	• 1%	• 1% harmful
Skin corrosion / irritation	• 1%	• 1%
Serious eye damage / eye irritation	• 1%	• 1%
Respiratory / skin sensitisation	• 1%	• 1%
Germ Cell Mutagenicity, Category 1	• 0.1%	• 0.1% cat. 1 or 2 mutagenic
Germ Cell Mutagenicity, Category 2	• 1%	• 1% cat. 3 mutagenic
Carcinogenicity, Category 1	• 0.1%	• 0.1% cat. 1 or 2 carcinogenic
Carcinogenicity, Category 2	• 1%	• 1% cat. 3 carcinogenic
Reproductive toxicity, Category 1	• 0.1%	• 0.1% cat. 1 or 2 reprotoxic
Reproductive toxicity, Category 2	• 1% (cf. 3.7.3.3 GHS)	• 1% cat. 3 reprotoxic
STOT (single exposure)	• 1%	• 0.1% very toxic • 0.1% toxic • 1% harmful
STOT (repeated exposure)	• 1%	• 0.1% toxic
Hazardous to the aquatic environment	• 1%	• 0.1% (N)

In case of the hazards high lighted in blue, the GHS would provide for relief from the requirements. Consequently, and supposing the above -mentioned interpretation is supported, toys which contain substances in concentrations between the EU and the GHS cut-off value would be allowed for use in toys in future.

**The application of cut-off values implies that hazard classification becomes a relevant criterion because cut-off values only apply to classified substances. Due to different mechanisms, the GHS may lead to additional substances and / or mixtures classified for the hazards acute toxicity, STOT (single / repeated exposure), skin corrosion / irritation, serious eye damage / eye irritation, reproductive toxicity , aspiration hazard and eventually hazardous to the aquatic environment.**

2. If the latter interpretation is supported, the GHS will have an indirect effect only which is deemed minimal: If migration is considered to be crucial, the evaluation is risk -based and classification as such is not relevant.

#### I.4.5. Perspective for the Toy Safety Directive in view of the GHS -implementing Regulation

Potential effects of the GHS -implementing Regulation on the Toy Safety Directive would be mainly due to the classification of additional substances and mixtures. Further effects will largely depend on the degree to which hazard -based provisions will be introduced in a revised Directive. In connection with this, current discussions are covering i.a. the following issues, cf. page 54-57 of the Commission study on the impact of the revision of Council Directive 88/378/EEC on the safety of toys:

- It was proposed to ban category 1 and 2 CMRs in toys completely;
- It was proposed that toys may not contain substances meeting the criteria for classification as *Toxic*, *Harmful* or *Corrosive* (above a certain concentration limit, e.g. 0.1%) according to the provisions of Directive 67/548/EEC unless the Scientific Committee has performed an evaluation and found the use to be acceptable in toys;
- It was proposed that substances that are skin sensitisers and respiratory tract sensitisers are banned for use in toys, but with the possibility of an authorisation under certain conditions after a risk assessment provided by the manufacturer has been evaluated by the Scientific Committee.

The next table shows those GHS hazard classes and categories which are most closely corresponding to the aforementioned EU categories of danger:

**Table I.4.4.1:** EU classifications referred to in the revision proposals and the most closely corresponding GHS hazard classifications

EU Category of Danger (Symbol), Risk Phrase	GHS Hazard Class / Category
Toxic (T), R25	Acute Toxicity, categories 2 or 3, oral
Toxic (T), R24	Acute Toxicity, categories 2 or 3, dermal
Toxic (T), R23	Acute Toxicity, categories 2 or 3, inhalation (dusts and mists)
Toxic (T), R23	Acute Toxicity, category 2, inhalation (vapours)
Toxic (T), R39 (25/24/23)	STOT (single exposure), category 1
Toxic (T), R48 (25/24/23)	STOT (repeated exposure), category 1
Harmful (Xn), R22	Acute Toxicity, categories 3 or 4, oral
Harmful (Xn), R21	Acute Toxicity, categories 3 or 4, dermal
Harmful (Xn), R20	Acute Toxicity, category 4, inhalation (dusts and mists)
Harmful (Xn), R20	Acute Toxicity, categories 3 and 4, inhalation (vapours)
Harmful (Xn), R48 (22/21/20)	STOT (repeated exposure), category 2
Harmful (Xn), R68 (22/21/20)	STOT (single exposure), category 2
Harmful (Xn), R65	Aspiration toxicity, category 1
Corrosive (C), R35	Skin Corrosive, category 1A

Corrosive (C), R34	Skin Corrosive, categories 1B or 1C
Harmful (Xn), R42	Respiratory Sensitiser, category 1
Irritant (Xi), R43	Skin Sensitiser, category 1

As stated earlier in this document, additional substances could be classified for the hazards *acute toxicity and STOT (single / repeated exposure)*. However, the manufacturer might then check whether or not an individual substance or mixture used in toys would actually be affected.

In general, it may be advisable to discuss the revision proposals in the light of the anticipated effects of the GHS Regulation.

#### Basic documents used for the analysis

- European Commission: Draft Proposal for a Directive of the European Parliament and of the Council on the Safety of Toys, document ENTR/TOYS/2005/50 (provisional and non-binding status)
- Expert Group on Toy Safety, Interpretation of Directive 88/378/EEC concerning classified chemicals, ENTR/TOYS/2005/49
- European Commission: Study on the Impact of the Revision of the Council Directive 88/378/EEC on the Safety of Toys, October 2004
- European Commission: Report of the Meeting on the Revision of Council Directive 88/378/EEC on the Safety of Toys – Chemicals Part

## **I.5. Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers**

[http://europe.eu.int/eur-lex/en/consleg/pdf/1975/en\\_1975L0324\\_do\\_001.pdf](http://europe.eu.int/eur-lex/en/consleg/pdf/1975/en_1975L0324_do_001.pdf)

Council Directive 75/324/EEC aims at harmonising the laws of the Member States pertaining to the mandatory technical specifications of aerosol dispensers. The harmonised mandatory technical specifications are set out in the Annex to the Directive. The Member States may not refuse, prohibit or restrict the marketing of any aerosol dispenser which complies with these requirements. Particular labelling provisions pertain to ‘flammable contents’ of aerosol dispensers, i.e. to substances and preparations (GHS: mixtures) which are classified according to the criteria laid down for the categories ‘extremely flammable’, ‘highly flammable’ and ‘flammable’ and listed in Annex VI to Council Directive 67/548/EEC. Beyond, a reference to GHS class *flammable aerosols* may be appropriate. Finally, it should be considered if the full range of the respective hazard classes needs to be adopted.

### **I.5.1. Abstract of the legislation**

Council Directive 75/324/EEC is based on Article 95 of the Treaty. It aims at harmonising the laws of the Member States pertaining to the mandatory technical specifications of aerosol dispensers. An aerosol dispenser is defined as “any non-reusable container made of metal, glass or plastic and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state”.

The field of application of the Directive is limited to aerosol dispensers made of metal, glass or plastic. The mandatory technical specifications are set out in the Annex to the Directive. The person responsible for the marketing of aerosol dispensers shall affix the symbol ‘3’ (inverted epsilon) to aerosol dispensers, as proof that they satisfy the requirements of this Directive and the Annex. The Member States may not refuse, prohibit or restrict the marketing of any aerosol dispenser which complies with these requirements. Particular labelling provisions pertain to ‘flammable contents’ of aerosol dispensers, i.e. to substances and preparations (GHS: mixtures) which are classified according to the criteria laid down for the categories ‘extremely flammable’, ‘highly flammable’ and ‘flammable’ and listed in Annex VI to Council Directive 67/548/EEC, namely:

### **Article 1.8. Flammable contents**

'Flammable contents' means the substances and preparations corresponding to the criteria laid down for the categories 'extremely flammable', 'highly flammable' and 'flammable' and listed in Annex VI to Council Directive 67/548/EEC. The flammability and flash point of the contents of the container shall be determined using the specific methods described in Part A of Annex V to the abovementioned Directive.

### **Article 2.2. Labelling**

Without prejudice to the Directives relating to the classification, packaging and labelling of dangerous substances and preparations, particularly as regards danger to health and/or the environment, any aerosol dispenser must visibly bear the following legible and indelible marking:

- (a) Whatever its contents: 'Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50 °C. Do not pierce or burn, even after use.';
- (b) Where the contents are flammable within the meaning of point 1.8: the flame symbol where appropriate, the indication that the substances and/or preparations contained in the aerosol dispenser, including the propellant, are flammable and the relevant risk phrases determined in accordance with the criteria in points 2.2.3, 2.2.4 or 2.2.5 of Annex VI to Directive 67/548/EEC and, as regards the flame symbol and the indication of danger, in accordance with the provisions of Annex II to the abovementioned Directive.

### **2.3. Special statements concerning use**

Without prejudice to the Directives relating to the classification, packaging and labelling of dangerous substances and preparations, particularly as regards danger to health and/or the environment, any aerosol dispenser must visibly bear the following legible and indelible wording:

- (a) Whatever its contents: the additional operating precautions which alert consumers to the specific dangers of the product;
- (b) Where the contents are flammable, the following warnings:
  - 'Do not spray on a naked flame or any incandescent material.'
  - 'Keep away from sources of ignition — No smoking.'
  - 'Keep out of the reach of children'.

Where the person responsible for the marketing of aerosol dispensers is in possession of test results or other data showing that although those aerosol dispensers have flammable contents they do not present any risk of ignition under normal or reasonably foreseeable conditions of use, he may on his own responsibility decide not to apply the provisions of points 2.2 (b) and 2.3 (b) of the Annex. He shall make a copy of such documents available to the Member States. In such a case the quantity of flammable material contained in the aerosol dispenser must be stated clearly on the label, in the form of the following legible and indelible wording: 'X % by mass of the contents are flammable'.

In order to allow a prompt adaptation of the technical specifications in line with technical progress, the Directive introduces a procedure which is set out in Council Decision 1999/468/EC.

### **I.5.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS**

The Directive on aerosol dispensers derives particular labelling provisions from the classification of its content as 'extremely flammable', 'highly flammable' and

‘flammable’ as defined in 2.2.3., 2.2.4. and 2.2.5. of Annex VI to Council Directive 67/548/EEC. Table I.5.2.1 below shows how the currently used classifications which are further described through the risk phrases in the second column translate into the corresponding GHS hazard classes and categories:

**Table I.5.2.1:** Overview over the EU classifications used in Directive 75/324/EEC and the most closely corresponding GHS classifications

EU Category of Danger	Definitions & R-phrases which further describe the hazardous properties	GHS Hazard Class	GHS Definitions & Subclassifications
Extremely flammable (F+)	R12 “Extremely flammable” - liquid substances and preparations which have a flash point lower than 0°C and a boiling point (or in case of a boiling range the initial boiling point) lower than or equal to 35°C ( $T_{fl} < 0^{\circ}\text{C}$ ; $T_{b,i} \leq 35^{\circ}\text{C}$ )	Flammable Liquids <u>Category 1:</u> $T_{fl} < 23^{\circ}\text{C}$ ; $T_{b,i} \leq 35^{\circ}\text{C}$	A flammable liquid means a liquid having a flash point of not more than 93°C. 4 categories (category 1-3 will be taken up in the GHS Regulation)
Extremely flammable (F+)	R12 “Extremely flammable” - gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure	Flammable Gases <u>Category 1</u>	A flammable gas is a gas having a flammable range with air at 20°C and a standard pressure of 101.3 kPa. 2 categories (only category 1 is taken up in the GHS draft Regulation)
Highly flammable (F)	R11 “Highly flammable” - liquid substances and preparations having a flash point below 21°C but which are not extremely flammable ( $T_{fl} < 21^{\circ}\text{C}$ )	Flammable Liquids <u>Category 2:</u> $T_{fl} < 23^{\circ}\text{C}$ ; $T_{b,i} > 35^{\circ}\text{C}$	A flammable liquid means a liquid having a flash point of not more than 93°C. 4 categories (category 1-3 is taken up in the GHS draft Regulation)
Highly flammable (F)	R11 “Highly flammable” - solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition	Flammable Solids	A flammable solid is a solid which is readily combustible, or may cause or contribute to fire through friction. Readily combustible solids are powdered, granular, or pasty substances which are dangerous if they can be easily ignited by brief contact with an ignition source, such as a burning match, and if the fire spreads rapidly. 2 categories according to results of burning rate test

Highly flammable (F)	R15 "Contact with water liberates extremely flammable gases" - substances and preparations which, in contact with water or damp air, evolve extremely flammable gases in dangerous quantities, at a minimum rate of one litre per kilogram per hour	Substances and mixtures which, in contact with water, emit flammable gases	Substances or mixtures which, in contact with water, emit flammable gases or solid or liquid substances or mixtures which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities. 3 categories
Highly flammable (F)	R17 "Spontaneously flammable in air" - substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any input of energy	Pyrophoric Liquids	A pyrophoric liquid is a liquid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air. 1 category
Highly flammable (F)	R17 "Spontaneously flammable in air" - substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any input of energy	Pyrophoric Solids	A pyrophoric solid is a solid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air. 1 category
Flammable	R10 "Flammable" - liquid substances and preparations having a flash point equal or greater than 21°C, and less than or equal to 55°C (21°C • T <sub>n</sub> • 55°C)	Flammable Liquids <u>Category 3:</u> 23°C • T <sub>n</sub> • 60°C	A flammable liquid means a liquid having a flash point of not more than 93°C. 4 categories (category 1-3 will be taken up in the GHS Regulation)

With regard to the conversion of R12 and R11 to *Self-Reactives Type C-F*, cf. Table V.3, Table I.5.2.1 above as well as Figure 2 below do not take account of this hazard – it is assumed that only a negligible part of substances and mixtures that are now classified as R12 or R11 will be covered by this hazard classification.

The GHS attributes intrinsic flammable properties to more hazard classes and subcategories than the EU system does, the latter usually assigning a particular R -phrase as distinction criterion from other properties. Especially *Highly Flammable* substances and mixtures are affected, as can be seen from Figure 2 below :

EU	Highly Flammable (F)	Highly Flammable (F)	Highly Flammable (F)	Highly Flammable (F)
	R11 “Highly flammable” Liquids	R11 “Highly flammable” Solids	R15 “Contact with water liberates extremely flammable gases”	R17 “Spontaneously flammable in air”
	⇓	⇓	⇓	⇓
GHS	Flammable Liquids (Cat. 2)	Flammable Solids	Substances and mixtures which, in contact with water, emit flammable gases	Pyrophoric Liquids
				Pyrophoric Solids

Figure 2: Conversion from EU *Highly Flammable (F)* to various GHS hazard classes

Although the GHS assigns intrinsic flammable properties to more hazard classifications compared to the EU system, this does not necessarily imply that more substances and mixtures are classified under GHS, cf. also Table V.3 of Part I of this study. In this connection it may generally be worthwhile to consider if the full range of subcategories under a GHS hazard class should be adopted for regulation under Directive 75/324/EEC.

With regard to flammable gases and solids, the corresponding GHS hazard classes cover effectively the same substances as the EU classifications do. Similarly, category 1 of GHS class *flammable liquids* covers the same substances as the EU category *extremely flammable*. For categories 2 and 3, the differences in the flash point limiting values will have very little effect; they are supposed to be within the margins of test method differences. With regard to measuring flash points, both the GHS and the EU system use closed cup methods, but the EU test methods are more specific than those of the GHS. The classification scheme for the GHS hazard class *flammable liquids* as compared to the corresponding EU categories of danger is summarised in the following table:

**Table I.5.2.4: Flammable Liquids – Comparison of Categories ;**  
 $T_{fl}$  = flash point,  $T_{b,i}$  = initial boiling point

EU Classification; R-phrase	EU Criteria	Flammable Liquids – Subcategory	GHS Criteria
Extremely Flammable F+, R12	$T_{fl} < 0\text{°C}$ and $T_{b,i} > 35\text{°C}$	category 1	$T_{fl} < 23\text{°C}$ and $T_{b,i} > 35\text{°C}$
Highly Flammable F, R11	$T_{fl} < 21\text{°C}$	category 2	$T_{fl} < 23\text{°C}$ and $T_{b,i} > 35\text{°C}$
Flammable R10	$21\text{°C} < T_{fl} < 55\text{°C}$	category 3	$23\text{°C} < T_{fl} < 60\text{°C}$
None	None	category 4	$60\text{°C} < T_{fl} < 93\text{°C}$

Another and particularly interesting feature of the GHS will be the introduction of the new hazard class *flammable aerosols*, cf. the GHS excerpt on the next page. Comparing the wording, the GHS defines the term “aerosol dispenser” in almost the same way as Directive 75/324/EEC does. With regard to flammable aerosols, the GHS uses the classification as *flammable liquid / gas / solid* of the content as basis for a potential classification as *flammable aerosol* (2 subcategories with different hazard statements). The decision on further classification will depend on the heat of combustion, cf. decision logic 2.3 (a). For spray aerosols and foam aerosols, any pre-classification is not relevant, cf. the corresponding decision logics 2.3 (b) and 2.3 (c) of 2.3.4.1 GHS:

## Chapter 2.3 Flammable Aerosols

### 2.3.1 Definition

Aerosols, this means aerosol dispensers, are any non-refillable receptacles made of metal, glass or plastics and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state or in a gaseous state.

### 2.3.2 Classification criteria

2.3.2.1 Aerosols should be considered for classification as flammable if they contain any component which is classified as flammable according to the GHS criteria, i.e.:

**Flammable liquids (see Chapter 2.6);**

**Flammable gases (see Chapter 2.2);**

**Flammable solids (see Chapter 2.7).**

*NOTE: Flammable components do not cover pyrophoric, self-heating or water-reactive substances and mixtures because such components are never used as aerosol contents.*

2.3.2.2 A flammable aerosol is classified in one of the two categories for this Class on the basis of its components, of its chemical heat of combustion and, if applicable, of the results of the foam test (for foam aerosols) and of the ignition distance test and enclosed space test (for spray aerosols). See decision logic in 2.3.4.1.

### 2.3.3 Hazard communication

General and specific considerations concerning labelling requirements are provided in *Hazard communication: Labelling* (Chapter 1.4). Annex 2 contains summary tables about classification and labelling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

	Category 1	Category 2
<b>Symbol</b>	Flame	Flame
<b>Signal word</b>	Danger	Warning
<b>Hazard statement</b>	Extremely flammable aerosol	Flammable aerosol

### 2.3.4 Decision logic and guidance

The decision logic and guidance, which follow, are not part of the harmonized classification system, but have been provided here as additional guidance. It is strongly recommended that the person responsible for classification studies the criteria before and during use of the decision logic. ...

### I.5.3. Suggestions how to minimise potential effects of the GHS

- Since GHS hazard class *flammable aerosols* will be taken up both in the transport and supply & use (GHS) legislation, it may be appropriate to introduce a reference to GHS hazard class *flammable aerosols* into Council Directive 75/324/EEC, in addition to the classifications *flammable liquids / gases / solids*, cf. also the last bullet point in Chapter I.5.2.
- With regard to the GHS classes *flammable solids* and *substances and mixtures which, in contact with water, emit flammable gases*, it has to be considered if reference to the full range (all subcategories) of the respective hazard class is necessary.
- It should be questioned if it is necessary to refer to the GHS hazard classes *pyrophoric liquids / solids* and *substances and mixtures which, in contact with water, emit flammable gases* – such components are normally not used as aerosol contents.
- In order to minimise any effect related to GHS class *Flammable Liquids, category 3*, it is proposed to exempt classified substances and mixtures with an upper flash point limit > 55°C, in accordance with **Solution 2**, cf. Table VI.2 of Part I of this study.

#### Basic documents used for the analysis

- ECB1/75/01 -Part A. rev.1
- UN document UN/SCEGHS/9/INF.8

## II. Handling of Chemicals for Particular Uses

### II.1. Directive 1998/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market

[http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/1\\_123/1\\_12319980424en00010063.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/1_123/1_12319980424en00010063.pdf)

Council Directive 1998/8/EC ( “Biocides Directive”) concerning the placing of biocidal products on the market provides a framework of rules pertaining to the establishment at EU level of positive lists of substances which may be used in biocidal products. Three Community lists will be produced. In addition to the list of active substances (Annex I), which can then be used in “normal” biocidal products, there will be a list of active substances that can be used in low -risk biocidal products (Annex IA); beyond, there will be a list of basic substances (Annex IB). The substances will be included in the lists after having passed successfully the evaluation procedure.

An active substance cannot be included in Annex IA if it is classified according to Directive 67/548/EEC as carcinogenic (cat. 1 or 2), mutagenic, (cat. 1 or 2), toxic for reproduction (cat. 1 or 2), sensitising or is bioaccumulative and does not readily degrade. In addition, low risk biocidal products may not contain any component that is a “substance of concern” in the meaning of Directive 67/548/EEC and is present at a concentration leading the product to be regarded as dangerous in the meaning of Directive 1999/45/EC. The recognition of a biocidal product as “low risk” will entail advantages for the notifier.

Under GHS, additional substances and mixtures will probably be classified. This could mean that some products may disqualify for the predicate “low -risk biocidal product”. However, if there are any effects for biocidal products will only be clear once a range of product evaluations is available: The review program has not yet reached a stage where products have to be evaluated in accordance with Annex VI to the Biocides Directive.

#### II.1.1. Abstract of the legislation

The objective of the Biocides Directive is to achieve a high level of protection, especially in relation to the environment, health and a sustainable development, and to minimise barriers to trade in biocidal products and in products treated with them. It is based on Article 95 of the Treaty (Internal Market).

The Biocides Directive provides a framework of rules concerning

- the authorisation and the placing on the market for use of biocidal products within Member States;
- the mutual recognition of authorisations within the Community;
- the establishment at Community level of positive lists of active substances which may be used in biocidal products.

Only authorised biocidal products may be placed on the market. **The Directive is based on risk:** Harmonised community provisions for evaluation and rules for inclusion on a positive list of active substances, followed by authorisation of biocidal products will provide the control of risks posed by biocidal products.

Three Community lists of active substances will be produced. In addition to the list of active substances (Annex I), which can then be used in “normal” biocidal products, there will be a list of active substances that can be used in low -risk biocidal products (Annex IA); beyond, there will be a list of basic substances (Annex IB). The substances will be included in the lists after having passed successfully the evaluation procedure. An active substance cannot be included in Annex IA if it is classified according to Directive 67/548/EEC as carcinogenic (cat. 1 or 2), mutagenic, (cat. 1 or 2), toxic for reproduction (cat. 1 or 2), sensitising or is bioaccumulative and does not readily degrade.

A biocidal product classified as CMR cat. 1 or 2 shall not be authorised for use by the general public. A low risk biocidal product cannot contain any component that is a “substance of concern”. The designation of a biocidal product as “low -risk biocidal product” entails a number of privileges for the applicant and the competent authorities:

- a) less testing costs: Instead of submitting a full product dossier that complies with the requirements of Annexes II B, IIIB and IVB, the applicant has only to provide a reduced biocidal product data set in accordance with the provisions set out in Article 8 (3). However, it has to be pointed out that the dossier requirements for the active substance itself to get it included into Annex IA are the same as for getting it included into Annex I;
- b) registration: Instead of a lengthy and more costly authorisation procedure<sup>1</sup>, the competent authority of a Member State, following an application submitted by an applicant, after verification that the dossier meets the relevant requirements of this Directive, may allow the placing on the market of a low -risk biocidal product in its territory or in a part thereof. For applications for biocidal products that require registration, the competent authority shall take a decision within a period of 60 days.

With regard to classification and labelling, biocidal products are subject to the provisions of Directives 67/548/EEC and 1999/45/EC. When the GHS enters into force, biocidal products will be subject to the provisions of the GHS implementing Regulation.

### **II.1.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS**

Article 20 is devoted to the classification, packaging and labelling of biocidal products, stating:

1. Biocidal products shall be classified in accordance with the provisions relating to classification in Directive 88/379/EEC. ...
3. Biocidal products shall be labelled in accordance with the provisions relating to labelling in Directive 88/379/EEC [repealed by Directive 1999/45/EC].

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<sup>1</sup> Registration fees are sometimes considerably lower than authorisation fees, although the available information is incomplete. In DK, they are below 10% of the authorisation fees, in FR at around 20%, in BE 50% and in ES around 100%. Absolute values differ between 500 EUR (BE) and 4.000 EUR (FR) for registration, and from 1.000 EUR (BE) up to 10.000 or even 40.000 EUR (FR and DK) for authorisation. However, these differences in fees have to be seen in the light of the much higher costs for evaluating dossiers for the active substances themselves to get them included in Annex I or IA. At this stage, there is no differentiation for the substances, and fees range from 100.000 up to 350.000 EUR, depending on the Member State. In addition, there are the dossier compilation costs, which depend strongly on the properties of the substances – i.e. certain chronic studies (which are the costliest so far) can be waived if relevant in-vitro studies are all negative.

When the GHS enters into force, biocidal products and their ingredients will be subject to the provisions of the new system. **This means that all active substances, basic substances and biocidal products will have to be reclassified and relabelled after the GHS Regulation has entered into force.**

The GHS Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*. A transitional period is foreseen where a supplier may choose to apply the current Directives on classification and labelling or the GHS. This is to encourage enterprises to make the most efficient use of their resources to align their practice to the new system. During the transitional period, Annex I to Directive 67/548/EEC will be legally binding. As the (re-)classification of mixtures depends on the preceding (re-)classification of substances, the GHS criteria will have to be applied to substances first and then to mixtures. The Commission Services Directorate -General (DG) Enterprise & Industry and DG Environment propose 3 years for substances and further 4 or 5 years for mixtures. These proposals will be subject to stakeholder comment in the public consultation on the GHS draft Regulation.

### **Specific Classification Issues**

In the Biocides Directive, most legal obligations are risk -based, i.e. based on a combination of hazard and exposure data. There are only three obligations where decisions are based on hazard and classification alone so that the GHS might have an effect:

#### **1. Article 10.1: Inclusion of an active substance in Annex IA**

An active substance cannot be included in Annex IA if it is classified according to Directive 67/548/EEC as:

- carcinogenic,
- mutagenic,
- toxic for reproduction,
- sensitising, or
- is bioaccumulative and does not readily degrade.

With regard to the hazards CMR and sensitisation, it is not expected that the kind and number of substances classified according to the GHS will change or increase compared to the current system, cf. Table V.3 of Part I or the analysis of the Cosmetics Directive (Chapter I.3.2).

#### **2. Article 5.2: Authorisation for marketing or use to the general public**

A biocidal product classified according to Article 20(1) as toxic, very toxic or as a category 1 or 2 carcinogen, or as a category 1 or 2 mutagen or classified as toxic for reproduction category 1 or 2, shall not be authorised for marketing to, or use by the general public.

The conversion of the EU categories of danger *Very Toxic* and *Toxic* to the corresponding GHS hazard classifications for the different routes of uptake is given in column 1 and 2 in Table II.2.2.1 below:

**Table II.2.2.1:** Conversion from EU *Very Toxic* and *Toxic* to the corresponding GHS classification

EU Category of Danger / Risk Phrase	Most closely corresponding GHS classification(s)	Potential effects on the number of classified biocidal products
Very Toxic (T+), R28 (oral)	Acute Toxicity, cat. 1 or 2 (oral)	Statement not possible
Very Toxic (T+), R27 (dermal)	Acute Toxicity, cat. 1 (dermal)	Statement not possible
Very Toxic (T+), R26 (inhalation of gases)	Acute Toxicity, cat. 1 (inhalation of gases)	Statement not possible
Very Toxic (T+), R26 (inhalation of vapours)	Acute Toxicity, cat. 1 (inhalation of vapours)	Statement not possible
Very Toxic (T+), R26 (inhalation of dusts or mists)	Acute Toxicity, cat. 1 or 2 (inhalation of dusts or mists)	Statement not possible
Toxic (T), R25 (oral)	Acute Toxicity, cat. 2 or 3 (oral)	Statement not possible
Toxic (T), R24 (dermal)	Acute Toxicity, cat. 2 or 3 (dermal)	Statement not possible
Toxic (T), R23 (inhalation of gases)	Acute Toxicity, cat. 2	Statement not possible
Toxic (T), R23 (inhalation of vapours)	Acute Toxicity, cat. 2 (inhalation of vapours)	Statement not possible
Toxic (T), R23 (inhalation of aerosols and particulates)	Acute Toxicity, category 2 or 3 (inhalation of dusts or mists)	Statement not possible

It has to be verified if the reference to *Very Toxic* includes also the reference to the risk phrase R39 and R48 (all routes of uptake). In this case, further conversions to *STOT (single / repeated exposure) category 1* according to Table V.3 of Part I of this study or according to the correlation table of Annex VII to the GHS Regulation would apply.

- **Acute Toxicity:** Whereas a clear-cut statement can be made concerning an increased / decreased number of classified substances in a defined classification interval under GHS, cf. Table V.3 of Part I, a corresponding statement for mixtures can hardly be made. This means that it cannot be predicted if the classification of a multi-ingredient biocidal product as derived by one of the GHS calculation approaches, cf. Chapter 3.1 GHS, will deviate from the most closely corresponding EU classification as derived from the EU conventional calculation method, cf. Annex II, Part A of Directive 1999/45/EC. Available

studies only provide preliminary answers for simple mixtures where one substance is diluted in an inert solvent, cf. Annex I to this study.

- Apart from the classification of a biocidal product, the conversion of the reference to a particular EU category to (a) defined GHS category (ies) in the Biocides Directive is crucial. For the oral route of uptake, it will be of relevance if the Biocides Directive will refer to category 1 GHS or to category 1 and 2 GHS in future, cf. Figure 3. In the former case, less biocidal products might be caught compared to the current situation. In the latter case, the opposite could occur in theory. A related situation may arise for *Toxic*: Will the reference to *Toxic* be replaced by category 3 GHS or by category 2 and 3 GHS in the Biocides Directive? In the former case, a wider LD<sub>50</sub> range is covered, due to the upper limit being LD<sub>50</sub> = 300 mg/kg bw. In the latter case, this trend is even more pronounced because the lower LD<sub>50</sub> limit would be lowered from 25 to 5 mg/kg bw. As a consequence of both cases, more biocidal products could potentially be caught. The situation and the underlying reasoning for the other routes of uptake are similar, though not completely the same as for the oral pathway.

Potential effects related to GHS class *acute toxicity* will depend on an adaptation of the reference to category 1-3 according to Table VI.2 of Part I of this study.

Figure 3: Acute Oral Toxicity – LD<sub>50</sub> ≤ 300 mg/kg bw

<b>EU</b>	T <sup>+</sup> R28		T R25		
<b>LD<sub>50</sub></b>	5	5-25	25-50	50-200	200-300
<b>GHS</b>	Cat. 1	Category 2		Category 3	

- *STOT (single / repeated exposure) category 1*: In case the references to *STOT (single / repeated exposure), category 1* are relevant, cf. above, additional biocidal products could be classified, cf. Table V.3 of Part I and the information given in Annex I to this study. Potential effects will then depend on an adaptation of the references to *STOT (single / repeated exposure) category 1* according to Table VI.2 of Part I of this study.
- With regard to the endpoints *carcinogenicity* and *mutagenicity*, the number of classified products is not likely to change, cf. the discussion in other chapters of this study. In case of reproductive toxicity, a lower concentration limit for reprotoxic ingredients (0.3% GHS category 1A and 1B versus 0.5% EU category 1 and 2) might lead to an increased number of biocidal products which are classified for *reproductive toxicity*. Consequential effects on the obligation of Article 5.2 may be prevented by exempting from the scope of Directive 1998/8/EC those biocidal products (mixtures!) where reprotoxic ingredients are contained at a concentration below 0.5%

### 3. Article 2.1 (b) and 2.1 (e): Low-risk biocidal products

A biocidal product which contains as active substance(s) only one or more of those listed in Annex IA and which does not contain any substance(s) of concern ... This may be any other than the active substance, which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to create such an effect. It would be normally a substance

classified as dangerous according to 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, and present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Article 3 of Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, as replaced by Directive 1999/45/EC.

The GHS may classify additional substances (here: “substances of concern”) and mixtures. The hazards which will probably be affected are listed in Table V.3 of Part I of this study. Additional classification could imply that some products (mixtures!) may disqualify for the predicate “low-risk biocidal product”. At the current stage, however, it is difficult to make concrete statements on this issue: The review program has not yet reached a stage where products are to be evaluated in accordance with Annex VI. Consequently, a quantification on how many products would be evaluated as “normal” or “low risk” in the current system and on how many of them would not qualify for the predicate “low risk biocidal product” is not yet possible.

### **Specific Labelling Issues**

Classified biocidal products will have to bear a corresponding label. Updating of a label due to new scientific or technical information is part of the approval decision (authorisation / registration) related to a biocidal product.

Suppliers are allowed to include additional information on the label if this does not interfere with the labelling information following from the application of the GHS.

During the above-mentioned transitional period, the EU and GHS labels will circulate in parallel.

#### **II.1.3. Suggestions how to minimise potential effects of the GHS**

In order to minimise potential effects related to additional classification under GHS, it is proposed to exempt from the reference to classified substances and mixtures those hazard classifications (classes and categories / types / divisions) which are newly introduced by the GHS, in accordance with **Solution 1**, cf. Part I of this study. The respective classifications are listed in Table VI.1 of Part I of this study.

With regard to *acute toxicity category 1-3*, it is proposed to adapt the LD<sub>50</sub>/LC<sub>50</sub>-ranges in accordance with **Solution 2**, cf. Table VI.2 of Part I of this study. This would imply to refer to GHS category 1-3 while at the same time extending or limiting the reference to the current cut-off limits for the oral and dermal routes of uptake.

In order to minimise potential effects related to additional classification under GHS for *STOT (single / repeated exposure) category 1*, it is proposed to adapt the range of the reference in accordance with **Solution 2**, cf. Table VI.2 of Part I of this study. This would imply to refer to the respective category 1 while at the same time limiting the reference to the current cut-off limits for the different routes of uptake.

In order to minimise any potential effects due to additional classification of biocidal products for *reproductive toxicity*, it is proposed to exempt those mixtures from the scope of Directive 1998/8/EC which contain reproductive toxicants in a concentration < 0.5%, cf. Table VI.2 of Part I of this study (**Solution 2**).

With regard to the reclassification of current entries in Annex I to Directive 67/548/EEC, the GHS Regulation will provide for conversions for CMR and respiratory sensitisers on the basis of equivalent criteria. It is planned to carry them over to Annex VI to the GHS Regulation. Non-harmonised, but classified CMRs can easily be reclassified by using the conversion table in Annex VII.

## II.2. Council Directive 91/414/EEC concerning the placing of plant protection products on the market

[http://europe.eu.int/eur-lex/en/consleg/pdf/1991/en\\_1991L0414\\_do\\_001.pdf](http://europe.eu.int/eur-lex/en/consleg/pdf/1991/en_1991L0414_do_001.pdf)

Council Directive 91/414/EEC (“Pesticides Directive”) concerning the placing of plant protection products on the market provides a framework of rules pertaining both to plant protection products and to the active substances contained in them. While for the latter a positive list at EU level is established (Annex I), so called Uniform Principles for the evaluation of plant protection products apply. Since the evaluation is risk -based, shifting to the GHS criteria will have minimal effects only. In cases where active substances are classified as *Very Toxic* or *Toxic* or where plant protection products are classified as *Very Toxic* some very limited effects might occur which could be minimised by a consequential adaptation of the respective hazard range.

### II.2.1. Abstract of the legislation

Council Directive 91/414/EEC (“Pesticides Directive”) is based on Article 43 of the Treaty. Its objective is to achieve a high level of protection of human and animal health and the environment and to minimise barriers to trade of plant protection products and of plant products treated with them. It is based on Article 43 of the Treaty.

The Pesticides Directive provides a framework of rules concerning

- The establishment at Community level of a positive list of active substances (Annex I to Directive 91/414/EEC) authorised for use in plant protection products;
- The authorisation and the placing on the market of plant protection products in Member States;
- The mutual recognition of authorisations within the Community;
- The control of plant protection products put on the market ;
- The setting-up of Uniform Principles for evaluation and authorisation of plant protection products.

Plant protection products must not be placed on the market unless they comply with the requirements specified by Directive 91/414/EEC. In particular, it has to be shown that they are sufficiently effective and do not cause harmful or unacceptable effects on human health, animals, plants or the environment. The evaluation of plant protection products is based on risk, involving comprehensive risk assessment procedures. Harmonised Community provisions for evaluation and criteria for inclusion on a positive list of active substances, followed by authorisation of plant protection products according to harmonised evaluation principles (Annex VI), provide for the management of possible risks posed by plant protection products.

## II:2.2. Analysis of the links to classification and labelling provisions and anticipation of the effects of GHS

Active substances as well as their preparations (called “mixtures” under GHS), i.e. plant protection products, are subject to the classification and labelling provisions of Council Directives 67/548/EEC and 1999/45/EC, cf. Articles 3.4, 15 and 16. When the GHS enters into force, plant protection products and their ingredients will be subject to the provisions of the new system. **This means that all active substances and the plant protection products themselves will have to be reclassified and relabelled after the GHS Regulation has entered into force.**

The GHS Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*. A transitional period is foreseen where a supplier may choose to apply the current Directives on classification and labelling or the GHS. This is to encourage enterprises to make the most efficient use of their resources to align their practice to the new system. During the transitional period, Annex I to Directive 67/548/EEC will be legally binding. As the (re-)classification of mixtures depends on the preceding (re-)classification of substances, the GHS criteria will have to be applied to substances first and then to mixtures. The Commission Services Directorate -General (DG) Enterprise & Industry and DG Environment propose 3 years for substances and further 4 or 5 years for mixtures. These proposals will be subject to stakeholder comment in the public consultation on the GHS draft Regulation.

With regard to labelling, the current risk and safety phrases as provided for in Directive 1999/45/EC as well as of their codification have to be converted into the corresponding GHS hazard and precautionary statements and their codifications. Additional risk phrases which were developed in the particular context of use of plant protection products may be kept as supplemental labelling.

### Specific Classification Issues

Directive 91/414/EEC defines the hazard of an active substance or a plant protection product containing it not only on the basis of their classifications according to Directives 67/548/EEC or 1999/45/EEC – hazard is also a matter of specific acute or long-term effects on potentially exposed sensitive non-target species, e.g. earthworms, birds, other terrestrial vertebrates et alia, cf. Annex III to Directive 91/414/EEC.

**In general, the evaluation of plant protection products is based on risk. This implies that the GHS will have marginal effects only.** Almost all legal obligations referring to active substances and plant protection products are risk-based, i.e. they are derived from exposure, and not exclusively from the hazard properties alone.

The risk-based approach is best revealed in the first sentence of paragraph 2.4.1.3. of Annex VI, Part C to Directive 91/414/EEC, stating:

“Plant protection products which because of particular properties or if mishandled or misused could lead to a high degree of risk must be subject to particular restrictions such as restrictions on the size of packaging, formulation type, distribution, use or manner of use”. A typical example of risk assessment that forms the basis for an authorisation decision is stated in paragraph 2.5.2.1 of Annex VI Part C to Directive 91/414/EEC: “Where there is a possibility of birds and other non-target terrestrial vertebrates being exposed, no authorization shall be granted if ... the acute and short-term toxicity / exposure ratio for birds and other non-target terrestrial vertebrates is less than 10 on the basis of LD<sub>50</sub>... or the long-term toxicity / exposure ratio is less than 5, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact occurs after use of the plant protection product according to the proposed conditions of use ...”

Beyond this general approach, there are some few specific obligations which are related to classification issues:

1. In Directive 91/414/EEC, the information required in the dossiers to be submitted for active substances (Annex II) and for the plant protection products containing them (Annex III) is to permit classification in accordance with Council Directives 67/548/EEC and 78/631/EEC (repealed by 1999/45/EC). Accordingly, testing requirements of Annex II and Annex III are often based on testing methods as provided in Annex V to Directive 67/548/EEC and subsequent amendments.

Annex V of Directive 67/548/EEC will be repealed as a consequence of the REACH Regulation. The deletion of this Annex will apply 12 months from the entry into force of the REACH Regulation; the testing methods will then be specified on the basis of Article 12 of the REACH Regulation in a further Commission Regulation or by recognition of other international test methods by the Commission or the Agency.

It has to be noted that not all endpoints for testing mentioned under the headline “acute toxicity” in paragraph 5.2. of Annex II to Directive 91/414/EEC are subcategories of the EU category of danger *acute toxicity* according to Directive 67/548/EEC, i.e. skin irritation, eye irritation and skin sensitisation.

2. The second sentence of paragraph 2.4.1.3. of Annex VI Part C to Directive 91/414/EEC establishes legal obligations based on hazardous properties only:

“Moreover, plant protection products which are classified as very toxic may not be authorized for use by non-professional users.”

The conversion of the EU category of danger *Very Toxic* to the corresponding GHS hazard classifications for the different routes of uptake is given in column 1 and 2 in Table II.2.2.1 below:

**Table II.2.2.1:** Conversion from EU *Very Toxic* to the corresponding GHS classification

EU Category of Danger / Risk Phrase	Most closely corresponding GHS classification(s)	Potential effects on the number of classified plant protection products
Very Toxic (T+), R28 (oral)	Acute Toxicity, cat. 1 or 2 (oral)	Statement not possible
Very Toxic (T+), R27 (dermal)	Acute Toxicity, cat. 1 (dermal)	Statement not possible
Very Toxic (T+), R26 (inhalation of gases)	Acute Toxicity, cat. 1 (inhalation of gases)	Statement not possible
Very Toxic (T+), R26 (inhalation of vapours)	Acute Toxicity, cat. 1 (inhalation of vapours)	Statement not possible
Very Toxic (T+), R26 (inhalation of aerosols and particulates)	Acute Toxicity, cat. 1 or 2 (inhalation of dusts or mists)	Statement not possible

It has to be verified if the reference to *Very Toxic* includes also the reference to the risk phrase R39 (all routes of uptake). In this case, the conversion to *STOT (single exposure) category 1* according to Table V.3 of Part I of this study or according to the correlation table of Annex VII to the GHS Regulation would apply.

- ***Acute Toxicity***: Whereas a clear-cut statement can be made concerning an increased / decreased number of classified substances in a defined classification interval under GHS, cf. Table V.3 of Part I, a corresponding statement for mixtures can hardly be made. This means that it cannot be predicted if the classification of a multi-ingredient plant protection product as derived by one of the GHS calculation approaches, cf. Chapter 3.1 GHS, will deviate from the most closely corresponding EU classification as derived from the EU conventional calculation method, cf. Annex II, Part A of Directive 1999/45/EC. Available studies only provide preliminary answers for simple mixtures where one substance is diluted in an inert solvent.

Apart from the classification of a plant protection product, the conversion of the reference to a particular EU category to (a) defined GHS category(ies) in the legislation on plant protection products is crucial. For the example of the oral route of uptake, it will be of relevance if the legislation on plant protection products will refer to category 1 GHS or to category 1 and 2 GHS in future, cf. Figure 3 in the Chapter on the Biocides Directive. In the former case, less plant protection products would be caught than in the latter case.

Potential effects related to the GHS classification *acute toxicity category 1* will depend on an adaptation of the reference to this category according to Table VI.2 of Part I of this study.

- ***STOT (single exposure) category 1***: In case the reference to *STOT (single exposure) category 1* is relevant, cf. above, additional plant protection products could be classified, cf. Table V.3 of Part I and the information given in Annex I to this study. Potential effects will then depend on an adaptation of the reference to *STOT (single exposure) category 1* according to Table VI.2 of Part I of this study.

### **Other Observations**

In the course of the evaluation of active substances and plant protection products various Guidance Documents have been developed (non-legally binding). In at least one Guidance Document used for substance evaluation, i.e. in the “Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC”, a direct reference to hazard classifications can be found, i.e. the classification as *Very Toxic*, *Toxic* and *CMR* of the parent molecule (which is the active substance) could trigger testing of the metabolite(s).

The conversions of the EU classifications to the corresponding GHS classifications can be found in Table V.3 of Part I or in the analysis of Directive 1998/8/EC in Chapter II.1.2.

With regard to *Very Toxic* and *Toxic*, the number of substances classified under GHS will depend on the GHS category limits, cf. Figure 3 above. For the oral route of uptake, it will then be of relevance if the reference to *Very Toxic* will be replaced by category 1 GHS or by category 1 and 2 GHS in the Guidance Document, cf. Figure 4 above. In the former case, less parent molecules (active substances) are likely to be caught compared to the current situation.

In the latter case, the opposite will probably occur. A related situation may arise for *Toxic*: Will the reference to *Toxic* be replaced by category 3 GHS or by category 2 and 3 GHS in the Guidance Document? In the former case, a wider range of parent molecules is likely to be caught due to the upper limit being  $LD_{50} = 300$  mg/kg bw. In the latter case, even more substances would be caught compared to the current situation because the lower  $LD_{50}$  limit would be lowered from 25 to 5 mg/kg bw. The situation and the underlying reasoning for the other routes of uptake is similar, though not completely the same as for the oral pathway.

With regard to CMR hazards, the number of classified substances is not likely to change, cf. Annex I and the discussion in other chapters of this study.

### II.2.3. Suggestions how to minimise potential effects of the GHS

In order to minimise potential effects related to additional classification under GHS for *acute toxicity category 1*, it is proposed to adapt the scope of this reference in accordance with **Solution 2**, cf. Table VI.2 of Part I of this study. This would imply to refer to GHS category 1 while at the same time extending the reference to the current cut-off limits for the different routes of uptake. It may be considered to proceed in a similar way for category 2 in the Guidance Document.

In order to minimise potential effects related to additional classification under GHS for *STOT (single exposure) category 1*, it is proposed to adapt the range of this hazard in accordance with **Solution 2**, cf. Table VI.2 of Part I of this study. This would imply to make use of GHS category 1 while at the same time limiting the reference to the current cut-off limits for the different routes of uptake.

With regard to the reclassification of current entries in Annex I to Directive 67/548/EEC, the GHS Regulation will provide for conversions for CMR and respiratory sensitisers on the basis of equivalent criteria. It is planned to carry them over to Annex VI to the GHS Regulation. Non-harmonised, but classified CMRs can easily be reclassified by using the conversion table in Annex VII.

#### Basic documents used for the analysis

“Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC”

### III. Control of Dangerous / Hazardous chemicals

#### III.1. Common Position on the proposed REACH Regulation, adopted by the Council on 27 June 2006

<http://register.consilium.europa.eu/pdf/en/06/st07/st07524.en06.pdf>

<http://register.consilium.europa.eu/pdf/en/06/st07/st07525.en06.pdf>

The proposed REACH Regulation has been the subject of extensive debate in the European institutions in the past years. It contains several links to the Directives on classification and labelling 67/548/EEC and 1999/45/EC or to selected classification criteria. When the current classification system will be repealed and the GHS criteria will have to be applied, possibly additional substances and mixtures could be classified. In particular, those new hazard classifications which have not existed under the current system would have an impact whenever the REACH Regulation refers to “classified as dangerous according to Directive 67/548/EEC”. In order to avoid that the scope and impact of REACH is altered, the Commission intends to exempt these GHS hazard classifications from provisions in which they would trigger additional obligations in the REACH Regulation. As far as the documentation of the hazard classification is concerned, for classifications that will have to be made under the GHS, results for all hazard classes and categories should have to be included in registration dossiers or notifications that are submitted to the Agency.

##### III.1.1. Abstract of the legislation

The proposal for the REACH Regulation has been the subject of extensive debates in the past years. For this reason, an abstract of the legislative proposal will not be presented here. Instead, it is recommended to refer to the following websites where the Common Position on the proposed REACH Regulation, adopted by the Council on 27 June 2006 (Interinstitutional Files 2003/0256 and 2003/0257 (COD)) can be found:

<http://register.consilium.europa.eu/pdf/en/06/st07/st07524.en06.pdf> and

<http://register.consilium.europa.eu/pdf/en/06/st07/st07525.en06.pdf>

For further information it is recommended to refer to the following website:

[http://europa.eu.int/comm/enterprise/reach/index\\_en.htm](http://europa.eu.int/comm/enterprise/reach/index_en.htm)

##### III.1.2. Analysis of the links to classification and labelling provisions

The REACH Regulation as agreed by the Council on 13 December 2005 contains numerous links to the current legislation on classification and labelling, i.e. to Council Directive 67/548/EEC and 1999/45/EC. The most important links in the body text of the REACH draft Regulation can be divided into four different groups:

**1. General references to the “classification as dangerous according to Directive 67/548/EEC”: results of classification to be included in documents (registration dossiers, notification) which have to be sent to the Agency.**

### **1.1. The main reference can be found in Annex V I, section 4:**

#### Annex VI.4., Classification and labelling:

4.1. The hazard classification of the substance(s), resulting from the application of Articles 4 and 6 of Directive 67/548/EEC;

In addition, for each entry, the reasons why no classification is given for an endpoint should be provided (i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification);

4.2. The resulting hazard label for the substance(s), resulting from the application of Articles 23, 24 and 25 of Directive 67/548/EEC;

4.3. Specific concentration limits, where applicable, resulting from the application of Article 4 (4) of Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC.

### **1.2. The following provisions refer to this section 4 in Annex V I:**

#### Article 7, Registration and notification of substances in articles:

4. The information to be notified shall include the following:

(d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;

#### Article 9, Exemption from the general obligation to register for product and process oriented research and development (PPORD):

1. Articles 5, 6, 7, 17, 18 and 21 shall not apply for a period of five years to a substance manufactured in the Community or imported for the purposes of product and process orientated research and development by a manufacturer or importer, by himself or in cooperation with listed customers and in a quantity which is limited to the purpose of product and process orientated research and development.

2. For the purpose of paragraph 1, the manufacturer or importer or producer of Articles shall notify the Agency of the following information: ...

(c) the classification of the substance as specified in section 4 of Annex VI, if any;

#### Article 10, Information to be submitted for general registration purposes :

A registration required by Article 6 or by Article 7(1) or (5) shall include all the following information:

(a) a technical dossier including: ...

(iv) the classification and labelling of the substance as specified in section 4 of Annex VI; ...

#### Article 17, Registration of on-site isolated intermediates:

Any manufacturer of an on-site isolated intermediate in quantities of 1 tonne or more per year shall submit a registration to the Agency for the on-site isolated intermediate.

2. A registration for an on-site isolated intermediate shall include all the following information, to the extent that the manufacturer is able to submit it without any additional testing:

(c) the classification of the intermediate as specified in section 4 of Annex VI;

#### Article 18, Registration of transported isolated intermediates:

1. Any manufacturer or importer of a transported isolated intermediate in quantities of 1 tonne or more per year shall submit a registration to the Agency for the transported isolated intermediate.

2. A registration for a transported isolated intermediate shall include all the following information:

(c) the classification of the intermediate as specified in section 4 of Annex VI;

#### Article 22, Further duties of registrants:

1. Following registration, a registrant shall be responsible on his own initiative for updating his registration without undue delay with relevant new information and submitting it to the Agency in the following cases:

(f) any change in the classification and labelling of the substance;

(g) any update or amendment of the chemical safety report or section 5 of Annex VI; ...

2. A registrant shall submit to the Agency an update of the registration containing the information required by the decision made in accordance with Articles 39, 40 or 45 or take into account a decision made in accordance with articles 59 and 72, within the deadline specified in that decision. The Agency shall notify the competent authority of the relevant Member State that the information is available on its database.

### Article 33, Duty to communicate information on substances and preparations up the supply chain:

Any actor in the supply chain of a substance or a preparation shall communicate the following information to the next actor or distributor up the supply chain:

- (a) new information on hazardous properties, regardless of the uses concerned;

### **2. Other general references to the “classification as dangerous according to Directive 67/548/EEC”:**

#### Article 14, Chemical safety report and duty to apply and recommend risk reduction measures:

1. Without prejudice to Article 4 of Directive 98/24/EC, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter if the registrant manufactures or imports such a substance in quantities of 10 tonnes or more per year.

The chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and with Annex I for either each substance on its own or in a preparation or a group of substances.

2. A chemical safety assessment in accordance with paragraph 1 need not be performed for a substance which is present in a preparation if the concentration of the substance in the preparation is less than the lowest of any of the following:

- (a) the applicable concentrations defined in the table of Article 3(3) of Directive 1999/45/EC;
- (b) the concentration limits given in Annex I to Directive 67/548/EEC;
- (c) the concentration limits given in Part B of Annex II to Directive 1999/45/EC;
- (d) the concentration limits given in Part B of Annex III to Directive 1999/45/EC;
- (e) the concentration limits given in an agreed entry in the classification and labelling inventory established under Title XI of this Regulation;
- (f) 0.1 % weight by weight (w/w), if the substance meets the criteria in Annex XIII of this Regulation.

3. A chemical safety assessment of a substance shall include the following steps:

- (a) human health hazard assessment;
- (b) physicochemical hazard assessment;
- (c) environmental hazard assessment;
- (d) persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.

4. If, as a result of carrying out steps (a) to (d) of paragraph 3, the manufacturer or importer concludes that the substance meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:

- (a) exposure assessment including the generation of exposure scenario(s) (or the identification of relevant use and exposure categories if appropriate) and exposure estimation;
- (b) risk characterisation.

The exposure scenarios (where appropriate the use and exposure categories), exposure assessment and risk characterisation shall address all identified uses of the manufacturer or importer.

5. The chemical safety report need not include consideration of the risks to human health from the following end uses:

- (a) in food contact materials within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on material and articles intended to come into contact with food;
- (b) in cosmetic products within the scope of Directive 76/768/EEC.

6. Any manufacturer or importer shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 31.

7. Any manufacturer or importer required to conduct a chemical safety assessment shall keep his chemical safety report available and up to date.

#### Article 31, Requirements for safety data sheets:

1. The supplier of a substance or a preparation shall provide the recipient of the substance or preparation with a safety data sheet compiled in accordance with Annex II:

- (a) where a substance or preparation meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC, or
- (b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII.

2. Any actor in the supply chain who is required, under Articles 16 or 36, to carry out a chemical safety assessment for a substance shall ensure that the information in the safety data sheet is consistent with the information in this assessment. If the safety data sheet is developed for a preparation and the actor in the supply chain has prepared a chemical safety assessment for that preparation, it is sufficient if the information in the safety data sheet is consistent with the chemical safety report for the preparation instead of with the chemical safety report for each substance in the preparation.

3. The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a preparation does not meet the criteria for classification as dangerous in accordance with Articles 5, 6 and 7 of Directive 1999/45/EC, but contains:

(a) in an individual concentration of • 1 % by weight for non-gaseous preparations and • 0,2 % by volume for gaseous preparations at least one substance posing human health or environmental hazards, or  
(b) in an individual concentration of • 0,1 % by weight for non-gaseous preparations at least one substance that is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, or

(c) a substance for which there are Community workplace exposure limits.

4. The safety data sheet need not be supplied where dangerous substances or preparations offered or sold to the general public are provided with sufficient information to enable users to take the necessary measures as regards the protection of human health, safety and the environment, unless requested by a downstream user or distributor.

5. The safety data sheet shall be supplied in an official language of the Member State(s) where the substance or preparation is placed on the market, unless the Member State(s) provide otherwise.

6. The safety data sheet shall be dated and shall contain the following headings:

1. identification of the substance/preparation and of the company/undertaking; 2. hazards identification; 3. composition/information on ingredients; 4. first-aid measures; 5. fire-fighting measures; 6. accidental release measures; 7. handling and storage; 8. exposure controls/personal protection; 9. physical and chemical properties; 10. stability and reactivity; 11. toxicological information; 12. ecological information; 13. disposal considerations; 14. transport information; 15. regulatory information; 16. other information.

7. Any actor in the supply chain who is required to prepare a chemical safety report according to Articles 14 or 36 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet covering identified uses and including specific conditions resulting from the application of section 3 of Annex XI.

Any downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses.

Any distributor shall pass on relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for uses for which he has passed on information according to Article 36(2).

8. A safety data sheet shall be provided free of charge on paper or electronically.

9. Suppliers shall update the safety data sheet without delay on the following occasions:

(a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;

(b) once an authorisation has been granted or refused;

(c) once a restriction has been imposed.

The new, dated version of the information, identified as "Revision: (date)", shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or preparation within the preceding 12 months. Any updates following registration shall include the registration number.

#### Article 37. Obligation for downstream users to report information:

4. A downstream user shall report to the Agency if his classification of a substance is different to that of his supplier.

#### Article 39. Examination of testing proposals:

1. The Agency shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes IX and X for a substance. Priority shall be given to registrations of substances which have or may have PBT, vPvB, sensitising and/or carcinogenic, mutagenic or toxic for reproduction (CMR) properties, or substances classified as dangerous according to Directive 67/548/EEC above 100 tonnes per year with uses resulting in widespread and diffuse exposure.

#### Article 118, Electronic public access:

1. The following information held by the Agency on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 76(2)(d):

...

(b) the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC;

(c) if applicable, the name of the substance as given in EINECs;

(d) the classification and labelling of the substance; ...

2. The following information on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 76(2)(d) except where a party submitting the information submits a justification in accordance with Article 10(a)(xi), accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned:

(a) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous; ...

There may be other provisions relating to the current legislation on classification and labelling, in particular in the Annexes to the REACH Regulation.

### **3. Reference to concentration limits**

#### Article 29(3), Requirements for Safety Data Sheets :

3. The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex Ia, where a preparation does not meet the criteria for classification as dangerous in accordance with Articles 5, 6 and 7 of Directive 1999/45/EC, but contains:

(a) in an individual concentration of • 1 % by weight for non-gaseous preparations and • 0.2 % by volume for gaseous preparations at least one substance posing human health or environmental hazards, or

(b) in an individual concentration of • 0.1 % by weight for non-gaseous preparations at least one substance that is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, or

(c) a substance for which there are Community workplace exposure limits.

#### Article 55, General provisions [related to authorisation]:

1. A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless: ...

2. A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.

6. Paragraphs 1 and 2 shall not apply to the use of substances when they are present in preparations:

(a) for substances referred to in Article 56(d), (e) and (f), below a concentration limit of 0.1 % weight by weight (w/w);

(b) for all other substances, below the lowest of the concentration limits specified in Directive 1999/45/EC or in Annex I to Directive 67/548/EEC which result in the classification of the preparation as dangerous.

### **4. Reference to specific categories of danger, in particular CMRs**

#### Article 23, Specific provisions for phase-in-substances:

1. Articles 5, Article 6, Article 7(1) and Article 21 shall not apply until [3 years after the entry into force of this Regulation] to the following substances:

(a) phase-in substances classified as **carcinogenic, mutagenic or toxic to reproduction**, category 1 or 2, in accordance with Directive 67/548/EEC and manufactured in the Community or imported, in quantities reaching 1 tonne or more per year per manufacturer or per importer, at least once after [date of entry into force of this Regulation];

(b) phase-in substances classified as very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment (**R50-53**) in accordance with Directive 67/548/EEC, and manufactured in the Community or imported in quantities reaching 100 tonnes or more per year per manufacturer or per importer, at least after [date of entry into force of this Regulation];

#### Article 56, Substances to be included in Annex XIV :

The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 57:

- (a) substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC;
- (b) substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC;
- (c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;
- (d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;
- (e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;
- (f) substances – such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) – for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 58.

### **5. The introduction of the classification and labelling inventory as a tool to harmonise classifications for substances**

#### **Title X, Classification and labelling inventory**

##### Article 109, Scope:

This Title shall apply to:

- (a) substances subject to registration by a manufacturer or importer;
- (b) substances within the scope of Article 1 of Directive 67/548/EEC, which meet the criteria for classification as dangerous in accordance with that Directive, and which are placed on the market either on their own, or in a preparation above the concentration limits specified in Directive 1999/45/EC, where relevant, which results in the classification of the preparation as dangerous.

##### Article 110, Obligation to notify the Agency:

1. Any importer or manufacturer, or group of importers or manufacturers, who place on the market a substance within the scope of Article 109, shall notify to the Agency the following information in order for it to be included in the inventory in accordance with Article 111, unless submitted as part of the registration:
  - (a) the identity of the manufacturer or importer responsible for placing the substance(s) on the market as specified in section 1 of Annex IV;
  - (b) the identity of the substance(s) as specified in part 2.1 to 2.3.4 of Annex VI;
  - (c) the hazard classification of the substance(s), resulting from the application of Articles 4 and 6 of Directive 67/548/EEC;
  - (d) the resulting hazard label for the substance(s), resulting from application of Article 23 (c) to (f), of Directive 67/548/EEC;
  - (e) specific concentration limits, where applicable, resulting from the application of Article 4(4) of Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC.
2. Where the obligation under paragraph 1 results in different entries on the inventory for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory.
3. The information listed in paragraph 1 shall be updated by the notifier(s) whenever:
  - (a) any new scientific or technical information is generated which results in a change to the classification and labelling of the substance;
  - (b) notifiers and registrants of differing entries for a single substance come to an agreed entry in accordance with paragraph 2.

##### Article 113, The classification and labelling inventory :

1. A classification and labelling inventory, listing the information referred to in Article 112(1), both for information notified under Article 112(1) as well as for information submitted as part of a registration, shall be established and maintained by the Agency in the form of a database. The information in this database identified in Article 118(1) shall be publicly accessible. The Agency shall grant access to the other data on each substance in the inventory to the notifiers and registrants who have submitted information on that substance in accordance

with Article 29(1). The Agency shall update the inventory when it receives updated information in accordance with Article 112(3).

2. In addition to the information referred to in paragraph 1, the Agency shall record the following information, where appropriate, against each entry:

- (a) whether, in respect of the entry, there is a harmonised classification and labelling at Community level by inclusion in Annex I of Directive 67/548/EEC;
- (b) whether, in respect of the entry, it is a joint entry between registrants of the same substance as per Article 11(1);
- (c) if the entry differs from another entry on the inventory for the same substance;
- (d) the relevant registration number(s), if available.

#### Article 114. Harmonisation of classification and labelling:

1. Harmonised classification and labelling at Community level shall, from [date of entry into force of this Regulation], normally be added to Annex I of Directive 67/548/EEC for classification of a substance as carcinogenic, mutagenic or toxic for reproduction categories 1, 2 or 3, or as a respiratory sensitiser. Harmonised classification and labelling for other effects may also be added to Annex I of Directive 67/548/EEC on a case-by-case basis if justification is provided demonstrating the need for action at Community level. To this end, Member State competent authorities may submit proposals to the Agency for harmonised classification and labelling in accordance with Annex XV.

2. The Risk Assessment Committee shall adopt an opinion on the proposal, giving parties concerned the opportunity to comment. The Agency shall forward this opinion and any comments to the Commission, which shall take a decision in accordance with Article 4(3) of Directive 67/548/EEC.

#### Article 115. Transitional arrangements:

The obligations set out in Article 112 shall apply from [3 years after entry into force of this Regulation].

### **III.1.3. Anticipation of the potential effects of the GHS**

As shown above, the proposed REACH Regulation refers in diverse ways to the current classification and labelling legislation: Reference is made to particular categories of danger as well as to the whole set of classification criteria, mostly expressed as “classification as dangerous in accordance with Directive 67/548/EEC” or simply as “dangerous substances”.

When the old classification system is repealed, these references have to be expressed in terms of the GHS.

When the criteria for CMR hazards are applied, the kind and amount of classified substances will stay the same. For some other hazards, the kind and number of classified substances may change, due to differences of the criteria in both systems. An overview of the potential change in scope is given in Table V.3 of Part I and in Annex I to this study.

In addition, there will be hazard classes and categories which have not existed under Directive 67/548/EEC, e.g. GHS hazard class *self-heating substances and mixtures*, cf. Table III.1.3. below.

### III.1.4. Suggestions how to minimise potential effects of the GHS

After the repeal of the criteria for classification in Directive 67/548/EEC, thus when the new criteria have to be applied to classify substances, the results for all hazard classes and categories will have to be included in any documentation that has to be sent to the Chemicals Agency, being either registrations or any notifications.

To avoid that additional obligations are triggered by the classification for new hazard classes, in case of general references to the classification rules, it is proposed to follow **Solution 1**: This means to exempt the following GHS hazard classifications (classes and categories / types) from the reference to classified substances and preparations in the REACH Regulation:

Table III.1.3: GHS hazard classifications proposed for exemption from REACH (Solution 1)

<i>Gases under pressure</i> , in accordance with Annex I Chapter 2.5
<i>Self-reactive substances and mixtures, Type C to G</i> , in accordance with Annex I Chapter 2.8
<i>Self-heating substances and mixtures</i> , in accordance with Annex I Chapter 2.11
<i>Oxidising liquids, category 3</i> , in accordance with Annex I Chapter 2.13
<i>Oxidising solids, category 3</i> , in accordance with Annex I Chapter 2.14
<i>Organic peroxides, Type G</i> , in accordance with Annex I Chapter 2.15
<i>Corrosive to metals</i> , in accordance with Annex I Chapter 2.16
<i>Reproductive toxicity, effects on or via lactation</i> , in accordance with Annex I Chapter 3.7
<i>STOT, single exposure, category 3 (narcotic effects)</i> , in accordance with Annex I Chapter 3.8

References to the location of the new concentration limits in the GHS Regulation, i.e. Articles or sections in the Annexes, will have to be specified as soon as the location of the new concentration limits is clear.

As the criteria for classification for CMR substances are equivalent, the replacement of the criteria will have no effect, and no specific adaptations are therefore necessary in that respect.

Furthermore, Articles 111 to 115 (Title XI) of the REACH Regulation will probably be repealed and transferred to the GHS Regulation.

### III.2. Council Directive 1996/82/EC of 9 December 1996 on the control of major -accident hazards involving dangerous substances, as amended by Directive 2003/105/EC of the European Parliament and of the Council of 16 December 2003

<http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31996L0082:EN:HTML>  
[http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l\\_345/l\\_34520031231en00970105.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_345/l_34520031231en00970105.pdf)

Council Directive 1996/82/EC (“Seveso II Directive”) is aimed at the prevention of major accidents which involve dangerous substances and mixtures, and the limitation of their consequences for humans and the environment, with a view to ensuring high levels of protection throughout the Community in a consistent and effective manner. It is based upon Article 175(1) of the Treaty.

The Seveso II Directive sets up rules for the safety of establishments where listed substances as well as certain categories of dangerous chemicals are present above defined threshold quantities. The categories are defined in accordance with the criteria as defined in Council Directive 67/548/EEC and Directive 1999/45/EC. Depending on the quantities present, the Seveso II Directive defines so-called lower- and upper-tier requirements for the operator.

The Globally Harmonised System sets up new rules for the classification and labelling of hazardous chemicals. At Community level, it will be implemented as Regulation which will repeal the current legislation after a transitional period. Some of the implemented GHS classification criteria deviate from the currently used criteria. This could entail that additional substances and mixtures may trigger the lower- or upper-tier requirements of the Seveso II Directive.

If the structure of Part 2 of Annex I to the Seveso II Directive is to be maintained, references to the EU categories of danger and risk phrases will have to be replaced by references to the most closely corresponding GHS classifications. Further adaptations of the Directive may have to be envisaged, in order to prevent the regulation of further chemicals. The objective of the revision is to achieve harmonisation with the GHS, guaranteeing a high and efficient level of protection for both man and the environment throughout the Community.

#### III.2.1. Abstract of the legislation

The Seveso II Directive sets up rules for the safety of establishments where dangerous substances and mixtures are present above defined threshold quantities. It works both on the basis of a list of explicitly named substances (Part 1 of Annex I) and on the basis of selected categories of danger which are defined according to Directive 67/548/EEC (Part 2 of Annex II). The categories of danger include the classifications *Very Toxic, Toxic, Oxidising, Explosive, Extremely Flammable, Highly Flammable, Flammable, Dangerous to the Environment*, in addition, further hazards as well as any substance or mixture classified in combination with the R-phrases R14 or R14/15 and R29.

The Directive defines a two-tier system of hazard sites. Each tier catches a number of sites where dangerous substances or mixtures (list / category according to Annex I) are present above certain volumes. A particular feature of the Seveso II Directive is that mixtures are treated the same as substances: A classified mixture will count with its total volume, and not

with the volume of the substance that triggers its classification. Depending on the tonnage, establishments will qualify for a defined tier:

- Lower-tier establishments are establishments where substances or mixtures are present in amounts which are mentioned in Annex I, Part 1, column 2 or Part 2, column 2. Articles 6 and 7 apply, setting out specific requirements: First, the operator has to notify the competent authority of characteristic features of the establishment and of any significant change related to the type and amount of dangerous substances and mixtures present at the site. Furthermore, he has to draw up a document where the operator's major -accident prevention policy is described in detail, complying with the requirements of Annex III;
- Upper-tier establishments are establishments where substances or mixtures are present in amounts which are mentioned in Annex I, Part 1, column 3 or Part 2, column 3. In 2002, around 3278 upper-tier establishments existed on the territory of the former 15 Member States of the EU. Apart from the notification of the establishment to the competent authority, Articles 9, 11 and 13 apply. The provisions require the following steps, namely:
  - The demonstration of compliance with the Seveso II Directive by the operator, i.d. that he has taken appropriate measures at technical, organisational and managerial level to implement the major -accident prevention policy and to limit the consequences of an accident on-site and off-site;
  - The preparation of a comprehensive safety report by the operator, which contains at least the data and information listed in Annex II. The safety report has to demonstrate that adequate safety measures and reliability have been incorporated into the design, construction, operation and maintenance of the establishment and its units. It shall also contain an updated inventory of the dangerous substances present in the establishment. Furthermore, it requires the verification of all quantitative data. As a recent dissertation showed for top tier sites in four Member States the effort required for preparing a safety report may vary widely <sup>2</sup>: It ranges from 7,5 man months up to 50 man months, cf. the report prepared by Esther Versluis.
  - Periodical review and update of the safety report when there is new knowledge on the prevention of major accidents or when the establishment has been modified so that significant repercussions on major -accident hazards have to be expected. This includes technical modifications as well as the nature or quantity of dangerous substances present at the site;
  - The setting-up of an internal emergency plan by the operator, for the measures to be taken inside the establishment, in accordance with the information requirements as set out in Annex IV. The internal emergency plan has to be reviewed, tested and eventually be revised at least every three years. To this end, qualified personnel has to be detached;
  - The setting-up of an external emergency plan by the competent authority, for the measures to be taken outside the establishment, in accordance with the information requirements set out in Annex IV. To this end, the public has to be consulted. External emergency plans are based on information provided by the operator. The competent

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<sup>2</sup> The preparation of a safety report may cost between some hundred thousand and some million Euros, representing a significant share of PAT for some enterprises – the technical background investments to be made in order to comply with the Seveso II Directive are much higher. The Technical Platform on Industrial Safety currently tries to provide for concrete figures related to these compliance investments. Other costs to be borne by operators relate to report assessment, inspector visits and the overall inspection effort, namely when Member States charge industry for these services, cf. the report of Esther Versluis.

authority may decide that in view of the information contained in the safety report, no further information has to be supplied. The external emergency plan has to be reviewed, tested and eventually be revised at least every three years;

- The identification of establishments or groups of establishments by the competent authority where the likelihood and the possibility of consequences of a major accident may be increased because of the location and the proximity of such establishments. Compliance with obligations related to land-use planning has to be ensured, e.g. with regard to the siting of new or modifications of existing establishments;
- The dissemination of information on safety measures to the concerned public and obligation to invite the public to give its opinion on planned upper-tier establishments, on modifications to existing establishments as well as on developments around such existing establishments;
- The examination of the safety report by the competent authority which subsequently decides to allow or prohibit the bringing into use or continued use of the establishment;
- A system / programme of inspections for all establishments which are covered by the Seveso II Directive; at least one on-site inspection per year by the competent authority. This also includes the check if the safety report is correct and complete. Observations and conclusions related to inspections have to be documented in an inspection report. The CA has to ensure that the operator takes due account of the inspection results.

An overview over the manifold legal obligations which operators have to comply with is given in Figure 4 below.

Further provisions relate to

- Transboundary information;
- Obligations in case of a major accident;
- Three-yearly reporting of the Member States to the European Commission;
- The setting-up of a register and information system containing details on recent major accidents by the European Commission (CDCIR / MARS), to be kept at the disposal of the Member States, industry, trade associations and other organisations of the civil society.

<b>Operators</b>				
<b>Upper Tier</b>	<b>Safety Management System</b> shall address the following: <ul style="list-style-type: none"> <li>- organisation and personnel</li> <li>- identification and evaluation of major hazards</li> <li>- operational control</li> <li>- management of change</li> <li>- planning for emergencies</li> <li>- monitoring performance</li> <li>- audit and review</li> </ul>	<b>Safety Report</b> must include information on <ul style="list-style-type: none"> <li>- major-accident prevention policy</li> <li>- safety management system</li> <li>- environment of the establishment</li> <li>- description of the installation</li> <li>- risk analysis and prevention methods</li> <li>- control and limitation of the consequences of an accident</li> </ul>	<b>Internal Emergency Plan</b> implies <ul style="list-style-type: none"> <li>- inside the establishment</li> <li>- consultation of personnel</li> <li>- review and test every 3 years</li> </ul> External emergency plans have to be set up by the competent authorities. The operator is required to provide appropriate information to the CA.	<b>Involving the Public</b> local authorities are corresponsable Information on safety measures and consultation of the public in case of <ul style="list-style-type: none"> <li>- planning for new upper-tier establishments</li> <li>- modifications of existing establishments</li> <li>- developments around existing establishments</li> </ul> Transboundary information has to be supplied to potentially affected Member States.

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<b>All</b>  = <b>Lower Tier and Upper Tier</b>	<b>General obligations</b> Operator shall <ul style="list-style-type: none"> <li>- take all measures to prevent a major accident</li> <li>- prove compliance with the Directive</li> </ul>	<b>Notification</b> Information to the competent authorities on <ul style="list-style-type: none"> <li>- establishment</li> <li>- dangerous substances (quantities and physical form)</li> <li>- activity of installation / storage facility</li> <li>- immediate environment</li> </ul>	<b>Major-Accident Prevention Policy</b> Written policy, <ul style="list-style-type: none"> <li>- taking account of the overall aims and principles pertaining to the prevention / control of major accidents (Annex III)</li> <li>- demonstrating a high level of protection of man and the environment</li> </ul>	<b>Preparation and Follow-up of Modifications</b> Review or revision of the <ul style="list-style-type: none"> <li>- major-accident prevention policy</li> <li>- management systems and procedures (upper tier only)</li> <li>- safety report (upper tier only)</li> </ul>	<b>Controls / Inspections by Authorities</b> Establishments subject to <ul style="list-style-type: none"> <li>- programme of systematic inspections; at least one on-site inspection per year</li> <li>- controls related to compliance with land-use policy</li> </ul>
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Figure 4: Legal obligations under Directive 1996/82/EC

### III.2.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS

The Seveso II Directive sets up rules for the safety of establishments where dangerous substances and mixtures are present above defined threshold quantities. With regard to the application of the GHS classification criteria, it is important to examine

- in how far particular GHS classifications are able to reflect the EU categories of danger or R-phrases which are referred to in Part 2 of Annex I to the Seveso II Directive. In case an EU category of danger is reflected by several GHS hazard classes, the Seveso II Directive would have to shift reference to all relevant GHS classifications. This is to maintain the current scope of dangerous substances and mixtures regulated by the Seveso II Directive and warrants maintaining the current level of protection for man and the environment;
- if a different kind or number of dangerous (GHS terminology: hazardous) substances and mixtures could be classified and regulated by the Seveso II Directive when the GHS classification scheme is applied. In case additional chemicals were classified, further establishments could fall under the regime of the Seveso II Directive or become subject to the upper-tier requirements.
- which provisions could be implemented in the Directive that are able to prevent or minimise non-desirable effects. In this connection it should be borne in mind that the GHS is a very similar classification system which does not change the intrinsic physico-chemical properties of dangerous substances and mixtures.

Table V.3 of Part I of this study gives an overview of the GHS hazard classifications which could result in a different kind or number of classified substances and mixtures compared to the current system. As to the classifications employed by the Seveso II Directive, further clarifications as well as conclusions drawn from potential effects of the GHS are presented in Table III.2.2.1 below:

Table III.2.2.1: Clarifications pertaining to potential effects of the proposed GHS Regulation and conclusions for the Seveso II Directive

EU Categories of Danger Referred to in the Seveso II Directive	Most Closely Corresponding GHS Hazard Classifications	Relevant Comparison Issues	Conclusions and Suggestions for Changes to Annex I, Part 2 Derived From the Identified Comparison Issues
<p><b>Explosive (E); R2, R3</b></p> <p><b>And</b></p> <p><b>A substance, preparation or article covered by class 1 of UN/ADR, as transposed by Council Directive 94/55/EC; included in this definition are pyrotechnic substances and mixtures as such or contained in articles</b></p>	<p><b>Explosives, Division 1.1-1.6</b></p> <p><b>Explosives, unstable explosives</b></p>	<ol style="list-style-type: none"> <li>1. The EU system covers substances, whereas the GHS covers substances as packaged and pyrotechnic articles. The GHS classification comprising 6 divisions corresponds to class 1 of UN/ADR.</li> <li>2. EU risk phrase R3 covers classified unstable substances whereas the GHS does not classify them within Divisions 1.1 to 1.6, but as <i>unstable explosive</i>.</li> <li>3. In the GHS, some unintentional explosives may not be classified, although they could have explosive properties (unpackaged) in some use settings (e.g. workplace).</li> <li>4. The EU system examines the ease of initiation by mechanical and thermal stimuli whereas the GHS is primarily concerned with the effects of initiation.</li> <li>5. The EU classifies on the basis of (some of) the intrinsic properties of the material whereas the GHS finally classifies as affected by the containment (package).</li> <li>6. The GHS has more tests and identifies more properties than the EU system. The GHS has detonation and deflagration tests.</li> </ol>	<p><u>From 1 and 2.</u> The Seveso II Directive refers to the EU risk phrases R2 and R3 as well as to class 1, divisions 1.1 – 1.6, of UN/ADR, including pyrotechnic substances and mixtures as such or contained in articles. Consequently, translation efforts will be limited to those substances and mixtures which are solely classified with E; R2 and E; R3. With regard to EU risk phrase R3, further considerations as to those substances and mixtures which are <i>not</i> covered under GHS may be necessary, cf. Annex I to this study.</p> <p><u>From 2.</u> Reference to the GHS category <i>unstable explosive</i> should be included in the Annex to the Seveso II Directive.</p> <p><u>From 3.</u> This classification issue has to be solved at UN level. With regard to the Seveso II Directive, it is suggested to refer to substances and mixtures for which test series A.14, cf. Directive 67/548/EEC, gives a positive test result.</p> <p><u>From 4.</u> Significantly affects the materials classified.</p> <p><u>From 5.</u> Significantly affects the materials</p>

		<p>7. The GHS (transport) system gives precedence to a classification as <i>organic peroxide</i> or <i>self-reactive substance (mixture)</i>, explosive properties being considered a secondary hazard, whereas the EU will always give precedence to explosive properties.</p>	<p>classified.</p> <p><u>From 6.</u> The GHS will probably classify more substances and mixtures as <i>explosives</i>.</p> <p><u>From 7.</u> If further reference to the GHS classes <i>organic peroxides (Type A and B)</i> and <i>self-reactive substances and mixtures (Type A and B)</i> is installed, more substances and mixtures are likely to be classified than currently. It is therefore proposed to refer instead to substances and mixtures for which test series A.14, cf. Directive 67/548/EEC, gives a positive test result.</p>
<b>Extremely flammable (F+); R12</b>	<b>Flammable Gases, Category 1</b>	<p>1. The EU system classifies into a single hazard level (F+; R12) whereas the GHS classifies into two hazard categories. The GHS draft Regulation proposes to take up category 1 only.</p>	<p><u>From 1.</u> No particular conclusions identified.</p>
<b>Oxidising (O)</b>	<b>Oxidising Gases</b>	<p>1. The EU system and the GHS are approximately equivalent in coverage.</p>	<p><u>From 1.</u> No particular conclusions identified.</p>
<b>Extremely flammable (F+); R12</b> <b>Highly flammable (F); R11</b> <b>Flammable; R10</b>	<b>Flammable Liquids, Category 1, 2 and 3</b>	<p>1. The GHS classifies into four hazard categories. GHS category 1-3 cover the EU categories of danger <i>Extremely Flammable (F+; R12)</i>, <i>Highly Flammable (F; R11)</i> and <i>Flammable (R10)</i> which are referred to by the Seveso II Directive.</p> <p>2. There are some differences in the limiting values for flash points between the EU categories of danger and the GHS hazard categories, cf. Table I.2 of Annex I.</p> <p>3. For GHS hazard category 3, the escape</p>	<p><u>From 2.</u> GHS hazard category 1 covers effectively the same substances as the EU category <i>Extremely Flammable (F+)</i>. Differences in the flash point limiting values for the other categories will have very little effect; they can probably not be distinguished from measurement errors.</p> <p><u>From 4.</u> Some mixtures which are classified with EU R10 will probably become declassified. It has to be checked if it is necessary to make a reference to the corresponding mixtures in the Notes of</p>

		<p>clause in Note 2 which is based on combustibility is different to that in 2.2.5 of Annex VI of Directive 67/548/EEC.</p> <p>4. The GHS has a further escape clause for viscous liquids in Note 3 that is contained in the EU land transport regulations.</p>	Part 2 of Annex I.
<b>Explosive (E); R2 and R3</b>	<b>Self-Reactive Substances and Mixtures, Type A and Type B</b>	<p>1. The GHS hazard class covers thermally unstable substances and mixtures, capable of exothermic decomposition, such as initiators and blowing agents.</p> <p>2. The GHS also covers explosive properties: Any self-reactive substance or mixture that possesses explosive properties will be defined as <i>self-reactive Type A or Type B</i> substance or mixture.</p> <p>3. The EU system classifies GHS Type A and Type B substances and mixtures as <i>Explosive (E)</i> by testing.</p>	<u>From 1.-3.</u> It is proposed to refer to GHS class <i>explosives</i> and to substances and mixtures for which EU test series A.14 gives a positive test result in the Seveso II Directive – if further reference to <i>self-reactive substances and mixtures, Type A and Type B</i> and <i>organic peroxides, Type A and Type B</i> were installed instead, more chemicals would probably be classified compared to the current situation.
<b>Highly flammable (F); R17</b>	<b>Pyrophoric Liquids and Pyrophoric Solids</b>	<p>1. The EU system subsumes pyrophoric liquids and solids under category <i>Highly Flammable (F)</i> and attributes to them risk phrase R17 which is also referred to in the Seveso II Directive.</p> <p>2. The EU system and the GHS have the same tests and criteria.</p>	<u>From 1.</u> For liquid substances and mixtures, the Seveso II Directive would have to switch reference from EU <i>Highly Flammable (F), R17</i> to the GHS classes <i>pyrophoric liquids</i> and <i>pyrophoric solids</i> .
	<b>Self-Heating Substances and Mixtures</b>	<p>1. This GHS hazard class (2 subcategories) is not covered by the current system of classification and labelling.</p> <p>2. In some documents it is stated that EU risk phrase R17 might be applicable to oxidative</p>	<u>From 1.</u> It may have to be discussed if this hazard classification should be added to the categories covered by the Seveso II Directive. In general, this hazard class has particular relevance for storage of

		<i>self-heating substances and mixtures</i> .	substances classified as self-heating, particularly in bulk phase. It covers many substances, such as ingredients of washing powders, charcoal, coal, fine particles of Iron(II)oxide etc.
<b>Oxidising (O)</b>	<b>Oxidising Liquids</b>	<ol style="list-style-type: none"> <li>1. GHS classifies into 3 subcategories which will cover substances and mixtures classified as R8.</li> <li>2. GHS category 1 corresponds also to EU risk phrase R9.</li> <li>3. The GHS may classify additional substances and mixtures compared to the current situation (in category 3).</li> </ol>	<p><u>From 1. and 2.</u> In case of oxidising liquids, the Seveso II Directive would have to switch reference from EU <i>Oxidising (O)</i> to GHS class <i>oxidising liquids</i>.</p> <p><u>From 3.</u> It may be advisable to check which / how many substances might be classified in future in addition to the current scope. To minimise potential effects, it is proposed to exempt category 3 from the scope of the Seveso II Directive.</p>
<b>Oxidising (O)</b>	<b>Oxidising Solids</b>	<ol style="list-style-type: none"> <li>1. The GHS will permit differentiation between 3 subcategories, whereas the EU system has one criterion and two risk phrases (R8, R9) with no criteria to permit differentiation.</li> <li>2. The GHS may classify additional substances and mixtures compared to the current situation (in category 3).</li> </ol>	<p><u>From 1.</u> In case of oxidising solids, the Seveso II Directive would have to switch reference from EU <i>Oxidising (O)</i> to GHS class <i>oxidising solids</i>.</p> <p><u>From 2.</u> It may be advisable to check which / how many substances might be classified in future in addition to the current scope. To minimise potential effects, it is proposed to exempt category 3 from the scope of the Seveso II Directive.</p>
<b>Explosive (E); R2 and R3 and Oxidising (O)</b>	<b>Organic Peroxides, Type A and Type B And Organic Peroxides,</b>	<ol style="list-style-type: none"> <li>1. The EU classifies such substances and mixtures as <i>Oxidising (O)</i> or <i>Explosive (E)</i>. The classification as <i>Oxidising (O)</i> is based upon chemical structure.</li> <li>2. The GHS classification is based upon</li> </ol>	<p><u>From 1. and 2.</u> In case of organic peroxides, the Seveso II Directive would have to switch reference from EU <i>Oxidising (O)</i> to GHS class <i>organic peroxides</i>.</p> <p><u>From 1.-4.</u> It is proposed to refer to GHS class</p>

	<b>Type C-G</b>	<p>chemical structure <u>and</u> on tests and criteria.</p> <ol style="list-style-type: none"> <li>The GHS hazard class <i>organic peroxides</i> also covers explosive properties. An organic peroxide that possesses explosive properties will be classified as <i>organic peroxide Type A</i> or <i>Type B</i> substance or mixture.</li> <li>In contrast, the EU system classifies GHS <i>Type A and Type B</i> substances and mixtures as <i>Explosive (E)</i> (by testing) <u>and</u> in the case of organic peroxides (chemical structure deciding) as <i>Oxidising (O)</i>.</li> <li>Both the EU system and the GHS have escape clauses for the classification which is based on the percentage of available oxygen (slightly different figures).</li> </ol> <p>NB: Organic peroxides are not oxidisers, but energetically unstable substances.</p>	<p><i>explosives and</i> to substances and mixtures for which EU test series A.14 gives a positive test result in the Seveso II Directive – if further reference to <i>self-reactive substances and mixtures, Type A and Type B</i> and <i>organic peroxides, Type A and Type B</i> were installed instead, more chemicals would probably be classified compared to the current situation.</p> <p><u>From 4.</u> To minimise potential effects related to the classification of additional substances and mixtures, it is proposed to exempt <i>Type G</i> from the scope of the Seveso II Directive.</p>
<b>Any classification not covered by those given above, in combination with risk phrase R14, including R14/R15</b>	<b>Substances and Mixtures which, in Contact with Water, Emit Flammable Gases</b>	<ol style="list-style-type: none"> <li>There is no direct equivalent to R14 as such.</li> <li>The EU system and the GHS are the same, but the GHS classifies into three subcategories and the EU only has a single hazard level, namely <i>Highly Flammable (F)</i>, with risk phrase R15.</li> </ol>	<p><u>From 1.</u> Reference to the underlying hazard should be retained.</p> <p><u>From 2.</u> For substances and mixtures classified as <i>F; R14/15</i>, the Seveso II Directive would have to switch reference to the GHS class <i>substances and mixtures which, in contact with water, emit flammable gases</i>.</p>
<b>Any classification not covered by those given above, in combination with risk phrase R29</b>	<b>No correspondence identified</b>	<ol style="list-style-type: none"> <li>GHS criteria for this hazard are currently under development at UN level.</li> </ol>	<p><u>From 1.</u> Reference to the underlying hazard should be retained.</p>
<b>Note 3(b)(1), second</b>	<b>Eventually</b>	<ol style="list-style-type: none"> <li>It is not clear if the underlying GHS</li> </ol>	<p><u>From 1.</u> Reference to the underlying hazard</p>

indent	Flammable Liquids	classification should be <i>flammable liquids</i> . It is also the physical state which is relevant here.	should be retained and include the intrinsic properties as well as the physical state.
Note 3(c)(3): flammable and highly flammable liquid substances and preparations maintained at a temperature above their boiling point	Flammable Liquids, Categories 2 and 3	1. The GHS hazard classification underlying this Note is <i>flammable liquids</i> , category 2 and 3. However, it is also the physical state which is relevant here.	<u>From 1.</u> Reference to the underlying hazard should be retained and include the intrinsic properties as well as the physical state.
Very Toxic (T+) and Toxic (T): R23, R24, R25, R26, R27, R28	Acute Toxicity, Categories 1, 2 and 3  (Inhalation route for gases and vapours: Cat. 1 and 2 only)	<ol style="list-style-type: none"> <li>Both the EU system and the GHS take account of different routes of uptake, i.e. oral, dermal and inhalation.</li> <li>The GHS classifications <i>acute toxicity, cat. 1, 2 and 3</i> comprise effects which are attributed to three different categories of danger in the EU, namely <i>Very Toxic (T+)</i>, <i>Toxic (T)</i> and <i>Harmful (Xn)</i>.</li> <li>In the GHS, the LD<sub>50</sub> / LC<sub>50</sub> ranges of the individual categories do not always coincide with the ranges of the corresponding EU categories of danger. For example, the current EU category <i>Very Toxic (T+)</i> for the oral route of uptake ranges from 0 • LD<sub>50</sub> • 25 mg/kg, while GHS category 1 ranges from 0 • LD<sub>50</sub> • 5 mg/kg and category 2 from 5 • LD<sub>50</sub> • 50 mg/kg. The EU category <i>Toxic (T)</i> ranges from 25 • LD<sub>50</sub> • 200 mg/kg for the oral route while GHS category 3 ranges from 50 • LD<sub>50</sub> • 300 mg/kg. Similar statements can be made for the dermal route of uptake and for inhalation</li> </ol>	<p><u>From 1. and 2.</u> In case of toxic properties which relate to different routes of uptake, the Seveso II Directive would have to switch reference from EU <i>Very Toxic (T+)</i> and <i>Toxic (T)</i> to GHS class <i>acute toxicity, categories 1, 2 and 3</i>.</p> <p><u>From 2. and 3.</u> The <i>GHS categories 1, 2 and 3</i> would cover more substances than are currently covered by the EU categories <i>Very Toxic (T+)</i> and <i>Toxic (T)</i>.</p> <p><u>From 3.</u> If GHS <i>acute toxicity category 1 and 2</i> (oral) were to replace EU category <i>Very Toxic (T+)</i> in the Seveso II Directive, more <b>substances</b> would be covered compared to the EU system. Accordingly, the quantities qualifying for the lower and the upper tier would be lowered significantly for those <i>GHS category 2</i> substances which are currently classified as <i>Toxic</i>. An opposite conclusion may be drawn if only GHS <i>category 1</i> (oral) were to replace EU <i>category Very Toxic (T+)</i> in the Seveso II</p>

		<p>of dusts &amp; mists.</p> <p>4. The number of mixtures within a defined LD<sub>50</sub> / LC<sub>50</sub> range may change, depending on the method applied to derive the classification of a mixture under GHS, cf. below. Migration of individual mixtures to lower or upper toxicity ranges might occur.</p> <p>5. The GHS uses formula 3.1.3.6.2.3 for the calculation of the classification of a mixture in case there is insufficient knowledge about the classifications of its ingredients. This formula will classify the more severe the less the classifications of the ingredients are known.</p>	<p>Directive. A similar reasoning will apply to the <i>Toxic</i> category: For the oral and dermal pathway, the number of classified substances which is covered by GHS category 3 or cat. 2 <u>and</u> 3 is likely to increase in any case so that also some EU <i>Harmful</i> substances would be covered by the Seveso II Directive.</p> <p>The situation for the other routes of uptake is similar, though not completely the same as for the oral pathway.</p> <p><u>From 3 and 4.</u> The GHS classification of a mixture has to be checked individually. Then it has to be decided which GHS category/ies shall replace <i>Very Toxic</i>, and which shall replace <i>Toxic</i>. If GHS <i>acute toxicity cat. 1 and 2</i> (oral) were to replace EU category <i>Very Toxic (T+)</i> in the Seveso II Directive, more <b>mixtures</b> are likely to be covered compared to the EU system. Accordingly, the quantities qualifying for the lower and the upper tier would be lowered significantly for those <i>GHS category 2</i> mixtures which are currently classified as <i>Toxic</i>. An opposite conclusion may be drawn if only GHS <i>category 1</i> (oral) were to replace EU category <i>Very Toxic (T+)</i> in the Seveso II Directive. The reasoning for <i>Toxic</i> and for the other routes of uptake is the same as under the previous point.</p> <p><u>From 5.</u> Mixtures which have not been classified under the current EU legislation may be classified in future. This situation will</p>
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			probably persist for some years only – after the transitional period, cf. below, sufficient information on the ingredients should be available so that additivity formula 3.1.3.6.1 GHS can be used. The latter is able to derive the toxicity of a mixture more adequately.
<b>Very Toxic (T+) and Toxic (T): R39 (all routes of uptake)</b>	<b>STOT (single exposure), category 1</b>	1. Due to higher cut-off values for substance classification for all routes of uptake, the GHS will probably classify additional substances and mixtures.	<u>From 1.</u> For substances and mixtures classified as <i>T+ / R39</i> or <i>T / R39</i> , the Seveso II Directive would have to switch reference to GHS class <i>STOT (single exposure), cat. 1</i> . <u>From 1.</u> The GHS will probably classify additional substances and mixtures.
<b>Toxic (T): R48 (all routes of uptake)</b>	<b>STOT (repeated exposure), category 1</b>	1. For <i>STOT (repeated exposure)</i> , the GHS criteria for the oral and the dermal route are twice as stringent as the current EU criteria for <i>R48</i> .	<u>From 1.</u> For substances and mixtures classified as <i>T / R48</i> , the Seveso II Directive would have to switch reference to GHS class <i>STOT (repeated exposure), category 1</i> . <u>From 1.</u> The GHS will probably classify additional substances and mixtures.
<b>Dangerous for the environment (N), in combination with risk phrases R50 and R51/53</b>	<b>Hazardous to the Aquatic Environment, Categories Acute I, Chronic I, Chronic II</b>	1. The classification under GHS reflects the current EU system: Both systems use two hazards, <i>acute aquatic toxicity</i> and <i>chronic aquatic toxicity</i> , with similar classification criteria. 2. Generally, the EU system combines the acute with the chronic toxicity, cf. combination of R-phrases, whereas the GHS puts them in separate hazard categories. 3. The concentration limits for the classification of mixtures are the same for the EU system and the GHS.	<u>From 1.</u> For substances and mixtures classified as <i>N; R50</i> and <i>N; R51/53</i> , the Seveso II Directive would have to switch reference to GHS class <i>hazardous to the aquatic environment, categories acute I, chronic I and chronic II</i> . <u>From 1.</u> In general, the GHS will maintain the current scope of substances and mixtures which the Seveso II Directive is currently covering. For individual substances and mixtures, the classification may change, cf. below.

		<p>4. Endpoints: In the EU, the testing criterion is 72h E<sub>r</sub>C<sub>50</sub> while under GHS, the testing criterion will probably be 72 OR 96h E<sub>r</sub>C<sub>50</sub> for algae (provided exponential growth in the control vessel).</p> <p>5. Bioconcentration: In the EU, the bioconcentration potential cut-offs of log K<sub>ow</sub>&lt;3 and BCF&lt;100 become log K<sub>ow</sub>&lt;4 and BCF&lt;500.</p> <p>6. Bioconcentration: In contrast to the EU system, bioconcentration will be used for ALL substances, and not only for substances with acute toxicity &gt; 10 mg/l.</p> <p>7. Degradation: Under GHS, inherent test data cannot be used to declassify.</p> <p>8. Escape Clause: Under Directive 67/548/EEC applied to substances with acute toxicity &gt;10mg/l, under GHS applied at &gt;1mg/l.</p> <p>9. Mixtures: Using the summation method, the introduction of M-factors is to reflect the toxic contribution of components &lt;1 mg/l.</p> <p>Further differences are not relevant in the context of the Seveso II Directive.</p>	<p><u>From 4.</u> The growth rate alone may alter some classifications.</p> <p><u>From 5.</u> Some substances may no longer require classification.</p> <p><u>From 6.</u> Some previously non-classified substances may require classification.</p> <p><u>From 7.</u> Declassification based on inherent data has not commonly been applied in the past, so the effect is likely to be small.</p> <p><u>From 8.</u> Some previously classified substances may no longer need classification under GHS.</p> <p><u>From 9.</u> It is claimed that the introduction of M-factors might lead to some mixtures being either classified or more severely classified than they are currently.</p>
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## Comments on the Table

### A. Effects related to physico-chemical hazards

- The classification criteria and testing methods for physical hazards in the GHS are already well-known: They are based on the existing TDG Manual of Tests and Criteria which has already been used globally for the classification of dangerous goods.
- Compared to the EU system, one apparent difference is a more differentiated sub - classification of various hazard classes into categories, divisions or types in the GHS. This is the case for *explosives, flammable gases / liquids / solids, oxidising gases / liquids / solids, self-reactive substances and mixtures, organic peroxides* and for *substances and mixtures which, in contact with water, emit flammable gases*, cf. also Table V.3 of Part I of this study.
- The GHS attributes various hazardous properties which have been attributed to one single EU category of danger to more than one hazard class, e.g. *explosives and self-reactive substances and mixtures, Type A and Type B and organic peroxides, Type A and Type B*. Another example is the EU category *Oxidising (O)* which is going to split up into *oxidising gases, oxidising liquids, oxidising solids* and *organic peroxides* under GHS. With regard to explosive properties, it is proposed to refer to GHS explosives and to substances and mixtures for which EU test series A.14 gives a positive test result – if further reference to *self-reactive substances and mixtures, Type A and Type B* and *organic peroxides, Type A and Type B* were installed instead, more chemicals would probably be classified compared to the current situation.
- Particular attention should be paid to those unintentional explosives which – due to a negative result in test series 6 – will not be classified as *explosive* under GHS. The issue is here that the chemical is tested in a defined packaging. However, a negative test result does only refer to that particular packaging and does not preclude that the substance may explode in another packaging or under particular conditions of use (workplace!). At UN level, the problem has been recognised: UN documents ST/SG/AC.10/C.3/2005/36 and ST/SG/AC.10/C.4/2005/5 propose to implement a test series for explosive properties in the GHS for *all* substances which might present an explosive hazard, i.e. test series A.14 according to Dir 67/548/EEC. In the same UN documents, it is proposed to include “desensitised explosives” as new category. Formal adoption of the UN documents will not take place before December 2006.
- Seen on a whole, **the physical hazard classes in the GHS mentioned in Table III.2.2.1. cover a wider range of properties** than the corresponding categories of danger in the EU system. This means that more substances and mixtures would potentially be classified under GHS, cf. the statements in the 4<sup>th</sup> column of the table above. In the case the legislator does not make further confinements concerning the physico-chemical properties which are to be regulated by the Seveso II Directive, **individual substances and mixtures will have to be attributed for the first time the qualifying quantities which define the lower and the upper tier in the Seveso II Directive.**

## B. Effects related to health hazards

### I. Acute Toxicity

- For *acute toxicity*, the cut-off concentrations of the individual GHS categories do not always coincide with those of the corresponding EU categories of danger. This difference is illustrated in Figure 5 below:

#### 1. Acute Toxicity - Oral

<b>EU</b>	T <sup>+</sup> R28		T R25			Xn R22	
<b>LD<sub>50</sub> (*)</b>	≤ 5	5-25	25-50	50-200	200-300	300-2000	2000-5000
<b>GHS</b>	Cat. 1	Category 2		Category 3		Category 4	Category 5

#### 2. Acute Toxicity - Dermal

<b>EU</b>	T <sup>+</sup> R27		T R24		Xn R21	
<b>LD<sub>50</sub></b>	≤ 50	50-200	200-400	400-1000	1000-2000	2000-5000
<b>GHS</b>	Category 1	Category 2	Category 3		Category 4	Category 5

**Figure 5:** Category ranges for acute oral and dermal toxicity under EU legislation and the GHS

- Whereas a clear-cut statement can be made concerning an increased / decreased number of classified *substances* under GHS, cf. Table V.3 of Part I, a corresponding statement for *preparations* (GHS terminology: “mixtures”) can hardly be made. The reason is firstly that it cannot be predicted if the classification of a multi -ingredient mixture as derived through application of one of the GHS calculation approaches, cf. Chapter 3.1 GHS , will deviate from the most closely corresponding classification as derived from the EU conventional calculation method, cf. Annex II, Part A of Directive 1999/45/EC. Available studies only provide preliminary answers for simple mixtures where one substance is diluted in an inert solvent, cf. Annex I to this study.
- Apart from the classification of a substance or mixture, the conversion of the reference to a particular EU category to (a) defined GHS category(ies) in the Seveso II Directive is crucial. For the oral route of uptake, it will then be of relevance if the Seveso II Directive will refer to category 1 GHS or to category 1 and 2 GHS in future. In the former case, less substances and mixtures will probably be caught compared to the current situation. In the latter case, the opposite could occur in theory. A related situation may arise for *Toxic*: Will the reference to *Toxic* be replaced by category 3 GHS or by category 2 and 3 GHS in the Seveso II Directive? In the former case, a wider LD<sub>50</sub> range is covered, due to the upper limit being LD<sub>50</sub> = 300 mg/kg bodyweight. In the latter case, this trend is even more pronounced because the lower LD<sub>50</sub> limit would be lowered from 25 to 5 mg/kg bodyweight. As a consequence of both cases, more substances and mixtures could potentially be caught. The situation and the underlying reasoning for the other routes of uptake are similar, though not completely the same as for the oral pathway.
- For the oral route of uptake, this may have the following consequences: Supposed *GHS acute toxicity categories 1 and 2* are to replace *EU Very Toxic* in Annex I, Part 2 of the Seveso II Directive, additional substances and mixtures would be assigned the strictest qualifying quantities. In a similar way, *GHS acute toxicity category 3* would probably comprise more substances and mixtures than the EU category of danger *Toxic* does. **When the additional chemicals are assigned more severe qualifying quantities in the Seveso II Directive, the establishments where these chemicals are present might qualify for the lower or even the upper tier requirements of the Seveso II Directive applying to the more severe classification. The respective qualification will depend on the actual quantities present.** Example: A lower-tier establishment where a *GHS category 2 / EU Toxic* mixture is present with 60 tonnes (lower -tier threshold: 50 tonnes) might in future qualify for the upper -tier requirements (threshold: 20 tonnes!) that are currently assigned to the category *Very Toxic*.
- It can be concluded that an opposite situation may arise for another scenario, cf. above.

**It has to be noted that the above -mentioned up - and downgrading effects of the GHS which may occur for individual substances and mixtures do not necessarily have implications for the establishments where they are present . This will be mainly due to the following reasons: Firstly, it is the quantity of a chemical being present at an establishment which counts. Secondly, the result of the aggregation formula in Annex I, Part 2, Notes (4) will determine the overall tier to be assigned to the establishment. Third, it is possible to minimise potential, but undesired effects pertaining to substance classification by consequential amendments to the provisions of Annex I, Part 2 of the Seveso II Directive.**

- For the oral route of uptake of the hazard *acute toxicity*, effects could be minimised by referring to the corresponding GHS classification and at the same time limiting the

reference to a cut-off value of LD<sub>50</sub> • 25 mg/kg for the most toxic substances and to LD<sub>50</sub> • 200 mg/kg for the less toxic substances, cf. also Table VI.2 of Part I of this study. This would also follow the model of the UNECE Convention on the Transboundary Effects of Industrial Accidents<sup>3</sup>. The same remedy may be applied to the affected categories for the other routes of uptake (dermal / inhalation), cf. Table VI.2 .

- As a consequence, at least the current scope of classified *substances* regulated by the Seveso II Directive can be maintained, with the respective qualifying quantities of 5 / 50 tonnes (lower tier) and 20 / 200 tonnes (upper tier). For mixtures, the calculation approach applied under GHS will probably determine whether additional mixtures are classified and covered by the provisions of the Seveso II Directive.

## II. Specific Target Organ Toxicity (STOT)

- For *Specific Target Organ Toxicity (single exposure)*, the GHS will probably classify additional substances and mixtures. This would be due to higher cut-off values for substance classification for all routes of uptake, cf. document DG ENTR, Comparison between EU and GHS Criteria, Human Health and Environment, June 2005 .
- For *STOT (repeated exposure)*, the GHS criteria for the oral and the dermal route are twice as stringent as the current EU criteria for R48 so that the number of substances and mixtures classified for this hazard will probably increase compared to the current situation: as indicated in section 15 of ECB document GHS/011/2005, classification as *STOT* after repeated exposure via the oral route will already be triggered when effects are observed in a 90 days study as per <10mg/kg/day (Category 1) in the frame of GHS, but only as per <5 mg/kg/day (T, R48) under the current EU system.

If additional substances and mixtures are classified under GHS, the establishments where these chemicals are present might be upgraded to the upper tier or would have to comply with the Seveso II requirements for the first time (lower or upper tier). The assignment to the upper- or lower-tier requirements would then depend on the overall quantities of the dangerous chemicals present at the establishment, cf. above.

**For both GHS hazard classifications, potential effects can be minimised by referring to the GHS classification criteria while at the same time extending or limiting the respective reference to the current cut-off limits or concentration thresholds for the different routes of uptake. The corresponding adaptations are presented in Table VI.2 of Part I of this study.**

## C. Effects related to hazards pertaining to the aquatic environment

As to this hazard, the GHS may have an effect: While the number of substances and mixtures to be classified for the hazard categories *GHS acute I, chronic I* and *chronic II* will be equivalent to the number of currently classified chemicals, individual substances and mixtures might change classification. In this connection it is sometimes stated that the introduction of M-factors in the summation method might lead to some mixtures being either classified or more severely classified than they are currently. For example, highly toxic substances could drive an environmental classification at concentrations even below 0.25 %. On the other hand,

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<sup>3</sup> At UNECE level, discussions on the relation between the UNECE Convention on the Transboundary Effects of Industrial Accidents and the GHS have started

due to various elements of the classification criteria, it cannot be excluded that some substances and the mixtures containing them will be declassified, cf. Annex I.

#### **D. Effect triggered by the Seveso II Directive itself**

As outlined above, the GHS may lead for various reasons to an increased number of classified substances and mixtures which would then be covered by the Seveso II Directive in its current form. In addition, **it will be the volume provision of the Seveso II Directive itself which will reinforce any potential effect the GHS might have with regard to mixtures:** The Seveso II Directive counts a classified mixture with its total volume, and not with the volume of the substance that triggers its classification, cf. paragraph 2 of the introduction of Annex I. For example, if a mixture is classified under GHS as *acute toxicity category 2*, the concentration of the toxic ingredient being only 10%, the mixture will count with its total volume. This in-built mechanism could add on effects which are due to the calculation method and might increase the number of mixtures to be regulated by the Seveso II Directive over-proportionally. As a result, an additional number of companies could become lower- or even upper-tier establishments in the meaning of the Seveso II Directive. Of course, this will also depend on the overall amount of dangerous substances and mixtures present, cf. above. To avoid this mechanism, the provision in paragraph 2 of the introduction of Annex I would have to be revised, e.g. by generally defining percentage compositions. The aggregation rule in Note 4 of Part 2 of Annex I would then have an effect at higher quantities present.

#### **III.2.3. Suggestions how to minimise potential effects of the GHS**

- Operators and suppliers are recommended to check substances and mixtures individually with regard to any classification effects of the GHS. Provided an effect can be identified, it should be verified if the quantities present could affect the status of an establishment in terms of the Seveso II Directive. In this connection it should be noted that even slight differences between the EU and the GHS classification criteria, e.g. a varying escape clause, may be relevant for the classification and the consequential status of an establishment.
- If the structure of Part 2 of Annex I to the Seveso II Directive is to be maintained, a minimum requirement will be to replace any explicit reference to Directives 67/548/EEC and 1999/45/EC by a corresponding reference to the future GHS-implementing Regulation. Switching from the EU system to the GHS, the Seveso II Directive will have to make reference to those classes and categories in Part 2 of Annex I which are enumerated in column 2 and / or column 4 of the table above or in Table V.3 of Part I of this study. Beyond, it will be necessary to redefine various references to particular hazards, both in the Table and in the Notes of Annex I, Part 2.
- **In order to minimise effects related to additional classification under GHS, it is proposed to adapt the references of certain relevant hazards in accordance with Table VI.2 (Solution 2) of Part I of this study. This would imply to refer to the GHS classification criteria while at the same time extending or limiting the respective reference to the current cut-off limits or concentration thresholds. Furthermore, the GHS classifications *Oxidising Solids / Liquids Category 3* and *Organic Peroxides Type G* could be exempted because they could also comprise further substances and**

**mixtures (Solution 1).** It is proposed to perform the said adaptations in the GHS Regulation itself.

- On the other hand, adaptations of the hazard ranges following e.g. the model of the UNECE Convention on the Transboundary Effects of Industrial Accidents may be applied in order to avoid an increased number of regulated chemicals.
- If there are any substances and mixtures which are *not* covered by the GHS classification system, cf. column 4 of the table above, further references and/or definitions might be included in the Table or the Notes of Annex I, Part 2.

#### Basic documents used for the analysis

- European Commission: Technical Assistance to the European Commission on the Implementation of the GHS (Ökopol, 2004)  
[http://europa.eu.int/comm/enterprise/reach/ghs\\_en.htm](http://europa.eu.int/comm/enterprise/reach/ghs_en.htm)
- ECBI/75/01-Part A. rev.1
- A.K. Brown, GHS - EU Explosives Comparison, July 2005
- DG ENTR, Comparison between EU and GHS Criteria, Human Health and Environment, June 2005
- R.-U. Förster, M. Wiertulla, Classification of substances and preparations – comparison of the EU and the Globally Harmonised System. November 2005
- CAL-TASK1-2/029 and CAL-TASK1-2/015
- ECBI/56/04
- Genevieve Hilgers, Comparison of criteria for the classification of substances between the Global Harmonisation and EU systems, August 25, 1999
- Ian Malcomber, Environmental GHS for Beginners. Presentation held at a CEGIC Classification Workshop by 3<sup>rd</sup> October 2005 (Brussels)
- European Commission: Report on the application in the Member States of Directive 96/82/EC on the control of major -accident hazards involving dangerous substances for the period 2000-2002
- Esther Versluis, Enforcement Matters – Enforcement and Compliance of European Directives in Four Member States, ISBN 90 5166 9720

### III.3. Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals

[http://europa.eu.int/smartapi/cgi/sga\\_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32003R0304&model=guichett](http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32003R0304&model=guichett)

Regulation (EC) No. 304/2003 implements the Rotterdam Convention. It applies to chemicals from the 88 different entries listed in Annex I Parts 1, 2 and 3 to the Regulation. These chemicals qualify for annual export notification, PIC notification, the PIC procedure and/or explicit consent.

The GHS may trigger some legal obligations of very limited scope: A limited effect may be due to the introduction of the GHS Regulation as such because then the export notifications have potentially to be repeated. Another effect will be due to lower concentration limits for the classification and labelling of certain mixtures which contain chemicals from Annex I: In case the lower cut-off concentrations trigger a change of labelling of the mixture, it will become subject to the provisions of the Regulation. However, since mixtures containing chemicals from eight entries of Annex I only would potentially be affected by this mechanism any effect will be very minor.

An option to decouple the requirement of export notification from the labelling of a mixture could be to introduce fixed concentration limits for the chemicals tabled in Annex I to the Regulation. However, it may be discussed if this is necessary and appropriate.

#### III.3.1. Abstract of the legislation

Regulation (EC) No. 304/2003 implements the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade at Community level. It is based upon Article 175(1) of the Treaty. The objectives of the Regulation are to promote shared responsibility and cooperative efforts in the international movement of hazardous chemicals, in order to protect human health and the environment from potential harm as well as to contribute to their environmentally sound use. These objectives are to be achieved by facilitating exchange of information relating to the hazardous properties and precautionary measures related to such chemicals and pesticides. To this end, the Regulation defines a decision-making process within the Community on their import and export. Moreover, it regulates how decisions are to be disseminated to Parties and other countries.

In general, chemicals which are classified as dangerous and which are intended for export shall be subject to the measures on packaging and labelling according to Directives 67/548/EEC, 1999/45/EC, 91/414/EEC and 1998/8/EC or any other specific Community legislation. The corresponding provisions in Article 16 apply without prejudice to any specific requirements of the importing Party or other country, taking into account relevant international standards (in future: GHS).

The chemicals covered by the provisions of the Regulation relating to export notification, PIC notification, the PIC procedure or explicit consent shall be as listed in Annex I which has three parts:

- Part 1 lists the chemicals or chemical groups that are subject to annual export notification. It comprises the chemicals that are banned or severely restricted within the EU in at least one of the use subcategories (plant protection products/other pesticides/industrial chemicals for professional use/industrial chemicals for use by the general public). It also includes the chemicals that qualify for PIC notification and the chemicals subject to the PIC procedure.
- § Part 2 lists the chemicals that qualify for PIC notification because they are banned or severely restricted within the Community in a Convention use category (i.e. pesticide or industrial chemical).
- § Part 3 lists the chemicals or chemical groups that are subject to the PIC procedure (being listed in Annex III to the Convention), except those POP chemicals that are completely prohibited in the EU and are banned for export by Article 14.2 of this Regulation (listing in Annex V).

In addition to export notification, the export of chemicals listed in Part 2 and Part 3 also requires the explicit consent of the importing country (cf. Article 13).

Any chemical that is completely banned for export is listed in Annex V.

It should be underlined that for the purposes of the export notification obligations of Article 7 and the explicit consent requirements of Article 13.6, mixtures are not always affected: They fall within the scope of these provisions only to the extent that the presence of (an) Annex I listed chemical(s) triggers compulsory labelling under Community legislation irrespective of the presence of any other substances.

### III.3.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS

In general, chemicals which are classified as dangerous and which are intended for export shall be subject to the measures on packaging and labelling according to Directives 67/548/EEC, 1999/45/EC, 91/414/EEC and 1998/8/EC or any other specific Community legislation. The corresponding provisions in Article 16 apply without prejudice to any specific requirements of the importing Party or other country, taking into account relevant international standards (in future: GHS).

The Regulation is working on the basis of lists of chemicals, with currently only 88 different entries in Part 1, 2 and 3 of Annex I to the Regulation. These chemicals have been severely restricted or banned by other Community legislation or are subject to the international PIC procedure and subsequently been subject to annual export notification, the obligation to obtain explicit consent or the PIC procedure, cf. above. Since the applicability of the Regulation is *not* triggered by classification as such, but depends on the outcome of evaluation and restriction under other EU legislation or inclusion of the chemical in Annex III of the Convention, **the GHS will have no direct effects which are due to (re)classification.**

1. One effect could be based on a provision in Article 7.3 of Regulation (EC) No. 304/2003: Accordingly, annual export notifications for the chemicals listed in Annex I Part 1 will have to be repeated if Community legislation with regard to labelling of those chemicals changes. This provision will consequently apply when the GHS enters into force. **However, that would be a one-off exercise. Moreover, Article 7.5 provides for various escape clauses:** Export notification is no longer required if

- the chemical has become a chemical subject to the PIC procedure (30 chemicals listed in Part 1), and
- the importing country being a party to the Convention has provided a response whether to consent or not to consent to import of the chemical, or if
- the appropriate authority of the importing party or other country has waived the requirement to be notified before the export of the chemical.

**At least for those 50 chemicals, i.e. substances and mixtures according to the definition in Article 3.2, which do not qualify for PIC notification or the PIC procedure the annual export notifications may have to be repeated when the GHS enters into force. Considering the low number of entries concerned, this effect will be limited.**

2. A similar effect could be based on a second provision in Article 7.3: Accordingly, annual export notifications may have to be repeated whenever the composition of a mixture changes so that the labelling of that mixture is altered. This would also include preparations (GHS terminology: mixtures) which will change labelling due to lower ingredient concentration limits under GHS for particular hazards. The hazard classifications which could be affected are *reproductive toxicity, skin corrosion / irritation and serious eye damage / eye irritation* :

**Table III.3.2.1:** Health hazard-related concentrations limits for the classification of mixtures

EU classification	GHS classification	Change of concentration limit
Reproductive toxicity, cat. 1 or 2, R60 or R61	Reproductive toxicity, category 1	from 0.5% EU to 0.3% GHS
Reproductive toxicity, cat. 1 or 2, R62 or R63	Reproductive toxicity, category 2	from 5% EU to 3% GHS
Corrosive C, R34	Skin corrosion, category 1B and 1C	from 10% EU to 5% GHS
Corrosive C, R35	Skin corrosion, category 1A	from 5% EU to 3% GHS
Irritant Xi, R38	Skin irritant, category 2	from 20% EU to 10% GHS
Irritant Xi, R36	Eye irritation, category 2A	from 20% EU to 10% GHS
Irritant Xi, R41	Serious eye damage, category 1	from 10% EU to 3% GHS

In other words: additional mixtures containing chemicals listed in Annex I in the concentration interval between the EU and the GHS concentration limits would carry a labelling – these mixtures would consequently be subject to the provisions of Regulation (EC) No. 304/2003, i.e. to annual export notification, explicit consent or the PIC procedure. In this connection, an evaluation of the classifications of the Annex I entries suggests that mixtures containing **2,4,5-T, Binapacryl, Dinoseb, its acetate and Dinoseb salts, Dinoterb, Ferbam, various Mercury compounds, Nonylphenol, Octabromodiphenylether and**

**Triorganostannic compounds** in the range between the EU and the GHS concentration limit are potential candidates for a repetition of the annual export notification, cf. Table III.3.2.2:

Table III.3.2.2: Candidate substances which may qualify additional mixtures for an annual export notification or PIC notification / the PIC procedure due to lower concentration limits under GHS. The classifications are provided by the EDEXIM database at ECB (June 2005) .

Annex I entry	Current EU classification	GHS hazard triggering the labelling of a mixture at the minimum concentration limit
2,4,5-T	Xn; R22 – Xi; R36/37/38 – N; R50/53	Skin irritant, category 2 at 10%
Binapacryl	Repr. cat. 2; R61 – Xn; R21/22 – N; R50/53	Reproductive toxicity, category 1 at 0.3%
Dinoseb, its acetate and Dinoseb salts	Repr. cat. 2; R61 – Repr. cat. 3; R62 – Xi; R36 – T; R24/25 – N; R50/53 – R44	Reproductive toxicity, category 1 at 0.3%
Dinoterb	Repr. cat. 2; R61 – T+; R28 – N; R50/53 – R44	Reproductive toxicity, category 1 at 0.3%
Ferbam	Xi; R36/37/38 – N; R50/53	Skin irritant, category 2 at 10%
various Mercury compounds	e.g. T; R48/24/25 – C; R34 – N; R50/53	Skin corrosion, category 1B or 1C at 5%
Nonylphenol	Repr. cat. 3; R62/63 – Xn; R22 – C; R34 – N; R50/53	Skin corrosion, category 1B or 1C at 5%
Octabromodiphenylether	Repr. cat. 2; R61 – Repr. cat. 3; R62	Reproductive toxicity, category 1 at 0.3%
various Triorganostannic compounds	T; R48/23/25 – Xn; R21 – Xi; R36/38 – N; R50/53	Skin irritant, category 2 at 10%

These eight chemicals represent 9% of the 88 entries only so that any potential effect would be very limited. However, apart from Ferbam, the same chemicals and their mixtures also qualify for PIC notification or the PIC procedure. Accordingly, the annual export notification is no longer required, cf. above. Nevertheless, new explicit consent might be necessary. However, whether new explicit consent is actually needed will depend on the nature and scope of the consent already provided. For example, if an importing country has given consent to the chemical in whatever form and concentration, no new consent would be needed (implicit from Article 13.6).

**Concluding, any potential effect of the GHS due to lower concentration limits will be very limited. With regard to mixtures containing chemicals from Annex I Part 1, only mixtures containing Ferbam in concentrations 10 -20% could be subject to a repetition of the annual export notification. Mixtures of seven further chemicals, i.e. 2,4,5 -T, Binapacryl, Dinoseb, its acetate and Dinoseb salts, Dinoterb, various Mercury compounds, Nonylphenol, Octabromodiphenylether and Triorganostannic compounds, which qualify for PIC notification or the PIC procedure could potentially be subject to new explicit consent.**

At this stage it cannot be predicted if the GHS criteria and calculation methods which have to be applied to classify mixtures for *hazardous to the aquatic environment* could drive a classification at concentrations which are even lower than the above -mentioned trigger concentration limits in column 3 of Table III. 3.2.2. In this connection it is sometimes stated that the introduction of M-factors in the GHS summation method would imply that highly toxic substances could drive an environmental classification at concentrations even below 0.25 %. If the trigger concentration limit were caused by the environmental classification, further mixtures would become potential candidates for a repetition of the annual export notification or explicit consent. In this case, both mixtures containing the chemicals mentioned above and mixtures containing other substances from Annex I would potentially be affected.

### **III.3.3. Suggestions how to minimise potential effects of the GHS**

It is recommended to verify if individual mixtures containing chemicals from Annex I to Regulation (EC) No. 304/2003 could qualify for annual export notification or explicit consent.

An option to decouple the requirement of export notification from the labelling of a mixture would be to introduce fixed concentration limits for the chemicals tabled in Annex I to the Regulation. This means that for any chemical included in Annex I a threshold is given for the necessary notification procedure which is completely independent of the labelling of the chemical. In general, there are two alternatives for the determination of these thresholds: Either, one fixed value could be proposed for all such chemicals (e.g. 0.1% as in Canada) or values related to exposure, i.e. to the use of the chemical, could be considered. The latter could be difficult to establish. The former option has the merit of simplicity. However, it could set an arbitrary threshold that would not necessarily achieve the ends sought, i.e. the need to focus on those mixtures that present a real risk and to avoid capturing so many others that the system becomes unmanageable and those of concern become lost.

On the other hand, export notifications have to be provided only once per year for a given chemical or mixture with a given labelling per importing country. Explicit consent, if needed at all, has to be obtained only once to remain valid for several years. Considering that the number of concerned chemicals listed in Annex I is limited, the effects of the GHS on Regulation (EC) No. 304/2003 are expected to be limited.

#### Basic documents used for the analysis:

- Regulation (EC) No. 304/2003 and Technical Notes for Guidance for Designated National Authorities

#### III.4. Control of volatile organic compounds

- § **Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations and**
- § **Directive 2004/42/EC of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in decorative paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC**

<http://europa.eu.int/eurlex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31999L0013:EN:HTML>

[http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l\\_143/l\\_14320040430en00870096.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_143/l_14320040430en00870096.pdf)

With regard to the control of volatile organic compounds, two Directives were analysed: Council Directive 1999/13/EC (“VOC-Directive”) is to prevent or reduce the direct and indirect effects of emissions of volatile organic compounds (VOCs) on the environment and human health. The VOC-Directive covers emissions of organic solvents from stationary commercial and industrial sources. It provides measures and procedures to be implemented for industrial activities defined in Annex I if these activities are operated above the solvent consumption thresholds listed in Annex IIA. Furthermore, it sets emission limits for VOCs. It requests that substances or mixtures which, because of their content of VOCs classified as *carcinogens*, *mutagens*, or *toxic to reproduction* under Directive 67/548/EEC, are assigned or need to carry the risk phrases *R45*, *R46*, *R49*, *R60*, *R61*, shall be replaced, as far as possible by less harmful substances or mixtures within the shortest possible time. Also, stricter emission values are specified for these substances and mixtures. Where a risk assessment is carried out in accordance with EU legislation of any of the substances causing the labelling *R40*, *R60* or *R61* which are controlled under this Directive, the Commission shall consider the conclusions of the risk assessment and shall take the necessary measures as appropriate.

A potential effect of the GHS could be that some additional mixtures would have to be classified for reprotoxicity when they contain a reprotoxic organic solvent in the concentration range between 0.5% and 0.3%. However, industrial activities covered by the VOC-Directive apparently use organic solvents in concentrations which significantly exceed even the current concentration limit which is 0.5%. Consequently, any potential effect pertaining to an increase in reprotoxic mixtures under GHS is likely to be of no relevance.

Directive 2004/42/EC does not contain specific legal provisions which are based on the legislation on classification and labelling. It is to complement Community provisions on the labelling of chemical substances and preparations as laid down in Directives 67/548/EEC and 1999/45/EC, cf. Recital 12. In this sense, the GHS will not have a direct effect on Directive 2004/42/EC.

### III.4.1. Abstract of the legislation

#### Council Directive 1999/13/EC

Council Directive 1999/13/EC (“VOC -Directive”) which is based on Article 130(r) of the Treaty is a tool to avoid pollution due to the formation of tropospheric ozone. It is to prevent or reduce the direct and indirect effects of emissions of volatile organic compounds (VOCs) on the environment and human health. It covers emissions of organic solvents from stationary commercial and industrial sources.

The VOC-Directive provides measures and procedures to be implemented for industrial activities defined in Annex I if these activities are operated above the solvent consumption thresholds listed in Annex IIA. Also, it sets emission limits for VOCs.

Member States must take the necessary measures to ensure that all new installations comply with the provisions of the Directive (cf. Article 3.1). Moreover, all new installations not already covered by Directive 96/61/EC concerning integrated pollution prevention and control must be registered or authorised before being put into service (cf. Article 3.2). Existing installations must be registered or their activities authorised if they have not yet been authorised under Council Directive 96/61/EC (cf. Article 4.2). They must comply with the same requirements as for new installations no later than 30 October 2007 (cf. Article 4.1). Where part of an existing installation undergoes a substantial change, it must comply with the requirements applicable to new installations (cf. Article 4.4).

The industrial operators concerned can conform with the specified emission limits in either of the following ways:

- by installing equipment to reduce emissions to comply with the emission limit values and the fugitive emission values, or total emission limit values (cf. Article 5.2(a) and 5.4) ;
- by introducing a reduction scheme to arrive at an equivalent emission level, in particular by replacing conventional products which are high in solvents with low-solvent or solvent-free products (cf. Article 5.2(b)).

Substances or mixtures which, because of their content of VOCs classified as *carcinogens*, *mutagens*, or *toxic to reproduction* under Directive 67/548/EEC, are assigned or need to carry the risk phrases *R45*, *R46*, *R49*, *R60*, *R61*, shall be replaced, as far as possible and by taking into account the guidance elaborated by the Commission, by less harmful substances or mixtures within the shortest possible time (cf. Article 5.6 and 7.1). Stricter emission values are specified for these substances (cf. Article 5.7). Where a risk assessment is carried out in accordance with EU legislation of any of the substances causing the labelling *R40*, *R60* or *R61* which are controlled under this Directive, the Commission shall consider the conclusions of the risk assessment and shall take the necessary measures as appropriate (cf. Article 5.13).

Member States may define and implement national plans for reducing emissions from the activities and industrial installations covered by Article 1 (excluding activities 4 and 11 of Annex IIA). The plans must result in a reduction of the annual emissions of VOCs by at least the same amount and within the same time-frame as would have been achieved by applying the emission limits under the Directive (cf. Article 5.2, 5.3 and 6.1). The national plan must include:

- a list of the measures (to be) taken and binding interim reduction targets against which progress towards the aim can be measured (cf. Article 6.2);

- a full description of the range of instruments through which its requirements will be achieved, evidence that these instruments will be enforceable and details of the means by which compliance with the plan will be demonstrated (cf. Article 6.2).

The Commission must consider the potential effects of organic substances on human health in general and occupational exposure in particular. Potential effects on the environment and the economic consequences will also be examined with a view to providing guidance on the use of techniques which have the least potential effects on air, water, soil, ecosystems and human health. The Commission must publish recommendations for each activity (cf. Article 7.1).

Operators are requested to demonstrate compliance with the emission-limit values tabled in Annex IIA, with the requirements of the reduction scheme under Annex IIB and with the provisions of Article 5.3 (cf. Article 9.1). The Member States are requested to provide for emission-monitoring and to safeguard compliance with the VOC-Directive. In case of non-compliance, further operation of the activity concerned may be suspended (cf. Article 10).

The Member States must take the necessary measures to ensure that the public has access to information concerning authorisations and decisions by the competent authorities, to general binding rules applicable to installations and to the results of emission-monitoring (cf. Article 12). Every three years, Member States must submit a report to the Commission on the implementation of the VOC-Directive (cf. Article 11).

### **Directive 2004/42/EC**

Directive 2004/42/EC which is based on Article 95 of the Treaty complements the provisions of Directive 1999/13/EC. It aims at preventing the negative environmental effects of emissions of VOCs from decorative paints and vehicle refinishing products.

Directive 2004/42/EC lays down maximum limits for the VOC content of these products. The subcategories of the relevant products are listed in Annex I to the Directive. Product categories falling within the scope of the Directive can be marketed in the EU only if they comply with the specifications in Annex II. Such products must carry a specific label, indicating

- (a) the subcategory of the product and the relevant VOC limit values in g/l as referred to in Annex II to the Directive;
- b) the maximum content of VOC in g/l of the product in a ready to use condition.

This means that Directive 2004/42/EC complements Community provisions on the labelling of chemical substances and preparations as laid down in Directives 67/548/EEC and 1999/45/EC.

Member States shall develop a market surveillance system to verify the VOC content of the products covered by this Directive. They shall designate a competent authority to be responsible for ensuring conformity with the provisions of the Directive. A system of effective, proportionate and dissuasive penalties should be established for infringements.

### III.4.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS

#### Council Directive 1999/13/EC

Directive 1999/13/EC derives the following legal obligations from classification:

- § Substances or preparations (GHS terminology: mixtures) which, because of their content of VOCs classified as *carcinogens*, *mutagens*, or *toxic to reproduction* under Directive 67/548/EEC, are assigned or need to carry the risk phrases *R45*, *R46*, *R49*, *R60*, *R61*, shall be replaced, as far as possible and by taking into account the guidance elaborated by the Commission, by less harmful substances or preparations within the shortest possible time (cf. Article 5.6 and 7.1). Stricter emission values are specified for these substances (cf. Article 5.7).
- § Where a risk assessment is carried out in accordance with EU legislation of any of the substances causing the labelling *R40*, *R60* or *R61* which are controlled under this Directive, the Commission shall consider the conclusions of the risk assessment and shall take the necessary measures as appropriate (cf. Article 5.13).

The EU classifications and the risk phrases referred to in this Directive will have to be converted to the most closely corresponding classifications of the GHS, cf. Table III.4.2.1 below.

Table III.4.2.1: GHS classifications / statements and EU risk phrases for CMR hazards

EU Classifications	GHS Classifications
Carcinogen Category 3 (Xn), R40	Carcinogen category 2
Carcinogen Category 1 (T), R45 Carcinogen Category 2 (T), R45	Carcinogen, category 1A or 1B
Mutagen Category 1 (T), R46 Mutagen Category 2 (T), R46	Mutagen, category 1A or 1B
Carcinogen Category 1 (T), R49 Carcinogen Category 2 (T), R49	Carcinogen, category 1A or 1B
Reprotoxic Category 1 (T), R60 Reprotoxic Category 2 (T), R60	Reproductive toxicity, category 1A or 1B
Reprotoxic Category (T), R61 Reprotoxic Category (T), R61	Reproductive toxicant, category 1A or 1B

With regard to CMR, the criteria for substance classification are the same for both the EU system and the GHS, cf. also Annex I to this study. This means that the kind and number of classified substances will not change compared to the current situation. The same statement can be made for mixtures which are classified for carcinogenicity or mutagenicity.

The only potential effect of the GHS would be due to the lowering of the concentration limits from 0.5% to 0.3% for the classification of preparations (GHS terminology: mixtures) which contain reprotoxic ingredients: In theory, additional preparations would have to be classified for reprotoxicity when they contain a reprotoxic organic solvent in the aforementioned concentration range. However, for reasons of confidentiality it is not known how many reprotoxic organic solvents are used in mixtures which are relevant for the industrial activities mentioned in Annex I to the VOC -Directive. Beyond, industrial activities covered by the VOC-Directive apparently use organic solvents in concentrations which significantly exceed even the current 0.5% threshold for mixture classification. This is no surprise: Organic solvents normally constitute the major part of a mixture where they are present in high concentrations. This implies that potential effects due to a theoretical increase in classified reprotoxic mixtures under GHS will be of no relevance. An example is given by the industrial activity "Coating of new buses", cf. Table III.4.2.2 below. This activity is an item in the table of Annex IIA, II, The Vehicle Coating Industry (Directive 1999/13/EC). The organic solvents referred to in the table are not necessarily classified as reprotoxic.

Material (wt-%)	Specific material consumption (g varnish/m <sup>2</sup> )
Cataphoric dip coating, water-based material, 3-4% organic solvents	120-135
Seam sealing and underbody protection ( water-based, manual application)	No data available
Filler (solvent-based: 45% organic solvents, manual application)	18-22
Filler (water-based: 8% organic solvents, manual application)	22-26
1-coat topcoat (solvent-based: 45% organic solvents, manual application)	10-40
Base coat (solvent-based: 75% organic solvents, manual application)	90-100
Base coat (water-based: 13% organic solvents, manual application)	100-110
Clear coat (solvent-based: 45% organic solvents, manual application)	50-65

**Table III.4.2.2:** Consumption of raw materials for the coating of buses. Specific material consumptions for different layers. <sup>4</sup> [57, O. Rentz et al., 1999]

Source: European Commission, Directorate-General Joint Research Center: Integrated Pollution Prevention and Control, Draft Reference Document on Best Available Techniques on Surface Treatment Using Organic Solvents, May 2004

<sup>4</sup> Normally a surface of about 200m<sup>2</sup> per bus is coated.

### **Directive 2004/42/EC**

Directive 2004/42/EC does not contain specific legal provisions which are derived from classification and labelling. It is to complement Community provisions on the labelling of chemical substances and preparations as laid down in Directives 67/548/EEC and 1999/45/EC, cf. Recital 12. This means that the GHS will have no direct effect on Directive 2004/42/EC.

### **III.4.3. Suggestions how to minimise potential effects of the GHS**

In the context of Directives 1999/13/EC and 2004/42/EC, the GHS will probably not have an effect. In order to minimise any potential effects due to additional mixtures classified for reproductive toxicity, it is proposed to exempt those mixtures from the scope of Directive 1999/13/EC which contain a reproductive toxicant in a concentration < 0.5%, cf. Table VI.2 of Part I of this study ( **Solution 2**).

With regard to the reclassification of current entries in Annex I to Directive 67/548/EEC, the GHS Regulation will provide for conversions for CMR and respiratory sensitisers on the basis of equivalent criteria. It is planned to carry them over to Annex VI to the GHS Regulation. Non-harmonised, but classified CMRs can easily be reclassified by using the conversion table in Annex VII.

#### **Basic documents used for the analysis:**

- European Commission, DG ENTR G1: Comparison between EU and GHS Criteria Human Health and Environment
- European Commission, Directorate -General Joint Research Centre: Integrated Pollution Prevention and Control, Draft Reference Document on Best Available Techniques on Surface Treatment Using Organic Solvents, May 2004

### III.5. Council Directive 96/62/EC of 27 September 1996 on ambient air quality assessment and management

[http://europa.eu.int/smartapi/cgi/sga\\_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31996L0062&model=guichett](http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31996L0062&model=guichett)

Council Directive 1996/62/EC is a Framework Directive. It establishes the basic principles of a common strategy to define and set objectives for ambient air quality. The aim is to avoid, prevent or reduce harmful effects on human health and the environment, assess ambient air quality in the Member States, inform the public, notably by means of alert thresholds, and improve air quality where it is unsatisfactory. The European Parliament and the Council must lay down limit values and alert thresholds for various well-known pollutants. Considerations of risk and exposure of humans and the environment form the basis when limit values and alert thresholds for further pollutants are proposed by the Commission. The pertinent danger criteria established under Directive 67/548/EEC and its successive adaptations must only be taken into account in the selection of these pollutants for further assessment. As considerations on risk and exposure are prevailing, the GHS will have minimal effects only, even when changing various classification criteria for substances and mixtures.

#### III.5.1. Abstract of the legislation

Directive 1996/62/EC which is based on Article 130s of the Treaty is a Framework Directive<sup>5</sup>. It establishes the basic principles of a common strategy to define and set objectives for ambient air quality. The aim is to avoid, prevent or reduce harmful effects on human health and the environment, assess ambient air quality in the Member States, inform the public, notably by means of alert thresholds, and improve air quality where it is unsatisfactory.

In order to maintain and improve air quality within the Community, this Directive defines basic principles which make it possible to

- establish quality objectives for ambient air (outdoor air in the troposphere);
- draw up common methods and criteria for assessing air quality;
- obtain and disseminate information on air quality.

The Member States are responsible for implementing the Directive. The European Parliament and the Council must lay down limit values and alert thresholds for the pollutants sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter and lead, benzene and carbon monoxide, ozone, polycyclic aromatic hydrocarbons (PAH), cadmium, arsenic, nickel and mercury (cf. Daughter Directives). For other pollutants, the Commission shall submit to the Council proposals for fixing limit values and, as appropriate, alert thresholds. When selecting other pollutants, the following criteria have to be applied, cf. Annex III:

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<sup>5</sup> The following abstract is based on the current legislation. The Commission is working on a proposal for an amended Directive. It is expected that the coming legislation will not change the role of classification and labelling so that the conclusions derived in this analysis will also be valid for the future Directive.

1. Possibility, severity and frequency of effects; with regard to human health and the environment as a whole, the irreversible effects must be of special concern ;
2. Ubiquity and high concentration of the pollutant in the atmosphere;
3. Environmental transformations or metabolic alterations, as these alterations may lead to the production of chemicals with greater toxicity;
4. Persistence in the environment, particularly if the pollutant is not biodegradable and can accumulate in humans, the environment or food chains;
5. Impact of the pollutant: size of exposed population, living resources or ecosystems; existence of particularly sensitive targets in the zone concerned;
6. Results of risk assessment methods.

The pertinent danger criteria established under Directive 67/548/EEC and its successive adaptations must be taken into account in the selection of the pollutants.

Ambient air quality must be monitored throughout the territory of the Member States. Different methods may be used for this: measuring, mathematical modelling, a combination of the two, or estimates. Assessment of this type is mandatory in built-up areas with more than 250 000 inhabitants, or in areas where concentrations are close to the limit values.

If the limit values are exceeded Member States must devise a programme for attaining them within a set deadline. The programme which must be made available to the public must contain at least the following information: the location where the pollution is excessive, the nature and an assessment of the pollution and the origin of the pollution.

Member States are required to draw up a list of the areas and conurbations where pollution levels exceed the limit values. Where the alert thresholds are crossed, Member States must inform the inhabitants and send the Commission any relevant information (recorded pollution level, duration of the alert, etc.). Where certain geographical areas and conurbations have pollution levels below the limit values, the Member States must maintain those levels below the said values.

The Directive contains further provisions on the forwarding of information and on reports on pollution levels and the areas concerned.

### **III.5.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of GHS**

In its Annex III, the Ambient Air Quality Directive makes reference to the Dangerous Substances Directive: it uses the classifications from Directive 67/548/EEC as criteria for choosing air pollutants:

#### **ANNEX III**

##### **GUIDELINES FOR SELECTING AIR POLLUTANTS FOR CONSIDERATION**

1. Possibility, severity and frequency of effects; with regard to human health and the environment as a whole, the irreversible effects must be of special concern.
2. Ubiquity and high concentration of the pollutant in the atmosphere.
3. Environmental transformations or metabolic alterations, as these alterations may lead to the production of chemicals with greater toxicity.

4. Persistence in the environment, particularly if the pollutant is not biodegradable and can accumulate in humans, the environment or food chains.

5. Impact of the pollutant:

- size of exposed population, living resources or ecosystems,
- existence of particularly sensitive targets in the zone concerned.

6. Risk-assessment methods may also be used.

The pertinent danger criteria established under Directive 67/548/EEC (1) and its successive adaptations must be taken into account in the selection of the pollutants.

However, as can be seen from the same quotation, any conclusions are derived from considerations of **risk and exposure** of humans and the environment to the pollutant of concern. This means that classification as such is not the decisive factor. **The GHS which is likely to classify additional chemicals will have minimal effects only in so far as additional air pollutants could be selected for further consideration.**

### III.5.3. Suggestions how to minimise potential effects of the GHS

The GHS will have minimal effects only. In order to minimise potential effects related to additional classification under GHS, it is proposed to exempt from the reference to classified substances and preparations those hazard classifications (classes and categories / types / divisions) which are newly introduced by the GHS, in accordance with **Solution 1**, cf. Part I of this study. The respective classifications are listed in Table VI.1 of Part I. Such an exemption would enable Member States to focus their resources on the most relevant risks.

### III.6. Water Framework Directive

- **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**
- **Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 establishing the list of priority substances**

<http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32000L0060:EN:HTML>

[http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l\\_331/l\\_33120011215en00010005.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_331/l_33120011215en00010005.pdf)

Directive 2000/60/EC („Water Framework Directive“) is based on Article 175(1) of the Treaty. It establishes a Community framework for the protection of inland surface waters, transitional waters, coastal waters and groundwater. It aims at preventing and reducing pollution, promoting sustainable water use, protecting the aquatic environment, improving the status of aquatic ecosystems and mitigating the effects of floods and droughts. The Water Framework Directive refers to hazardous properties and hazardous substances at numerous places in the legislation. In particular, Decision 2455/2001/EC sets up a list of priority hazardous substances in accordance with Article 16 of the Water Framework Directive. However, the prevailing approach for defining priority hazardous substances is based on risk, and not on hazard – hazardous properties may only serve as basis for selecting defined pollutants for further assessment. Accordingly, any legislation on classification and labelling, be it the current system or the GHS, will only have minimal effects on the legal obligations stipulated in the Water Framework Directive.

#### III.6.1. Abstract of the legislation

Directive 2000/60/EC („Water Framework Directive“) is based on Article 175(1) of the Treaty. It establishes a Community framework for the protection of inland surface waters, transitional waters, coastal waters and groundwater. It aims at preventing and reducing pollution, promoting sustainable water use, protecting the aquatic environment, improving the status of aquatic ecosystems and mitigating the effects of floods and droughts.

Under the Water Framework Directive, Member States have to identify all the river basins lying within their national territory and assign them to individual river basin districts. River basins covering the territory of more than one Member State will be assigned to an international river basin district. By 22 December 2003 at the latest, a competent authority will be designated for each of the river basin districts.

Four years after the date of entry into force of this directive, Member States must complete an analysis of the characteristics of each river basin district, a review of the impact of human activity on the water, an economic analysis of water use and a register of areas requiring special protection. All bodies of water used for the abstraction of water intended for human consumption providing more than 10 m<sup>3</sup> a day as an average or serving more than 50 persons must be identified.

Nine years after the date of entry into force of the Directive, a management plan and programme of measures must be produced for each river basin district, taking account of the results of the analyses and studies provided for in point 2.

The measures provided for in the river basin management plan seek to:

- prevent deterioration, enhance and restore bodies of surface water, achieve good chemical and ecological status of such water and reduce pollution from discharges and emissions of hazardous substances;
- protect, enhance and restore all bodies of groundwater, prevent the pollution and deterioration of groundwater, and ensure a balance between abstraction and recharge of groundwater;
- preserve protected areas.

The abovementioned objectives have to be achieved at the latest fifteen years after the date of entry into force of the Directive, but this deadline may be extended or relaxed, albeit under the conditions laid down by the Directive.

The Member States will encourage the active involvement of all interested parties in the implementation of this Directive, in particular as regards the river basin management plans.

Temporary deterioration of bodies of water is not in breach of the requirements of this Directive if it is the result of circumstances which are exceptional or could not reasonably have been foreseen and which are due to an accident, natural cause or *force majeure*.

By 2010, Member States must ensure that water pricing policies provide adequate incentives for users to use water resources efficiently and that the various economic sectors contribute to the recovery of the costs of water services including those relating to the environment and resources.

The Commission submitted a list of priority substances selected amongst those which present a significant risk to or via the aquatic environment. Measures to control such substances, as well as quality standards applicable to concentrations thereof, will also be proposed. The aim of such measures is to reduce, stop or eliminate discharges, emissions and losses of priority substances. This list forms Annex X to the present Directive.

Two years after the entry into force of this Directive, the Commission will publish a proposal with specific measures to prevent and control the pollution of groundwater.

At the latest twelve years after the date of entry into force of this Directive and every six years thereafter, the Commission will publish a report on the implementation of the Directive. The Commission will convene when appropriate a conference of interested parties on Community water policy which will involve Member States, representatives from the competent authorities, the European Parliament, NGOs, the social and economic partners, consumer bodies, academics and other experts.

The Directive lays down that Member States will determine penalties applicable to breaches of the provisions adopted which are effective, proportionate and dissuasive.

Seven years after the entry into force of the Directive, the following legislation will be repealed: Directive 75/440/EEC, Decision 77/795/EEC and Directive 79/869/EEC.

### III.6.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS

The Water Framework Directive refers to hazardous properties and hazardous substances at numerous places in the legislation, inter alia:

#### Article 2, Definitions:

29. "Hazardous substances" 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.

30. "Priority substances" means substances identified in accordance with Article 16(2) and listed in Annex X.

Among these substances there are "priority hazardous substances" which means substances identified in accordance with Article 16(3) and (6) for which measures have to be taken in accordance with Article 16(1) and (8).

31. "Pollutant" means any substance liable to cause pollution, in particular those listed in Annex VIII.

#### Annex II.1., Surface Waters, 1.3, Estimation of pressures:

Member States shall collect and maintain information on the type and magnitude of the significant anthropogenic pressures to which the surface water bodies in each river basin district are liable to be subject, in particular the following.

Estimation and identification of significant point source pollution, in particular by substances listed in Annex VIII, from urban, industrial, agricultural and other installations and activities, based, inter alia, on information gathered under:

(i) Articles 15 and 17 of Directive 91/271/EEC;

(ii) Articles 9 and 15 of Directive 96/61/EC(1);

and for the purposes of the initial river basin management plan:

(iii) Article 11 of Directive 76/464/EEC; and

(iv) Directives 75/440/EC, 76/160/EEC(2), 78/659/EEC and 79/923/EEC(3).

Estimation and identification of significant diffuse source pollution, in particular by substances listed in Annex VIII, from urban, industrial, agricultural and other installations and activities; based, inter alia, on information gathered under:

(i) Articles 3, 5 and 6 of Directive 91/676/EEC(4);

(ii) Articles 7 and 17 of Directive 91/414/EEC;

(iii) Directive 98/8/EC; ...

#### Annex VIII, Indicative list of main pollutants:

4. Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment.

As can be seen from this first set of quotations, the definition of the term „hazardous“ as well as of the properties “toxic” and “carcinogenic or mutagenic” is **not explicitly** based on the criteria set out Directive 67/548/EEC. However, even if we assumed that the underlying criteria are based on Directive 67/548/EEC, any shift to the GHS criteria would not have an effect for the hazards “carcinogenic” and “mutagenic” since the hazard criteria will not change under GHS. With regard to toxic properties, it is not clear which kind of toxicity is referred to. However, whatever the underlying criteria may be: the attribute “toxic” will only serve as basis for selecting defined pollutants for further assessment.

#### Article 16, Strategies against pollution of water:

1. The European Parliament and the Council shall adopt specific measures against pollution of water by individual pollutants or groups of pollutants presenting a significant risk to or via the aquatic environment, including such risks to waters used for the abstraction of drinking water. For those pollutants measures shall be aimed at the progressive reduction and, for priority hazardous substances, as defined in Article 2(30), at the cessation or phasing-out of discharges, emissions and losses. Such measures shall be adopted acting on the proposals presented by the Commission in accordance with the procedures laid down in the Treaty.

2. The Commission shall submit a proposal setting out a list of priority substances selected amongst those which present a significant risk to or via the aquatic environment. Substances shall be prioritised for action on the basis of risk to or via the aquatic environment, identified by:

- (a) risk assessment carried out under Council Regulation (EEC) No 793/93(22), Council Directive 91/414/EEC(23), and Directive 98/8/EC of the European Parliament and of the Council(24), or
- (b) targeted risk-based assessment (following the methodology of Regulation (EEC) No 793/93) focusing solely on aquatic ecotoxicity and on human toxicity via the aquatic environment.

When necessary in order to meet the timetable laid down in paragraph 4, substances shall be prioritised for action on the basis of risk to, or via the aquatic environment, identified by a simplified risk-based assessment procedure based on scientific principles taking particular account of:

- evidence regarding the intrinsic hazard of the substance concerned, and in particular its aquatic ecotoxicity and human toxicity via aquatic exposure routes, and
- evidence from monitoring of widespread environmental contamination, and
- other proven factors which may indicate the possibility of widespread environmental contamination, such as production or use volume of the substance concerned, and use patterns.

3. The Commission's proposal shall also identify the priority hazardous substances. In doing so, the Commission shall take into account the selection of substances of concern undertaken in the relevant Community legislation regarding hazardous substances or relevant international agreements.

4. The Commission shall review the adopted list of priority substances at the latest four years after the date of entry into force of this Directive and at least every four years thereafter, and come forward with proposals as appropriate.

5. In preparing its proposal, the Commission shall take account of recommendations from the Scientific Committee on Toxicity, Ecotoxicity and the Environment, Member States, the European Parliament, the European Environment Agency, Community research programmes, international organisations to which the Community is a party, European business organisations including those representing small and medium-sized enterprises, European environmental organisations, and of other relevant information which comes to its attention.

6. For the priority substances, the Commission shall submit proposals of controls for:

- the progressive reduction of discharges, emissions and losses of the substances concerned, and, in particular
- the cessation or phasing-out of discharges, emissions and losses of the substances as identified in accordance with paragraph 3, including an appropriate timetable for doing so. The timetable shall not exceed 20 years after the adoption of these proposals by the European Parliament and the Council in accordance with the provisions of this Article.

In doing so it shall identify the appropriate cost-effective and proportionate level and combination of product and process controls for both point and diffuse sources and take account of Community-wide uniform emission limit values for process controls. Where appropriate, action at Community level for process controls may be established on a sector-by-sector basis. Where product controls include a review of the relevant authorisations issued under Directive 91/414/EEC and Directive 98/8/EC, such reviews shall be carried out in accordance with the provisions of those Directives. Each proposal for controls shall specify arrangements for their review, updating and for assessment of their effectiveness.

7. The Commission shall submit proposals for quality standards applicable to the concentrations of the priority substances in surface water, sediments or biota.

8. The Commission shall submit proposals, in accordance with paragraphs 6 and 7, and at least for emission controls for point sources and environmental quality standards within two years of the inclusion of the substance concerned on the list of priority substances. For substances included in the first list of priority substances, in the absence of agreement at Community level six years after the date of entry into force of this Directive, Member States shall establish environmental quality standards for these substances for all surface waters affected by discharges of those substances, and controls on the principal sources of such discharges, based, inter alia, on consideration of all technical reduction options. For substances subsequently included in the list of priority substances, in the absence of agreement at Community level, Member States shall take such action five years after the date of inclusion in the list.

9. The Commission may prepare strategies against pollution of water by any other pollutants or groups of pollutants, including any pollution which occurs as a result of accidents.

10. In preparing its proposals under paragraphs 6 and 7, the Commission shall also review all the Directives listed in Annex IX. It shall propose, by the deadline in paragraph 8, a revision of the controls in Annex IX for all those substances which are included in the list of priority substances and shall propose the appropriate measures including the possible repeal of the controls under Annex IX for all other substances.

All the controls in Annex IX for which revisions are proposed shall be repealed by the date of entry into force of those revisions.

11. The list of priority substances of substances mentioned in paragraphs 2 and 3 proposed by the Commission shall, on its adoption by the European Parliament and the Council, become Annex X to this Directive. Its revision mentioned in paragraph 4 shall follow the same procedure.

**Annex VII.A. River basin management plans:**

7.7. a summary of the measures taken in accordance with Article 16 on priority substances; ...

With regard to the priority substances, Article 16 deserves particular attention: It sets out a "Strategy against pollution of water", comprising the establishment of a first list of priority substances to become Annex X to the Directive as a first step. This list was set up by Decision 2455/2001/EC which was adopted on 20 November 2001.

The list identifies 33 substances or group of substances, which have been shown to be of major concern for European Waters, cf. Table III.6.2.1 below. Within this list, 11 substances have been identified as priority hazardous substances which are of particular concern for the inland, transitional, coastal and territorial waters. These substances will be subject to cessation or phasing out of discharges, emissions and losses within an appropriate timetable that shall not exceed 20 years. A further 14 substances are identified as being subject for review for identification as possible "priority hazardous substances".

No.	CAS number	EU number	Name of priority substance	Identified as priority hazardous substance
(1)	15972-60-8	240-110-8	Alachlor	
(2)	120-12-7	204-371-1	Anthracene	(X)***
(3)	1912-24-9	217-617-8	Atrazine	(X)***
(4)	71-43-2	200-753-7	Benzene	
(5)	n.a.	n.a.	Brominated diphenylethers (**)	X****
(6)	7440-43-9	231-152-8	Cadmium and its compounds	X
(7)	85535-84-8	287-476-5	C <sub>10-13</sub> -chloroalkanes (**)	X
(8)	470-90-6	207-432-0	Chlorfenvinphos	
(9)	2921-88-2	220-864-4	Chlorpyrifos	(X)***
(10)	107-06-2	203-458-1	1,2-Dichloroethane	
(11)	75-09-2	200-838-9	Dichloromethane	
(12)	117-81-7	204-211-0	Di(2-ethylhexyl)phthalate (DEHP)	(X)***
(13)	330-54-1	206-354-4	Diuron	(X)***

(14)	115-29-7	204-079-4	Endosulfan	(X)***
	959-98-8	n.a.	(alpha-endosulfan)	
(15)	206-44-0	205-912-4	Fluoranthene (*****)	
(16)	118-74-1	204-273-9	Hexachlorobenzene	X
(17)	87-68-3	201-765-5	Hexachlorobutadiene	X
(18)	608-73-1	210-158-9	Hexachlorocyclohexane	X
	58-89-9	200-401-2	(gamma-isomer, Lindane)	
(19)	34123-59-6	251-835-4	Isoproturon	(X)***
(20)	7439-92-1	231-100-4	Lead and its compounds	(X)***
(21)	7439-97-6	231-106-7	Mercury and its compounds	X
(22)	91-20-3	202-049-5	Naphthalene	(X)***
(23)	7440-02-0	231-111-4	Nickel and its compounds	
(24)	25154-52-3	246-672-0	Nonylphenols	X
	104-40-5	203-199-4	(4-(para)-nonylphenol)	
(25)	1806-26-4	217-302-5	Octylphenols	(X)***
	140-66-9	n.a.	(para-tert-octylphenol)	
(26)	608-93-5	210-172-5	Pentachlorobenzene	X
(27)	87-86-5	201-778-6	Pentachlorophenol	(X)***
(28)	n.a.	n.a.	Polyaromatic hydrocarbons	X
	50-32-8	200-028-5	(Benzo(a)pyrene),	
	205-99-2	205-911-9	(Benzo(b)fluoroanthene),	
	191-24-2	205-883-8	(Benzo(g,h,i)perylene),	
	207-08-9	205-916-6	(Benzo(k)fluoroanthene),	
	193-39-5	205-893-2	(Indeno(1,2,3-cd)pyrene)	
(29)	122-34-9	204-535-2	Simazine	(X)***
(30)	688-73-3	211-704-4	Tributyltin compounds	X
	36643-28-4	n.a.	(Tributyltin -cation)	

(31)	12002-48-1	234-413-4	Trichlorobenzenes	(X)***
	120-82-1	204-428-0	(1,2,4-Trichlorobenzene)	
(32)	67-66-3	200-663-8	Trichloromethane (Chloroform)	
(33)	1582-09-8	216-428-8	Trifluralin	(X)***

**Table III.6.2.1:** List of priority substances in the field of water policy (\*)

- \* Where groups of substances have been selected, typical individual representatives are listed as indicative parameters (in brackets and without number). The establishment of controls will be targeted to these individual substances, without prejudicing the inclusion of other individual representatives, where appropriate.
- \*\* These groups of substances normally include a considerable number of individual compounds. At present, appropriate indicative parameters cannot be given.
- \*\*\* This priority substance is subject to a review for identification as possible "priority hazardous substance". The Commission will make a proposal to the European Parliament and Council for its final classification not later than 12 months after adoption of this list. The timetable laid down in Article 16 of Directive 2000/60/EC for the Commission's proposals of controls is not affected by this review.
- \*\*\*\* Only Pentabromobiphenylether (CAS number 32534-81-9)
- \*\*\*\*\* Fluoranthene is on the list as an indicator of other, more dangerous Polyaromatic Hydrocarbons

As can be seen from the table, the list includes selected existing chemicals, plant protection products, biocides, metals and other groups like Polyaromatic Hydrocarbons (PAH) that are mainly incineration by-products and Polybrominated Biphenylethers (PBDE) that are used as flame retardants. In identifying priority hazardous substances, account was taken of the precautionary principle, relying in particular on the determination of any potentially adverse effects of the product and on a scientific assessment of the risk, cf. Recital 44 of Directive 2000/60/EC. This means that in setting up the list, the hazard of a substance was of subordinate relevance – the risk of a substance was determining the status as priority hazardous substance.

**In general, the findings above suggest that any legislation on classification and labelling, be it the current system or the GHS, will have no effect on the legal obligations stipulated in the Water Framework Directive. The prevailing approach for defining priority hazardous substances is based on risk, and not on hazard – hazardous properties may only serve as basis for selecting defined pollutants for further assessment.**

### III.6.3. Suggestions how to minimise potential effects of the GHS

The GHS will have no effect.

## IV. Occupational Health and Safety

### IV.1. Council Directive 1998/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work

[http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l\\_131/l\\_13119980505en00110023.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_131/l_13119980505en00110023.pdf)

Council Directive 1998/24/EC (“Chemical Agents Directive”) lays down minimum requirements for the protection of workers from risks to their safety and health arising from the effects of chemical agents that are present at the workplace. The requirements apply where hazardous chemical agents are present or may be present at the workplace. A hazardous chemical agent normally is a substance or a mixture which meets the criteria for classification as dangerous according to Directive 67/548/EEC or 1999/45/EC.

The Chemical Agents Directive imposes various legal obligations on the employer. The obligation to replace a dangerous chemical agent by a less hazardous chemical as well as protection and prevention measures are derived from the request to eliminate or reduce risk. Hazard classification is the trigger for risk assessments to be carried out.

Due to new hazard classifications and to differences between the EU and GHS classification criteria, additional chemical agents are likely to be classified compared to the current situation. In order to minimise effects related to additional classification under GHS, it is proposed to exempt from the reference to classified substances and mixtures those hazard classifications (classes and categories / types / divisions) which are newly introduced by the GHS.

#### IV.1.1. Abstract of the legislation

Council Directive 1998/24/EC (“Chemical Agents Directive”) is based on Article 137 of the Treaty. It lays down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents. **The requirements of this Directive apply where hazardous chemical agents are present at the workplace.** A hazardous chemical agent is a substance or a mixture which meets the criteria for classification as dangerous according to Directive 67/548/EEC or 1999/45/EC. Any substance or mixture that only meets the criteria for classification as dangerous for the environment is excluded from the scope of Directive 1998/24/EC. Other hazardous chemical agents are defined, namely those which present a risk to the safety and health of workers even if they do not meet the classification criteria.

The Chemical Agents Directive requests the European Commission to evaluate the relationship between the health effects of hazardous chemical agents and the level of occupational exposure. The Commission is then to establish indicative or binding occupational exposure limit values (OELV) as well as (binding) biological limit values. Based on the Community level value, Member States will have to set an indicative or binding national occupational exposure limit value or a (binding) biological limit value, respectively.

With regard to the protection of health and safety of workers from the risks related to chemical agents at work, the Chemical Agents Directive implements the principles substitution, prevention, protection and control. It imposes various legal obligations on the employer. The scope of obligations depends on the evaluation of the risks arising from the presence of hazardous chemicals at the workplace:

- A general obligation is that the employer shall ensure that the risk from a hazardous chemical agent to the safety and health of workers at work is eliminated or reduced to a minimum;
- Substitution of dangerous substances shall by preference be undertaken: the employer shall avoid the use of a hazardous chemical agent by replacing it with a chemical agent or process which, under its condition of use, is not hazardous or less hazardous to workers' safety and health;
- The evaluation reveals a slight risk to the safety and health of workers: In this case, the provisions of Articles 6 ("Specific protection and prevention measures"), 7 ("Arrangements to deal with accidents, incidents and emergencies") and 10 ("Health surveillance") don't apply;
- The evaluation reveals a significant risk to the safety and health of workers: In this case, the specific protection, prevention and monitoring measures laid down in Articles 6, 7 and 10 apply;

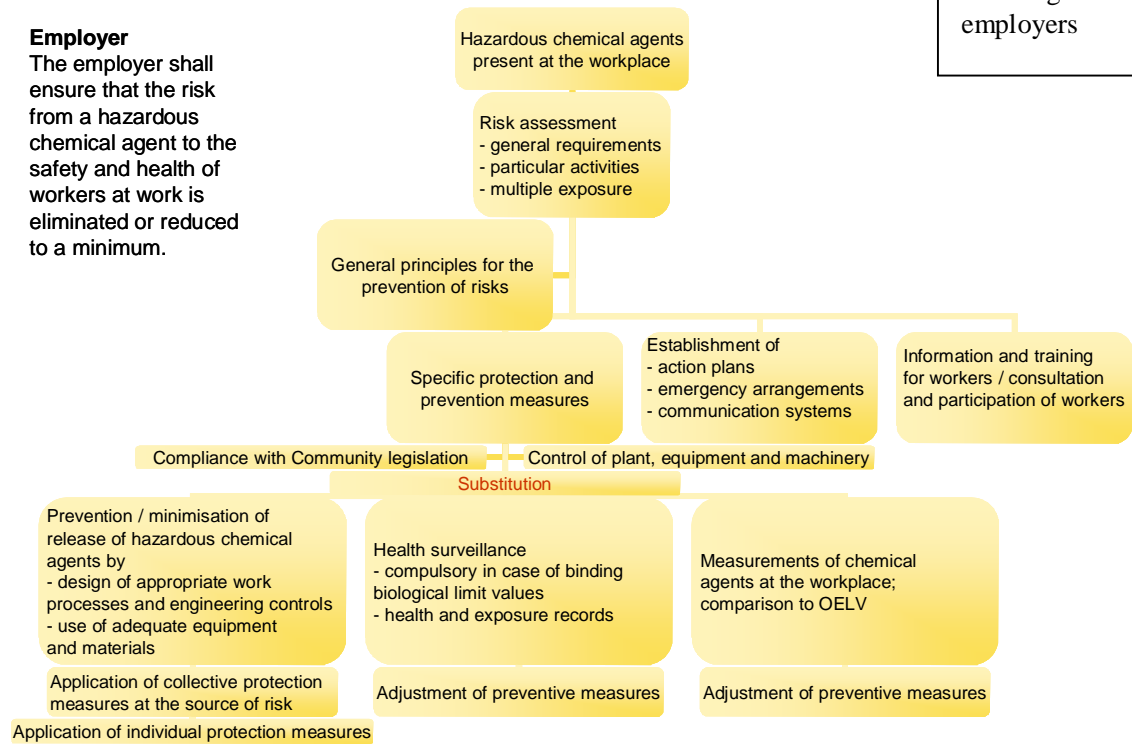
In case occupational exposure limit values or biological limit values have been set, additional obligations may apply:

- Measurements of hazardous chemicals agents at the workplace may demonstrate that an occupational exposure limit value effectively established on the territory of a Member State has been exceeded. In this case, the employer shall immediately take steps, taking into account the nature of that limit, to remedy the situation by carrying out preventive and protective measures;
- Where a binding biological limit value has been set (cf. Annex II to Directive 1998/24/EC), health surveillance is a compulsory requirement for work with the hazardous chemical agent in question. Workers shall be informed of this requirement before being assigned to the task involving risk of exposure to the hazardous chemical agent.

Other obligations relate to information and training of workers as well as to consultation and participation of workers.

**Employer**  
 The employer shall ensure that the risk from a hazardous chemical agent to the safety and health of workers at work is eliminated or reduced to a minimum.

Figure 6: Overview of the obligations for employers



Further provisions relate to precautions and arrangements to deal with accidents, incidents and emergencies (cf. Article 7). To prevent the exposure of workers to health risks from certain chemical agents and/or certain activities involving chemical agents, the production, manufacture or use at work of the chemical agents and the activities set out in Annex III shall be prohibited to the extent specified therein (cf. Article 9.1). The Council, in accordance with the procedure laid down in Article 138 of the Treaty, may amend the list of prohibitions to include further chemical agents or activities. Derogations for the activities listed in Annex III are possible under particular conditions; Member States may provide a system of individual authorisations (cf. Article 9.2).

Adjustments of a strictly technical nature to the Annexes shall be adopted in committee, cf. the procedure laid down in Article 17 of Directive 89/391/EEC (cf. Article 12.1). The Commission has, after consultation of the Advisory Committee on Safety, Hygiene and Health Protection at Work, drawn up practical guidelines of a non-binding nature. These guidelines address the topics referred to in Articles 3, 4, 5, 6 and Annex II, section I. They are available as “Practical guidelines of a non-binding nature on the protection of the health and safety of workers from the risks related to chemical agents at work” (Dok. 2261 -00-00-EN final). In the context of the application of this Directive, Member States shall take account as far as possible of these guidelines in drawing up their national policies for the protection of the health and safety of workers (cf. Article 12.2).

#### **IV.1.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS**

The legal obligations of the Chemical Agents Directive are based both on hazard / classification and on risk / exposure.

##### A. Risk reduction by substitution of hazardous chemical agents

In general, the Directive requests to ensure that the risk from a hazardous chemical agent to the safety and health of workers at work is eliminated or reduced to a minimum. First of all, substitution should be considered. This is revealed in Article 6:

1. The employer shall ensure that the risk from a hazardous chemical agent to the safety and health of workers at work is eliminated or reduced to a minimum.

2. In applying paragraph 1, **substitution shall by preference be undertaken**, whereby the employer shall avoid the use of a hazardous chemical agent by replacing it with a chemical agent or process which, under its conditions of use, is not hazardous or less hazardous to workers' safety and health, as the case may be.

Where the nature of the activity does not permit risk to be eliminated by substitution, having regard to the activity and risk assessment referred to in Article 4, the employer shall ensure that the risk is reduced to a minimum by application of protection and prevention measures, consistent with the assessment of the risk made pursuant to Article 4. ...

Due to new hazard classifications and to differences between the EU and GHS classification criteria, additional chemical agents are likely to be classified compared to the current situation, cf. Table V.3 of Part I and Annex I to this study. For *explosives*, also the materials classified will change. An increase in classification implies that Article 6 of the Chemical Agents Directive will apply to further hazardous chemical agents compared to the current situation: it will have to be checked for further chemicals if there is a risk that needs to be eliminated by substitution.

## B. Risk reduction – protection and prevention measures

The Chemical Agents Directive is **exposure-based** and **risk-driven: risk assessments related to workers' exposure to the hazardous chemicals present at the workplace form the precondition for general risk reduction and specific protection and prevention measures**, cf. the Figure above and the Practical Guidelines.

Accordingly, Article 4 – “Determination and assessment of risk of hazardous chemical agents” defines the performance of a risk assessment as a crucial obligation for each employer. The risk assessment shall take account of

- the hazardous properties of the chemical agents present at the workplace,
- information on safety and health from the supplier,
- the level, type and duration of exposure,
- the circumstances of work involving such agents, including their amount,
- OELV or biological limit values established on the territory of a Member State,
- where available, the conclusions to be drawn from any health surveillance already undertaken.

Under GHS, additional chemical agents are likely to be classified compared to the current situation, due to new hazard classifications and to differences between the EU and GHS classification criteria, cf. Table V.3 of Part I of this study. This implies that more substances and mixtures would trigger the obligations of Council Directive 1998/24/EC in so far as they would trigger further assessments of exposure and risk. With regard to risk reduction and prevention, however, further action which goes beyond the currently applied measures may not be necessary.

**Concluding, the risk-based approach implies that the classification of a chemical agent as such is not the decisive factor for the measures to be taken. Accordingly, the GHS will only have minimal effects on the obligations of the Chemical Agents Directive.**

### **IV.1.3. Suggestions how to minimise potential effects of the GHS**

- The shift of reference to the GHS in the Chemical Agents Directive will result in the need for a consequential amendment of the Guidelines to Directive 1998/24/EC (Dok. 2261-00-00-EN final) in the specific section that mentions chemical risk phrases.
- In order to minimise effects related to potential additional classification under GHS, it is proposed to exempt from the reference to classified substances and mixtures those hazard classifications (classes and categories / types / divisions) which are newly introduced by the GHS, in accordance with **Solution 1**, cf. Part I of this study. The respective classifications are listed in Table VI.1 of Part I. Such an exemption would enable the employer to focus his resources on the most relevant risks.
- With regard to the reclassification of current entries in Annex I to Directive 67/548/EEC, the GHS Regulation will provide for conversions for CMR and respiratory sensitisers on the basis of equivalent criteria. It is planned to carry them over to Annex VI to the GHS Regulation. Non-harmonised, but classified CMRs can easily be reclassified by using the conversion table in Annex VII.

Basic documents used for the analysis

Practical Guidelines of a non-binding nature on the protection of the health and safety of workers from the risks related to chemical agents at work (Articles 3, 4, 5 and 6; Annex II, section 1 of Directive 1998/24/EC). Dok. 2261 -00-00-EN final.

## **IV.2. 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**

[http://europa.eu.int/eur-lex/pri/en/oj/d/2004/l\\_158/l\\_15820040430en00500076.pdf](http://europa.eu.int/eur-lex/pri/en/oj/d/2004/l_158/l_15820040430en00500076.pdf)

[http://europa.eu.int/smartapi/cgi/sga\\_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&n\\_umdoc=31990L0394&model=guichett](http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&n_umdoc=31990L0394&model=guichett)

Directive 2004/37/EC (“Carcinogens Directive”) derives legal obligations from the presence of substances and mixtures at the workplace which meet the criteria for classification as carcinogenic or mutagenic category 1 or 2 according to Directives 67/548/EEC and 1999/45/EC. Due to a mainly risk-based approach and equivalent hazard criteria in the current classification system and in the GHS, it can be expected that the GHS Regulation will have no effect on the legal obligations of the Carcinogens Directive. Consequently changes to Directive 2004/37/EC are not deemed necessary.

### **IV.2.1. Abstract of the legislation**

Directive 2004/37/EC (“Carcinogens Directive”) is based on Article 137 (2) of the Treaty. It lays down minimum requirements to protect workers against risks arising specifically from exposure to carcinogens and mutagens, to lessen exposure with a view to reducing health risks, to establish exposure limit values and to take preventive measures. Carcinogens and mutagens are defined as substances or preparations (GHS: mixtures) which meet the classification criteria for categories 1 and 2 as set out in Directives 67/548/EEC and 1999/45/EC. Beyond, carcinogens are defined as substances, preparations or processes referred to in Annex I to the Carcinogens Directive as well as substances or preparations released by a process referred to in that Annex.

The nature, degree and duration of workers' exposure to carcinogens or mutagens must be regularly determined in order to assess any health risk and decide the measures to be taken. Account must be taken of all routes of exposure, including absorption into and/or through the skin.

The employer must reduce the use of and exposure to carcinogens or mutagens at work, in particular by replacing them, in so far as is technically possible, by a substance, preparation or process which is not dangerous or is less dangerous. Where this is not possible, exposure must be prevented or reduced to as low a level as is technically possible, preferably by manufacture / use in a closed system. Various preventive measures have to be applied by the employer when use of a carcinogen or mutagen cannot be circumvented or when situations of exceptional high exposure occur, e.g. maintenance or emergency. These measures pertain to working processes and procedures, technical facilities and engineering control measures, individual and collective protection measures, measurement of exposure, emergency plans and storage and waste disposal. Also, information and training of workers as well as regular health surveillance are foreseen. On request of the competent authority, information on the reasons for using carcinogens and/or mutagens, on preventive measures taken and the number of workers exposed to carcinogens and/or mutagens is to be made available by the employer. Workers have to be consulted in matters covered by this Directive.

Member States must make suitable arrangements for monitoring the health of exposed workers, with a view to implementing the necessary corrective measures and determining the protective or preventive measures to be taken in respect of individual workers. Practical recommendations are given in Annex II. All cases of cancer identified as resulting from occupational exposure must be notified to the competent authority. The up-to-date list of exposed workers, which the employer is required to keep, and individual medical records, are to be kept for at least 40 years following the end of exposure.

The Council lays down limit values for occupational exposure in separate Directives with respect to all those carcinogens and mutagens for which it is possible and, where necessary, other directly related provisions. Currently, limit values for benzene, vinyl chloride monomer and hardwood dusts have been set.

Annexes I and III may be amended only by the Council (Article 138 of the Treaty), whilst technical adjustments to Annex II are adopted by the Commission, assisted by the designated committee.

#### **IV.2.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS**

The legal obligations of the Carcinogens Directive are based both on hazard / classification and on risk / exposure. The main reason for a substance or a mixture to be subject to the provisions of this Directive is meeting the criteria for classification as carcinogen or mutagen category 1 or 2, based on the criteria set out in Directives 67/548/EEC and 1999/45/EC. This is revealed in [Article 2](#):

For the purposes of this Directive,

a) "carcinogen" means:

- i) a substance which meets the criteria for classification as a category 1 or 2 carcinogen set out in Annex VI to Directive 67/548/EEC;
- ii) a preparation composed of one or more substances referred to in point (i) where the concentration of one or more of the individual substances meets the requirements for concentration limits for the classification of a preparation as a category 1 or 2 carcinogen set out either:
  - in Annex I to Directive 67/548/EEC; or
  - in Part B of Annex II to Directive 1999/45/EC where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
- iii) a substance, preparation or process referred to in Annex I to this Directive as well as a substance or preparation released by a process referred to in that Annex;

b) "mutagen" means:

- i) a substance which meets the criteria for classification as a category 1 or 2 mutagen set out in Annex VI to Directive 67/548/EEC;
- ii) a preparation composed of one or more substances referred to in point (i) where the concentration of one or more of the individual substances meets the requirements for concentration limits for the classification of a preparation as a category 1 or 2 mutagen set out in either:
  - Annex I to Directive 67/548/EEC; or
  - Part B of Annex II to Directive 1999/45/EC where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits; ...

The requirement to substitute CMR, where technically possible, is triggered by the carcinogenic or mutagenic hazard of a chemical agent alone. This is revealed in Article 4:

1. The employer shall reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to workers' health or safety, as the case may be.
2. The employer shall, upon request, submit the findings of his investigations to the relevant authorities.

Further prevention measures are based on risk. This is revealed in Article 5:

1. Where the results of the assessment referred to in Article 3(2) reveal a risk to workers' health or safety, workers' exposure must be prevented.
2. Where it is not technically possible to replace the carcinogen or mutagen by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to health or safety, the employer shall ensure that the carcinogen or mutagen is, in so far as is technically possible, manufactured and used in a closed system.
3. Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers is reduced to as low a level as is technically possible.
4. Exposure shall not exceed the limit value of a carcinogen as set out in Annex III.
5. Wherever a carcinogen or mutagen is used, the employer shall apply all the following measures:
  - a) limitation of the quantities of a carcinogen or mutagen at the place of work;
  - b) keeping as low as possible the number of workers exposed or likely to be exposed;
  - c) design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens or mutagens into the place of work;
  - d) evacuation of carcinogens or mutagens at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;
  - e) use of existing appropriate procedures for the measurement of carcinogens or mutagens, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;
  - f) application of suitable working procedures and methods;
  - g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures;
  - h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces;
  - i) information for workers;
  - j) demarcation of risk areas and use of adequate warning and safety signs including "no smoking" signs in areas where workers are exposed or likely to be exposed to carcinogens or mutagens;
  - k) drawing up plans to deal with emergencies likely to result in abnormally high exposure;
  - l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers;
  - m) means for safe collection, storage and disposal of waste by workers, including the use of sealed and clearly and visibly labelled containers.

The EU CMR hazard classifications translate into the respective GHS classifications 1:1 as follows:

EU Classification	GHS Classification
Carcinogen category 1	Carcinogen category 1A
Carcinogen category 2	Carcinogen category 1B
Mutagen category 1	Mutagen category 1A
Mutagen category 2	Mutagen category 1B

Table IV.2.2.1: Conversion of EU carcinogen and mutagen classifications into the corresponding GHS classifications

Figure 7: Mutagenicity Criteria as defined in Council Directive 67/548/EC and in the GHS

EU	Category 1 T R46	Category 2 T R46	Category 3 Xn R68
Criteria	<p><b>Substances <i>known</i> to be mutagenic to man.</b></p> <p>Sufficient evidence to establish a causal association between human exposure to a substance and heritable genetic damage.</p>	<p><b>Substances which <i>should be regarded</i> as if they are mutagenic to man.</b></p> <p>There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in the development of heritable genetic damage, generally on the basis of:</p> <ul style="list-style-type: none"> <li>- appropriate animal studies,</li> <li>- other relevant information.</li> </ul>	<p><b>Substances which <i>cause concern</i> for man owing to possible mutagenic effects.</b></p> <p>Substances which cause concern for man owing to possible mutagenic effects. There is evidence from appropriate mutagenicity studies, but this is insufficient to place the substance in Category 2.</p>
GHS	Category 1		Category 2
	Category 1A	Category 1B	
Criteria	<p><b>Chemicals <i>known</i> to induce heritable mutations in germ cells of humans.</b></p> <p>Positive evidence from human epidemiological studies.</p>	<p><b>Chemicals which <i>should be regarded</i> as if they induce heritable mutations in germ cells of humans.</b></p> <ul style="list-style-type: none"> <li>- Positive result(s) from <i>in vivo</i> heritable germ cell mutagenicity tests in mammals; or</li> <li>- Positive result(s) from <i>in vivo</i> somatic cell mutagenicity tests in mammals, in combination with some evidence that the substance has potential to cause mutations to germ cells. This supporting evidence may, for example, be derived from mutagenicity/genotoxicity tests in germ cells <i>in vivo</i>, or by demonstrating the ability of the substance or its metabolite(s) to interact with the genetic material of germ cells; or</li> <li>- Positive results from tests showing mutagenic effects in the germ cells of humans, without demonstration of transmission to progeny; for example, an increase in the frequency of aneuploidy in sperm cells of exposed people.</li> </ul>	<p><b>Chemicals which <i>cause concern</i> for man owing to the possibility that they may induce heritable mutations in germ cells of humans</b></p> <p>Positive evidence obtained from experiments in mammals and/or in some cases from <i>in vitro</i> experiments, obtained from:</p> <ul style="list-style-type: none"> <li>- Somatic cell mutagenicity tests <i>in vivo</i>, in mammals; or</li> <li>- Other <i>in vivo</i> somatic cell genotoxicity tests which are supported by positive results from <i>in vitro</i> mutagenicity assays.</li> </ul> <p><b>Note :</b></p> <ul style="list-style-type: none"> <li>- Chemicals which are positive in <i>in vitro</i> mammalian mutagenicity assays, and which also show chemical structure activity relationship to known germ cell mutagens, should be considered for classification as Category 2 mutagens.</li> </ul>

Figure 8: Carcinogenicity Criteria as defined in Council Directive 67/548/EC and in the GHS

EU	Category 1 T R45 & T R49		Category 2 T R45 & T R49	Category 3 Xn R40
Criteria	<p><b>Substances <i>known</i> to be carcinogenic to man.</b></p> <p>Sufficient evidence to establish a causal association between human exposure to a substance and the development of cancer.</p>	<p><b>Substances <i>which should be regarded</i> as if they are carcinogenic to man.</b></p> <p>There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development of cancer, generally on the basis of:</p> <ul style="list-style-type: none"> <li>- appropriate long-term animal studies,</li> <li>- other relevant information.</li> </ul>	<p><b>Substances which <i>cause concern</i> for man owing to possible carcinogenic effects.</b></p> <p>Substances which cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in Category 2.</p>	
GHS	<p style="text-align: center;">Category 1</p> <p style="text-align: center;">Category 1A                      Category 1B</p>		Category 2	
Criteria	<p><b>Chemicals <i>known</i> to have carcinogenic potential for humans; the placing of a chemical is largely based on human evidence</b></p>	<p><b>Chemicals <i>presumed</i> to have carcinogenic potential for humans; the placing of a chemical is largely based on animal evidence</b></p> <p>Based on strength of evidence together with additional considerations, such evidence may be derived from human studies that establish a causal relationship between human exposure to a chemical and the development of cancer (known human carcinogen). Alternatively, evidence may be derived from animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity (presumed human carcinogen). In addition, on a case by case basis, scientific judgement may warrant a decision of presumed human carcinogenicity derived from studies showing limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in experimental animals.</p>	<p><b>Suspected human carcinogens</b></p> <p>The placing of a chemical in Category 2 is done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the chemical in Category 1. Based on strength of evidence together with additional considerations, such evidence may be from either limited evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies.</p>	

- **Carcinogenicity**: The GHS classification criteria are identical to those applied by Directive 67/548/EEC, cf. Annex I to this study. Guidance on how to interpret the data for potentially carcinogenic substances and derive a particular classification is still under development at UN level. The overall conclusion to be drawn is that the same kind and number of substances and preparations (GHS terminology: mixtures) will be classified under the GHS Regulation as are currently classified.
- **Mutagenicity**: The GHS classification criteria are identical to those applied by Directive 67/548/EEC, cf. Annex I to this study. The same kind and number of substances and preparations (GHS terminology: mixtures) will be classified under the GHS Regulation as are currently classified.

**Concluding, the GHS will have no effect on the kind and number of carcinogenic and mutagenic substances and mixtures regulated by Directive 2004/37/EC. This means that the GHS-Regulation will have no effect on the obligations of the latter Directive.**

#### **IV.2.3. Suggestions how to minimise potential effects of the GHS**

The GHS will have no effect.

With regard to the reclassification of current entries in Annex I to Directive 67/548/EEC, the GHS Regulation will provide for conversions for CMR and respiratory sensitisers on the basis of equivalent criteria. It is planned to carry them over to Annex VI to the GHS Regulation. Non-harmonised, but classified CMRs can easily be reclassified by using the conversion table in Annex VII.

#### Basic documents used for the analysis

- UN Document ST/SG/AC.10/C.4/2005/2 (OECD)
- DG ENTR, Comparison between EU and GHS Criteria, Human Health and Environment, June 2005

### **IV.3. Council Directive 1994/33/EC of 22 June 1994 on the protection of young people at work**

[http://europa.eu.int/smartapi/cgi/sga\\_doc?s martapi!celexapi!prod!CELEXnumdoc&lg=EN&n umdoc=31994L0033&model=guichett](http://europa.eu.int/smartapi/cgi/sga_doc?s martapi!celexapi!prod!CELEXnumdoc&lg=EN&n umdoc=31994L0033&model=guichett)

Council Directive 1994/33/EC (“Young Workers Directive”) requires Member States to ensure that young people are protected from any specific risks to their safety, health and development. To this end, Member States shall prohibit the employment of young people for certain work, such as work involving harmful exposure to agents which are toxic, carcinogenic, cause heritable genetic damage or harm to the unborn child or which in any other way chronically affect human health. The Young Workers Directive also requires Member States to ensure that employers adopt measures necessary to protect the safety and health of young people taking into account the specific risk to young people. The employers shall implement the protective measures on the basis of an assessment of the hazards to young people and, in that context, pay particular attention to the nature, degree and duration of exposure to chemical agents.

The Young Workers Directive further lays down that work which is likely to entail specific risks to young people includes work involving harmful exposure to the physical, biological and chemical agents referred to in the Annex to the Directive. The chemical agents comprise substances and preparations which are classified according to selected criteria as defined in Council Directive 67/548/EEC and Directive 1999/45/EC. The legal obligations in the Directive are in principle based on exposure and risk rather than on the particular classification of chemicals as such. For this reason, the GHS is deemed to have limited effects only – additional assessments of risk and exposure may have to be performed whereas the results and conclusions of those assessments may not necessitate further action.

#### **IV.3.1. Abstract of the legislation**

Council Directive 1994/33/EC (“Young Workers Directive”) is based on Article 118a of the Treaty establishing the European Community. It applies to all young people below 18 years who have an employment contract or an employment relationship defined by the law in force in a Member State and/or subject to the law in force in a Member State.

One of the main objectives of the Directive is to establish minimum requirements to guarantee the health and safety of young workers. It requires the Member States to prohibit the employment of adolescents in defined cases, i.e. when the work involves harmful exposure to agents which are toxic, carcinogenic, cause heritable genetic damage or harm to the unborn child or which in any other way chronically affect human health, cf. Article 7.2(b). Furthermore, the Member States shall ensure that the employment of adolescents is strictly controlled and protected under the conditions provided for in the Directive. However, they may stipulate that the Directive shall not be applicable to occasional work or work carried out for a limited period involving domestic service in a private household or to work which is regarded as not being harmful, damaging or dangerous to young people in a family undertaking.

In general, the Directive requires Member States to ensure that young people are protected from any specific risks to their safety, health and development which are a consequence of their lack of experience, of absence of awareness of existing or potential risks or of the fact that young people have not yet fully matured. It also stipulates that the employer has the general obligation to protect the health and safety of young people, to assess the risks to young people associated with their work, to assess and monitor the health of young people and to inform the young workers and the children's legal representatives on the potential risks to the health and safety. Work which is likely to entail specific risks for young people includes work involving harmful exposure to the physical, biological and chemical agents referred to in point I ("Agents") of the Annex, inter alia:

### I. 3. Chemical agents

(a) Substances and preparations classified according to 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 (2) with amendments and Council Directive 88/379/EEC<sup>6</sup> of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (3) as toxic (T), very toxic (T+), corrosive (C) or explosive (E);

(b) Substances and preparations classified according to Directives 67/548/EEC and 88/379/EEC<sup>7</sup> as harmful (Xn) and with one or more of the following risk phrases:

- danger of very serious irreversible effects (R39),
- possible risk of irreversible effects (R40),
- may cause sensitization by inhalation (R42),
- may cause sensitization by skin contact (R43),
- may cause cancer (R45),
- may cause heritable genetic damage (R46),
- danger of serious damage to health by prolonged exposure (R48),
- may impair fertility (R60),
- may cause harm to the unborn child (R61);

(c) Substances and preparations classified according to Directives 67/548/EEC and 88/379/EEC as irritant (Xi) and with one or more of the following risk phrases:

- highly flammable (R12);
- may cause sensitization by inhalation (R42),
- may cause sensitization by skin contact (R43),

(d) Substances and preparations referred to in Article 2(a)(iii) of Directive 2004/37/EC;

(e) Lead and compounds thereof, inasmuch as the agents in question are absorbable by the human organism;

(f) Asbestos

and

II. 6. Work with vats, tanks, reservoirs or carboys containing chemical agents referred to in 1.3.

Where the risk assessment performed by the employer shows that there is a risk to the safety, the physical or mental health or development of young people, an appropriate free assessment and monitoring of their health shall be provided at regular intervals without prejudice to Directive 89/391/EEC. If work involves harmful exposure to agents which are toxic, carcinogenic, cause heritable genetic damage, or harm to the unborn child or which in any other way chronically affect human health, Member States shall prohibit the employment of young people.

<sup>6</sup> Replaced by Directive 1999/45/EC

<sup>7</sup> cf. above

### IV.3.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS

With regard to health and safety of young workers, the **Young Workers Directive is exposure-based and risk-driven. Legal obligations, e.g. protection and prevention measures, health surveillance and the prohibition of employment for certain work are in principle derived from an assessment of risk and harmful exposure, and not only from classification as such.**

The exposure-based and risk-driven structure of the Directive follows from the texts of Article 6 and 7 of the Directive. Article 6 stipulates that the employer shall adopt measures to protect young people against specific risks referred to in Article 7. The protective measures shall be implemented on the basis of an assessment of hazards. In this connection, particular attention shall be paid to inter alia the nature, degree and duration of exposure to chemical agents.

Article 7 provides inter alia:

#### Article 7

##### Vulnerability of young people - Prohibition of work

1. Member States shall ensure that young people are protected from any specific risks to their safety, health and development which are a consequence of their lack of experience, of absence of awareness of existing or potential risks or of the fact that young people have not yet fully matured.

2. Without prejudice to Article 4 (1), Member States shall to this end prohibit the employment of young people for:

... (b) work involving harmful exposure to agents which are toxic, carcinogenic, cause heritable genetic damage, or harm to the unborn child or which in any other way chronically affect human health; ...

Work which is likely to entail specific risks for young people within the meaning of paragraph 1 includes:

- work involving harmful exposure to the physical, biological and chemical agents referred to in point I of the Annex, and

- processes and work referred to in point II of the Annex.

As mentioned above, these chemical agents comprise substances and mixtures which are classified according to Directives 67/548/EEC and 1999/45/EC. With regard to harmful exposure to CMR and chronically toxic agents, the Directive requires that Member States shall prohibit the employment of young people for work involving harmful exposure to the corresponding agents, cf. Article 7.2(b) above.

**Due to differences in the classification criteria, additional substances and mixtures are likely to be classified under GHS compared to the current situation.** An overview of the potentially affected hazards including those which are referred to in the Annex of the Young Workers Directive is given in Table V.3 of Part I and Annex I to this study. The hazards where additional classification might occur comprise also chronic effects, i.e. *reproductive toxicity* (possibly additional mixtures) and *STOT, repeated exposure* (additional substances / mixtures).

Generally, the chemical agents which could be classified in addition to the current scope would consequently be the reason for further assessments of exposure and risk. With regard to risk reduction and prevention, however, further action which goes beyond the currently applied measures may not be necessary.

On the whole, the exposure-based approach of the Young Workers Directive implies that **the GHS will have only limited effects on the Young Workers Directive.**

### IV.3.3. Suggestions how to minimise potential effects of the GHS

In order to minimise potential effects related to additional classification under GHS, it is proposed to adapt the range of certain hazards referred to in the Young Workers Directive in accordance with **Solution 2**, cf. Table VI.2 of Part I of this study. This would imply to refer to the GHS classification criteria while at the same time extending or limiting the respective reference to the current cut-off limits or concentration thresholds.

With regard to the reclassification of current entries in Annex I to Directive 67/548/EEC, the GHS Regulation will provide for conversions for CMR and respiratory sensitizers on the basis of equivalent criteria. It is planned to carry them over to Annex VI to the GHS Regulation. Non-harmonised, but classified CMRs can easily be reclassified by using the conversion table in Annex VII.

#### Basic documents used for the analysis;

- UN Document ST/SG/AC.10/C.4/2005/2 (OECD)
- DG ENTR, Comparison between EU and GHS Criteria, Human Health and Environment, June 2005
- Genevieve Hilgers, Comparison of criteria for the classification of substances between the Global Harmonisation and EU systems, August 25, 1999
- Genevieve Hilgers, Impact of GHS standardized approach of skin/eye irritation/corrosion on AISE products, March 2001
- Contributions from industry and Commission experts

**IV.4. Council Directive 1992/85/EEC of 19 October 1992 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**  
(Tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

<http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31992L0085:EN:HTML>

Council Directive 1992/85/EC (“Pregnant Workers Directive”) covers work of pregnant workers and workers who have recently given birth or are breastfeeding. The employer is required to assess the exposure to certain chemical agents and to decide what measures should be taken in order to protect the exposed workers against any risks to their safety or health and any possible effect on the pregnancy or breastfeeding. The chemical agents at issue include carcinogenic and mutagenic substances labelled R40, R45, R46 or R47 (no longer applicable) under Directive 67/548/EEC. Due to the risk-based approach and equivalent hazard criteria, it can be expected that the GHS Regulation will have no effect on the legal obligations of the Pregnant Workers Directive.

**IV.4.1. Abstract of the legislation**

This Directive is based on Article 137(2) of the Treaty. Its purpose is to implement measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or who are breastfeeding. The provisions of Directive 89/391/EEC, except for Article 2 (2) thereof, shall apply in full without prejudice to any more stringent and/or specific provisions contained in Council Directive 1992/85/EEC.

For all activities liable to involve a specific risk of exposure to agents, processes or working conditions of which a list is given in Annex I, the employer shall assess the nature, degree and duration of exposure, either directly or by way of the protective and preventive services referred to in Article 7 of Directive 89/391/EEC. This shall be done in order to assess any risks to the safety or health and any possible effect on the pregnancy or breastfeeding, and to decide what measures should be taken. The Commission shall draw up guidelines on the assessment of the chemical, physical and biological agents and industrial processes considered dangerous for the health and safety of the relevant workers.

Substances listed on Annex I include (a) substances labelled R40, R45, R46 and R47<sup>8</sup> under Directive 67/548/EEC in so far as they do not appear on Annex II, (b) chemical agents in Annex I to Directive 90/394/EEC (2004/37/EC) and (f) chemical agents of known and dangerous percutaneous absorption.

If the results of the risk assessment reveal a risk to the safety or health or an effect on the pregnancy or breastfeeding of a worker, the employer shall avoid that risk by provisionally adjusting the working conditions or the working hours for this worker. Where such adjustment is not technically and/or objectively feasible, or cannot reasonably be required on duly substantiated grounds, the employer shall take the necessary measures to move the worker concerned to another job. Where transfer to

<sup>8</sup> In the initial version of Directive 1992/85/EEC, reference was made also to risk phrase R47. This risk phrase is not applicable any more and could be replaced by R60 and R61.

another activity is not feasible, the workers in question must be granted leave for the whole of the period considered necessary to protect their safety and health.

In addition to the general provisions referring to the protection of workers, in particular those relating to the limit values for occupational exposure, cases in which exposure is prohibited are listed in Annex II: Pregnant workers may under no circumstances be obliged to perform duties for which the assessment has revealed a risk of exposure to the agents and working conditions listed in Annex II, Section A, and, in the case of workers who are breastfeeding, to the agents and working conditions listed in Annex II, Section B.

Various other provisions are made, pertaining to the prohibition of night work and dismissal during pregnancy and maternity leave, to insurance and payment during maternity leave as well as to the defense of rights.

Technical adjustments to Annex I shall be adopted in accordance with the procedure laid down in Article 17 of Directive [89/391/EEC](#). Annex II may be amended only in accordance with Article 138 of the Treaty.

#### **IV.4.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS**

For the purposes of this analysis, the chemical agents mentioned in Annex I, A.3(a) are relevant:

##### 3. Chemical agents

The following chemical agents in so far as it is known that they endanger the health of pregnant women and the unborn child and in so far as they do not yet appear in Annex II:

- (a) substances labelled R40, R45, R46, and R47 under Directive 67/548/EEC <sup>(2)</sup> in so far as they do not yet appear in Annex II;
- (b) chemical agents in Annex I to Directive 90/394/EEC <sup>(3)</sup>;
- (c) mercury and mercury derivatives;
- (d) antimetabolic drugs;
- (e) carbon monoxide;
- (f) chemical agents of known and dangerous percutaneous absorption

With regard to health and safety of pregnant/breastfeeding workers, **Directive 1992/85/EEC is exposure-based and risk-driven. Specific legal obligations related to pregnant / breastfeeding workers are derived from risk assessment, and not from classification as such.** This is best revealed in [Article 4.1](#) where the Directive requests the employer to assess any risks from the agents referred to in Annex I to the safety or health on the pregnancy or breastfeeding, and to decide what measures should be taken. These chemical agents comprise substances labelled *R40, R45, R46 and R47*<sup>9</sup> under Directive 67/548/EEC in so far as they do not appear on Annex II.

The risk-based approach of the Pregnant Workers Directive implies that the classification of a chemical agent is not decisive. Moreover, the kind and number of classified chemicals is not likely to change compared to the current situation, due to equivalent classification criteria under the EU legislation and the GHS, cf. Table V.3. of Part I Annex I to this study.

Concluding, **the GHS will have no effect.**

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<sup>9</sup> cf. Footnote 1

#### **IV.4.3. Suggestions how to minimise potential effects of the GHS**

The GHS Regulation will have no effect.

The shift of reference to the GHS in Directive 1992/85/EEC will result in a need for a consequential amendment of the Guidelines to Directive 1992/85/EEC (COM(2000)466) in the specific section that mentions chemical risk phrases.

With regard to the reclassification of current entries in Annex I to Directive 67/548/EEC, the GHS Regulation will provide for conversions for CMR and respiratory sensitisers on the basis of equivalent criteria. It is planned to carry them over to Annex VI to the GHS Regulation. Non-harmonised, but classified CMRs can easily be reclassified by using the conversion table in Annex VII.

#### Basic documents used for the analysis

- DG ENTR, Comparison between EU and GHS Criteria, Human Health and Environment, June 2005
- Genevieve Hilgers, Comparison of criteria for the classification of substances between the Global Harmonisation and EU systems, August 25, 1999
- Contributions from industry and Commission experts

#### **IV.5. Council Directive 1992/58/EEC of 24 June 1992 on the minimum requirements for the provisions of safety and/or health signs at work**

[http://europa.eu.int/smartapi/cgi/sga\\_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=DE&numdoc=31992L0058&model=guichett](http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=DE&numdoc=31992L0058&model=guichett)

Council Directive 1992/58/EEC stipulates that employers must provide health and/or safety signs where hazards cannot be avoided or adequately reduced by preventive measures. The Directive specifies in its Annexes both the general requirements and particular features pertaining to the different types of signs. It refers to dangerous substances and preparations classified and labelled according to the provisions as set out in Directives 67/548/EEC and 1999/45/EC only in so far as the visibility of the labelling is concerned. Consequently, the GHS-implementing Regulation will have no effect.

##### **IV.5.1. Abstract of the legislation**

Council Directive 1992/58/EEC is based on Article 138 of the EC Treaty and is an individual Directive within the meaning of Article 16 of Directive 89/391/EEC. It requests employers to provide safety and/or health signs as laid down in this Directive where hazards cannot be avoided or risks cannot be adequately reduced by techniques for collective protection or measures, methods or procedures used in the organization of work, or ensure that such signs are in place. In this connection, the employer shall take into account any risk evaluation made in accordance with Article 6(3)(a) of Directive 89/391/EEC. Wherever appropriate, signs used for road, rail, inland waterway, sea and air transport must be installed inside undertakings.

The Directive defines health and/or safety signs as signs providing information or instructions about health and/or safety at work by means of a signboard, a colour, an illuminated sign or acoustic signal, a hand signal or a verbal communication. Accordingly, it defines the terms "prohibition sign", "warning sign", "mandatory sign", "emergency escape or first-aid sign", "information sign", "signboard", "supplementary signboard", "safety colour", "symbol or pictogram", "illuminated sign", "acoustic signal", "verbal communication" and "hand signal".

The Directive does not apply to signs for the placing on the market of dangerous substances and preparations, products and/or equipment, nor to signs used for regulating traffic.

In the Annexes to the Directive, general requirements as well as particular features pertaining to the different types of signs are specified:

- Annex I sets out the general minimum requirements (types of signs, interchanging and combining signs);
- Annex II defines the requirements concerning signboards (intrinsic features, conditions of use, list of signboards to be used);
- Annex III concerns signs on containers and pipes (labelling and colouring);
- Annex IV concerns the identification and location of fire-fighting equipment;
- Annex V sets out the minimum requirements governing signs used for obstacles and dangerous locations and for marking traffic routes;

- Annex VI deals with illuminated signs (intrinsic features and specific rules governing use);
- Annex VII deals with acoustic signs (intrinsic features and codes to be used);
- Annex VIII deals with direct and indirect communication (intrinsic features and specific rules governing use);
- Annex IX deals with hand signals (list of coded signals to be used).

Technical adaptations to the Annexes will be adopted by the Commission, assisted by an advisory committee. Member States may specify certain exemptions from the requirements within certain precise limits.

Workers must be informed of the measures to be taken and must be given appropriate training (precise instructions). Furthermore, they have to be consulted on the matters covered by the Directive.

Member States are required to report to the Commission every five years on the practical implementation of the Directive. The Commission is required to report periodically to the European Parliament, the Council and the Economic and Social Committee on the implementation of the Directive.

#### **IV.5.2. Analysis of the links to classification and labelling provisions and anticipation of the effects of GHS**

Directive 1992/58/EEC makes reference to the EU legislation on classification and labelling in its Annexes:

- Annex I, General minimum requirements concerning safety and/or health signs at work

12. Areas, rooms or enclosures used for the storage of significant quantities of dangerous substances or preparations must be indicated by a suitable warning sign taken from section 3.2. of Annex II, or marked as provided in section 1 of Annex III, unless the labelling of the individual packages or containers is adequate for this purpose.

- Annex III, Minimum requirements governing signs on containers and pipes

1. Containers used at work for dangerous substances or preparations defined in Directives 67/548/EEC <sup>(1)</sup> and 88/379/EEC <sup>(2)</sup> and containers used for the storage of such dangerous substances or preparations, together with the visible pipes containing or transporting dangerous substances and preparations, must be labelled (pictogram or symbol against a coloured background) in accordance with those Directives.

Paragraph 1 does not apply to containers used at work for brief periods nor to containers whose contents change frequently, provided that alternative adequate measures are taken, in particular for information and/or training, which guarantee the same level of protection.

The labels referred to in paragraph 1 may be:

- replaced by warning signs as provided for in Annex II, using the same pictograms or symbols,
  - supplemented by additional information, such as the name and/or formula of the dangerous substance or preparation and details of the hazard,
  - for the transporting of containers at the place of work, supplemented or replaced by signs applicable throughout the Community for the transport of dangerous substances or preparations.
- ...

4. Without prejudice to sections 1, 2 and 3, the labels used on pipes must be positioned visibly in the vicinity of the most dangerous points, such as valves and joint, and at reasonable intervals.

5. Areas, rooms or enclosures used for the storage of significant quantities of dangerous substances or preparations must be indicated by a suitable warning sign taken from section 3.2 of Annex II, or marked as provided in section 1 of Annex III, unless the labelling of the individual packages or containers is adequate for this purpose, taking into account Annex II, point 1.5 with regard to dimensions.

Stores of a number of dangerous substances or preparations may be indicated by the warning sign for general danger.

The signs or labels referred to above must be positioned, as appropriate, near the storage area or on the door leading into the storage room.

As can be seen from the quotations, any reference to the EU legislation on classification and labelling is confined to labelling: It refers to dangerous substances and preparations classified and labelled according to the provisions as set out in Directives 67/548/EEC and 1999/45/EC only in so far as the visibility of the labelling is concerned. Classification as such is not decisive for the obligations stipulated in Directive 1992/58/EEC. Consequently, the GHS will have no effect.

#### **IV.5.3. Suggestions how to minimise potential effects of the GHS**

The GHS will have no effect. The GHS labelling elements are listed in Annexes III-V to the GHS draft Regulation.

## V. Waste and End-of-Life Products

### V.1. Legislation on Hazardous Waste

- Council Directive 91/689/EEC of 12 December 1991 on hazardous waste
- Council Directive 75/442/EEC of 15 July 1975 on waste
- Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 1994/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste (as last amended by Decision 2001/573/EC)

[http://europe.eu.int/eur-lex/en/consleg/pdf/1975/en\\_1975L0442\\_do\\_001.pdf](http://europe.eu.int/eur-lex/en/consleg/pdf/1975/en_1975L0442_do_001.pdf)

[http://europe.eu.int/eur-lex/en/consleg/pdf/1991/en\\_1991L0689\\_do\\_001.pdf](http://europe.eu.int/eur-lex/en/consleg/pdf/1991/en_1991L0689_do_001.pdf)

[http://europa.eu.int/eur-](http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32000D0532:EN:HTML)

[lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32000D0532:EN:HTML](http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32000D0532:EN:HTML)

Council Directive 91/689/EEC is concerned with the management, recovery and adequate disposal of hazardous wastes which are featuring on the so-called European Waste List. "Hazardous waste" means waste displaying one or more of the properties (H-characteristics) listed in Annex III to Directive 91/689/EEC. These properties as well as the concentration thresholds for hazardous waste ingredients are further defined in Article 2 of Decision 2000/532/EC, as last amended by Decision 2001/573/EC. Most of the properties underlying the H-characteristics as well as the concentration limits for the respective dangerous substances contained in waste are based on Directives 67/548/EEC and 1999/45/EC.

When the reference is shifted to the most closely corresponding classifications of the GHS Regulation, a different number of substances (additional / fewer) will be covered by those GHS classifications which correspond most closely to EU *Very Toxic* and *Toxic*. This would imply that currently non-hazardous wastes become hazardous waste under GHS, and vice versa. In order to minimise effects related to additional classification under GHS, it is proposed to adapt the hazard criteria for substances referred to in the Hazardous Waste Directive as well as in Decision 2000/532/EC. This would imply to make use of the GHS criteria while at the same time extending or limiting the range of the respective hazards to the current cut-off limits or concentration thresholds. With regard to generic concentration limits, it is proposed to retain them as they are currently. This implies that any reference to concentration limits as provided in footnote 7 being related to Article 2 of Decision 2000/532/EC, as last amended by Decision 2001/573/EC, should be repealed.

Any amendment of the Hazardous Waste Directive should also take account of most recent developments at UN level: It is sought to align the H-characteristics of the Basle Convention with the GHS criteria.

### V.1.1. Abstract of the legislation

Council Directive 91/689/EEC (“Hazardous Waste Directive”) is based on Article 175(1) of the Treaty. It is concerned with the management, recovery and adequate disposal of hazardous waste. Hazardous waste means

- wastes featuring on a list to be drawn up in accordance with the procedure laid down in Article 18 of Directive 75/442/EEC on the basis of Annexes I and II to the latter Directive, not later than six months before the date of implementation of this Directive, cf. Article 1.4. of Directive 91/689/EEC. These wastes must have one or more of the properties listed in Annex III to Directive 91/689/EEC. The list shall take into account the origin and composition of the waste and, where necessary, limit values of concentration. This list shall be periodically reviewed and if necessary by the same procedure;
- any other waste which is considered by a Member State to display any of the properties listed in Annex III. Such cases shall be notified to the Commission and reviewed in accordance with the procedure laid down in Article 18 of Directive 75/442/EEC with a view to adaptation of the list.

The harmonised list mentioned in the first indent (European Waste List) as well as more precise criteria for the classification of hazardous waste were set up by Commission Decision 2000/532/EC<sup>10</sup>, as last amended by Decision 2001/573/EC : Article 2 states that wastes which are considered “hazardous” display one or more of the properties listed in Annex III to Directive 91/689/EEC and, as regards H3 to H8, H10 and H11 of that Annex, meet one or more of the following requirements:

- flash point • 55 °C,
- one or more substances classified as very toxic at a total concentration • 0,1 %,
- one or more substances classified as toxic at a total concentration • 3 %,
- one or more substances classified as harmful at a total concentration • 25 %,
- one or more corrosive substances classified as R35 at a total concentration • 1 %,
- one or more corrosive substances classified as R34 at a total concentration • 5 %,
- one or more irritant substances classified as R41 at a total concentration • 10 %,
- one or more irritant substances classified as R36, R37, R38 at a total concentration • 20 %,
- one or more substances known to be carcinogenic of category 1 or 2 at a total concentration • 0,1 %,
- one or more substances toxic for reproduction of category 1 or 2 classified as R60, R61 at a total concentration • 0,5 %,
- one or more substances toxic for reproduction of category 3 classified as R62, R63 at a total concentration • 5 %,
- one or more mutagenic substances of category 1 or 2 classified as R46 at a total concentration • 0,1 %,
- one or more mutagenic substances of category 3 classified as R40 at a total concentration • 1 %.

The classification as well as the R-phrases refer to Council Directive 67/548/EEC and its subsequent amendments, cf. footnote 7. The concentration limits refer to those laid down in Council Directive 1999/45/EC which had repealed Council Directive 88/379/EEC and its subsequent amendments.

Article 3 provides that Member States may decide, in exceptional cases, that a specific waste indicated in the list as being hazardous does not display any of the properties which render them hazardous.

In point 6 of the introduction to the Annex to Commission Decision 2000/532/EC, it is stated:

6. If a waste is identified as hazardous by a specific or general reference to dangerous substances, the waste is hazardous only if the concentrations of those substances are such (i.e. percentage by weight) that the waste

<sup>10</sup> For reasons of readability, we will abstain from adding the phrase “as last amended by decision 2001/573/EEC in the following text.

presents one or more of the properties listed in Annex III to Council Directive 91/689/EEC. As regards H3 to H8, H10 and H11, Article 2 of this Decision applies. For the characteristics H1, H2, H9 and H12 to H14 Article 2 of the present Decision does not provide specifications at present.

For the characteristics H1, H2, H9, H12, H13 and H14, however, various Member States have developed threshold concentrations which are based on Directive 1999/45/EC, cf. for example p. 15-16 of the UK guidelines on hazardous waste:

Threshold concentrations for the hazardous properties not covered by Article 2 (H1, H2, H3-A (second to fifth indent), H9, H12, H13 and H14 (with the exception of H9: Infectious), have been developed based on the classification and risk phrases from the CHIP3 which implement Directive 88/379/EEC<sup>11</sup>. ... Risk phrase N: R50, 53 is appropriate to hazardous property H14 "Ecotoxic". The threshold concentration for N: R50, 53 chemicals is 0.25%. This threshold is exceeded and the waste should be classified as H14 "Ecotoxic".

The EWL (European Waste List) which was established by Commission Decision 2000/532/EC consists of three types of entries:

1. **Mirror Entries:** Some wastes have the potential to be either hazardous or not, depending on whether they contain "dangerous substances" at or above certain thresholds. These wastes which constitute about 33% of all entries are covered by linked (usually paired) entries, collectively called "mirror entries" that comprise; a hazardous waste entry marked with an asterisk (\*) and a non-hazardous waste entry (or entries) not marked with an asterisk, e.g.

17 05 05\* Dredging spoil containing dangerous substances

17 05 06 Dredging spoil other than those mentioned in 17 05

2. **Absolute Hazardous Entries:** A number of wastes marked with an asterisk (\*) are deemed in ordinary cases to be consisting of hazardous substances, or containing or contaminated with hazardous substances, e.g.:

07 07 03\* Organic halogenated solvents, washing liquids and mother liquors  
05

3. **Non-Hazardous Entries:** Where a waste is not listed in the EWL with an asterisk, then it is not hazardous.

01 04 09 Waste sand and clays

Waste holders have a duty to determine if a "mirror entry" waste is hazardous, cf. Article 4.2. This implies the assessment whether the hazardous or non-hazardous waste entry is applicable. Where there are any reasons to indicate that the waste may be hazardous, such as test results, knowledge of the production process or the raw materials used, and/or the composition of a waste is not known, cannot be determined or is insufficient to allow classification using the ASL or other sources, the waste needs to be tested to determine if it possesses any hazardous properties. The Hazardous Waste Directive identifies the test methods in Annex V of Directive 67/548/EEC as the methods to be used to test for hazardous properties, cf. the paragraph "Test Methods" in Annex III to Directive 91/689/EEC.

The Hazardous Waste Directive sets up manifold obligations if waste turns out to be hazardous:

- Member States are requested to take the necessary measures to require that on every site where tipping (discharge) of hazardous waste takes place the waste is recorded and identified, cf. Article 2. Moreover and in general, they shall take the necessary measures to require that establishments and undertakings which dispose of, recover, collect or transport hazardous waste do not mix different categories of hazardous waste or mix

<sup>11</sup> Repealed by Council Directive 1999/45/EC

hazardous waste with non hazardous waste. If mixing takes place, this operation is subject to the permit requirement as set out in Directive 75/442/EEC;

- If an establishment is subject to the permit requirement for reasons set out in Directive 75/442/EE, a Member State may waive the permit requirement for undertakings which recover hazardous waste if there is no danger for human health or the environment or if the Member State has set up general rules related to the recovery, cf. Article 3;
- Producers of hazardous waste are subject to regular controls by the competent authorities, cf. Article 4.1;
- Producers and transporters of hazardous waste have to set up an inventory where details on the handling of hazardous waste are stated; this information has to be submitted to the competent authorities, cf. Article 4.2;
- The competent authorities shall draw up plans for the management of waste and shall make these plans public, cf. Article 6.1. The Commission shall compare these plans and make this information available to the competent authorities of the Member States, cf. Article 6.2;
- In cases of emergency or grave danger, Member States shall take all necessary steps to ensure that hazardous waste is so dealt with as not to constitute a threat to the population or the environment, including temporary derogations from this Directive, cf. Article 7;

The amendments necessary for adapting the Annexes to this Directive to scientific and technical progress and for revising the list of wastes referred to in Article 1(4) shall be adopted in accordance with the procedure laid down in Article 18 of Directive 75/442/EEC (comitology procedure).

Further legal obligations derived from the classification as hazardous waste are set out in Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste.

### **V.1.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS**

#### **Characterisation of hazardous properties**

At first sight, the Hazardous Waste Directive defines its own set of criteria for the classification of hazardous waste, i.e. the H-characteristics H1-H14. With regard to the health hazards underlying the criteria H4-H8 and H10-H11, it is clearly stated in paragraph 1 and 2 of the Notes of Annex III to Directive 91/689/EEC that the H-characteristics are to reflect the classifications *Very Toxic, Toxic, Harmful, Corrosive, Irritant and CMR* according to Directive 67/548/EEC and its amendments. Although a similar provision is not explicitly made for the physico-chemical hazards (H1, H2, H3A, H3B, H12) and for the environmental hazard (H14), the test methods to define these properties shall be those as described in Annex V to Directive 67/548/EEC and its adaptations to technical progress, cf. the paragraph "Test Methods" in Annex III to Directive 91/689/EEC :

The test methods serve to give specific meaning to the definitions given in Annex III. The methods to be used are those described in Annex V to Directive 67/548/EEC, in the version as amended by Commission Directive 84/449/EEC (2), or by subsequent Commission Directives adapting Directive 67/548/EEC to technical progress. These methods are themselves based on the work and recommendations of the competent international bodies, in particular the OECD.

This suggests that the classification criteria as laid down in Directive 67/548/EEC are also used for the physico-chemical hazards underlying H1 (*Explosive*), H2 (*Oxidising*), H3A and H3B (*Extremely Flammable, Highly Flammable, Flammable*) and H12 (R29, R31, R32).

Annex V of Directive 67/548/EEC will be repealed as a consequence of the REACH Regulation. The deletion of this Annex will apply 12 months from the entry into force of the REACH Regulation; the testing methods will then be specified on the basis of Article 12 of the REACH Regulation in a further Commission Regulation or by recognition of other international test methods by the Commission or the Agency.

With regard to H9 (infectious) and H13 (yielding of another substance), tests and criteria are derived from other sources because the underlying properties are not subject to classification. With regard to H14 (ecotoxic), the test methods and criteria to be used are not harmonised; they are a repeated topic of discussion in the Member States. At least some Member States would characterise waste as hazardous (H14) if it contains a substance which is classified as N/R50-53, in accordance with the criteria defined in Directive 67/548/EEC, e.g. the UK Guidelines.

The reference to the EU classification system for the health hazards is made more explicit in Decision 2000/532/EC which refers to actual classifications and R-phrases, i.e. to *Very Toxic, Toxic, Harmful, C/R35, C/R34, Xi/R41, Xi/R36, Xi/R37, Xi/R38, Carcinogen Cat. 1 and 2, Toxic to Reproduction Cat. 1 and 2 (R60 and R61), Toxic to Reproduction Cat. 3 (R62 and R63), Mutagen Cat. 1 and 2 (R46) and Mutagen Cat. 3 (R40)*, cf. the previous chapter. From the legislation it is not clear if the risk phrases R39 and R48 (all routes of uptake) are also included in the general reference.

When the GHS criteria are applied, a different number of substances (additional / fewer) will be covered by those GHS classifications which correspond most closely to EU *Very Toxic* and *Toxic*. This would be due to different LD<sub>50</sub>- or LC<sub>50</sub>-cut-off values related to the individual categories, cf. column 3 of Table V.3 and Annex I to this study. **This implies that non-hazardous entries in the EWL, being part of a mirror entry or not, could become “hazardous waste”** if the references in Decision 2000/532/EC would be shifted to the most closely corresponding GHS classifications only. In this case, the corresponding provisions of Directive 91/689/EEC will have to be complied with, cf. above. Vice versa, waste that is currently considered “hazardous” could become declassified under GHS.

Potential effects related to additional classification under GHS may be prevented by adapting the references to the various GHS categories of the hazard class *acute toxicity*, in accordance with **Solution 2**, cf. Table VI.2 of Part I of this study. This would imply to make use of the GHS classification criteria while at the same time extending or limiting the scope of the respective reference to the current cut-off limits. If Article 2 of Decision 2000/532/EC includes also the reference to the risk phrases R39 and R48 (all routes of uptake), the same kind of adaptations could be applied to the corresponding GHS classifications which are *STOT (single / repeated exposure)*, in accordance with Table VI.2 of Part I of this study.

### **Generic concentration limits**

With regard to minimum concentrations, Decision 2000/532/EC makes use of generic concentration limits which are to reflect the lowest thresholds as defined in the Tables in Part B of Annex II to Directive 1999/45/EC, cf. the footnote 7 being related to Article 2 of Decision 2000/532/EC. Specific concentration limits, however, as defined in Annex I to Directive 67/548/EEC, are not explicitly referred to.

With regard to generic concentration limits, the GHS Regulation will lower the concentration limits for the following health hazards:

Table V.1.1: Health hazard-related concentration limits for the classification of mixtures

EU category of danger, R-phrase	EU concentration limit	Most closely corresponding GHS hazard classification	GHS concentration limit
Corrosive C, R34	10%	Skin corrosion, cat. 1B and 1C	5%
Corrosive C, R35	5%	Skin corrosion, cat. 1A	3%
Irritant Xi, R38 and R36	20%	Skin irritation, cat. 2	10%
Irritant Xi, R36	20%	Eye irritation, cat. 2A	10%
Irritant Xi, R41	10%	Serious eye damage, cat. 1	3%
Reproductive toxicity, R60 or R61	0.5%	Reproductive toxicity, cat. 1	0.3%
Reproductive toxicity, R62 or R63	5%	Reproductive toxicity, cat. 2	3%

**If references to the GHS generic concentration limits were installed in Decision 2000/532/EC, waste would become “hazardous” at lower concentrations of a dangerous substance than currently.** As a consequence, the corresponding non-hazardous mirror entries containing ingredients classified for the above -mentioned hazards could become hazardous waste and subject to the corresponding provisions of Directive 91/689/EEC.

**To prevent effects which would be due to lower ingredient concentration limits as defined in the GHS, the current limits should be retained.** In this case, any reference to concentration limits as provided in footnote 7 being related to Article 2 of Decision 2000/532/EC should be repealed.

#### Additivity of hazards

With regard to concentration limits, it is not obvious from Decision 2000/532/EC if the summing procedures as set up in Annex II (and III) to Directive 1999/45/EC should be followed in classifying hazardous waste which contains several substances of different classification below the respective concentration limit (generic and/or specific). Accordingly, different interpretations are derived in different Member States: Whereas the Danish Guidelines for classifying hazardous waste are based on the procedures laid down in Directive 1999/45/EC, the UK Guidelines do not require concentrations related to different classifications to be added, cf. the column “Comments” of Table 3.1 of the UK Guidelines . This implies that those wastes are not regulated by the Hazardous Waste Directive which contain constituents of differing classification below the respective concentration limits, e.g. wastes displaying toxic and harmful, corrosive and irritant properties.

The GHS will make wide use of the additivity of hazards, e.g. when mixtures have to be classified for *acute toxicity* (Chapter 3.1 GHS), *skin irritation / corrosion* (Chapter 3.2 GHS) *serious eye damage / eye irritation* (Chapter 3.3 GHS) or *hazardous to the aquatic environment* (Chapter 4.1 GHS). Without prejudice to potential reference to the GHS classification criteria, it should be examined if the additivity of hazards should be built into the legislation on hazardous waste at all:

**Taking account of hazard additivity would be a final step to considering wastes as mixtures. On the other hand, ignoring the additivity of hazards would imply that some wastes would not be regulated by the Hazardous Waste Directive.**

In this connection, it is often assumed that differences between the classification and labelling system and the Hazardous Waste Directive as explained above may have implications for workers' protection. However, the definitions set out in the Article 2 ("Definitions") of Directive 1998/24/EC reveal that waste involving hazardous chemical agents is covered by the provisions of that Directive.

For the purpose of this Directive, the terms used shall have the following meanings:

(a) 'Chemical agent' means 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 produced intentionally and whether or not placed on the market;

(b) 'Hazardous chemical agent' means:

(i) any chemical agent which meets the criteria for classification as a dangerous substance according to the criteria in Annex VI to Directive 67/548/EEC, whether or not that substance is classified under that Directive, other than those substances which only meet the criteria for classification as dangerous for the environment;

(ii) any chemical agent which meets the criteria for classification as a dangerous preparation within the meaning of Directive 88/379/EEC, whether or not that preparation is classified under that Directive, other than those preparations which only meet the criteria for classification as dangerous for the environment; ...

and that

(c) 'Activity involving chemical agents' means any work in which chemical agents are used, or are intended to be used, in any process, including production, handling, storage, transport or disposal and treatment, or which result from such work;

This means that any chemical agent, be it an ingredient of a product or of waste, is subject to the provisions of the Chemical Agents Directive. The attribute "hazardous" clearly refers to Council Directive 67/548/EEC and 1999/45/EC, and not to the H-characteristics. In other words: the classification of products containing dangerous substances as hazardous waste is **not** relevant in the context of occupational health and safety – the H-characteristics are only relevant with regard to the applicability of the provisions of the legislation on hazardous waste.

### V.1.3. Suggestions how to minimise potential effects of the GHS

It is proposed to shift reference to the corresponding GHS classification criteria as listed in the Part I ("reference table") of Annex VIII to the GHS draft Regulation. In order to minimise effects related to additional classification under GHS, it is proposed to adapt the references to the various GHS categories of the hazard class *acute toxicity*, in accordance with **Solution 2**, cf. Table VI.2 of Part I of this study. This would imply to refer to the GHS classification criteria while at the same time extending or limiting the respective reference to the current cut-off limits.

If Article 2 of Decision 2000/532/EC includes also the reference to the risk phrases R39 and R48 (all routes of uptake), adaptations in accordance with **Solution 2** are equivocally proposed for the corresponding GHS classifications ( *STOT single / repeated exposure* ).

With regard to generic concentration limits, it is proposed to retain them as they are currently. This implies that any reference to concentration limits as provided in footnote 7 being related to Article 2 of Decision 2000/532/EC should be repealed.

Any amendment of the Hazardous Waste Directive with regard to the link to classification and labelling legislation should take account of recent developments at UN level: The UN Subcommittee of Experts on GHS (UN SCE GHS) set up a correspondence group for cooperation with the Basle Convention in 2005, in order to explore possible links between the work undertaken on hazardous waste characteristics and the GHS classification and labelling elements (biennium 2005 -2006), cf. UN/SCEGHS/8/INF.11.

With regard to the reclassification of current entries in Annex I to Directive 67/548/EEC, the GHS Regulation will provide for conversions for CMR and respiratory sensitisers on the basis of equivalent criteria. It is planned to carry them over to Annex VI to the GHS Regulation. Non-harmonised, but classified CMRs can easily be reclassified by using the conversion table in Annex VII.

In view of the discussions reflected in the previous chapter, it is recommended to check potential implications of the change of the classification system for related acts such as Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste or national waste legislation.

#### Basic documents used for the analysis:

- European Commission, Implementation of the European Waste List from the Perspective of the Commission (Presentation DG ENV/G4, Berlin, November 2005)
- UK Environment Agency: Hazardous Waste: Interpretation of the definition of the classification of hazardous waste (2nd edition)
- OVAM, LoW – Implementation in Flanders, problems and solutions, future evolution (Presentation, Berlin, November 2005)
- European Commission: Comparison of criteria for the classification of substances between the Global Harmonisation and EU systems, June 2005
- Contributions from experts from the Member States and from Industry

## V.2. Legislation on End -of-Life Products

### V.2.1. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end -of-life vehicles

<http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32000L0053:EN:HTML>

Directive 2000/53/EC (“ELV Directive”) aims at waste prevention. Its provisions apply to vehicles and end-of-life vehicles, including their components and materials. Vehicle manufacturers, in liaison with material and equipment manufacturers, shall be encouraged to limit the use of hazardous substances in vehicles and to reduce them as far as possible from the conception of the vehicle onwards. Member States shall take the necessary measures to ensure that hazardous materials and components are removed from end-of-life vehicles before their final treatment and segregated in a selective way. With regard to dismantling information, Member States shall ensure that producers provide information on the different components and materials of a vehicle as well as on the location of all hazardous substances in the vehicle.

In view of these legal obligations, it could be of relevance that additional substances are expected to be classified under GHS, compared to the current situation. It is proposed to exempt from the reference to classified substances those hazard classifications which are newly introduced by the GHS.

#### V.2.1.1. Abstract of the legislation

Directive 2000/53/EC (“ELV Directive”) is based on Article 175(1) of the Treaty. Its provisions apply to vehicles and end-of-life vehicles, including their components and materials. It defines an end-of-life vehicle as any type of vehicle that is waste within the meaning of Directive 75/442/EEC. The Directive covers in general:

- any end-of-life vehicle designated as category M1 or N1 (as defined in section A of Annex II to Directive 70/156/EEC);
- two- or three-wheel motor vehicles and their components.

Waste prevention is the priority objective of the Directive. To this end, it stipulates that vehicle manufacturers and material and equipment manufacturers must:

- endeavour to reduce the use of hazardous substances when designing vehicles;
- design and produce vehicles which facilitate the dismantling, re-use, recovery and recycling of end-of-life vehicles;
- increase the use of recycled materials in vehicle manufacture;
- ensure that components of vehicles placed on the market after 1 July 2003 do not contain mercury, hexavalent chromium, cadmium or lead, except in the applications listed in Annex II. The Commission shall amend Annex II on a regular basis according to scientific and technical progress in order to establish maximum concentration values up to which the existence of mercury, hexavalent chromium, cadmium or lead in specific materials and components of vehicles shall be tolerated, to exempt certain materials and components of

vehicles from the heavy metal ban if the use of these substances is unavoidable, delete materials and components of vehicles from Annex II if the use of these substances is avoidable, and designate those materials and components of vehicles that can be stripped before further treatment.

The Directive also introduces provisions on the collection of all end-of-life vehicles (Article 5). Member States must set up collection systems for end-of-life vehicles and for waste used parts. They must also ensure that all vehicles are transferred to authorised treatment facilities, and must set up a system of deregistration upon presentation of a certificate of destruction. Such certificates are to be issued when the vehicle is transferred, free of charge, to a treatment facility.

The last holder of an end-of-life vehicle will be able to dispose it free of charge ("free take-back" principle). Producers must meet all, or a significant part of, the cost of applying this measure.

The storage and treatment of end-of-life vehicles is also subject to strict control, in accordance with the requirements of Directive 75/442/EEC and those of Annex I to the ELV Directive. Establishments or undertakings carrying out treatment operations must strip end-of-life vehicles before treatment and recover all environmentally hazardous components. Priority must be given to the re-use and recycling of vehicle components, i.e. batteries, tyres, oil.

At the moment, at least 75% of end-of-life vehicles are recycled (metal content). The aim of this Directive is to increase the rate of re-use and recovery to 85% by average weight per vehicle and year by 2006, and to 95% by 2015, and to increase the rate of re-use and recycling over the same period to at least 80% and 85% respectively by average weight per vehicle and year. Less stringent objectives may be set for vehicles produced before 1980.

Member States must ensure that producers use material coding standards which allow identification of the various materials during dismantling. The Commission must establish European standards on material coding and identification.<sup>12</sup>

Economic operators must provide prospective purchasers of vehicles with information on the recovery and recycling of vehicle components, the treatment of end-of-life vehicles and progress with regard to re-use, recycling and recovery. On the basis of this information, Member States must report to the Commission every three years on the implementation of the Directive. The Commission must then publish a report on the implementation of the Directive.

Member States may transpose certain of the Directive's provisions by means of agreements with the economic sectors concerned.

Amending acts are Directive 2002/525/EC (first technical adaptation of Annex II), Decision 2005/438/EC (exemption for spare parts for old vehicles from the heavy metal ban) and Decision 2005/673/EC (second technical adaptation of Annex II).

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<sup>12</sup> For details see Commission Decision 2003/138/EC of 27 February 2003 establishing component and material coding standards for vehicles pursuant to Directive 2000/53/EC, OJ L 53, 28.2.2003, p. 58.

### V.2.1.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS

With regard to classification and labelling provisions, the following links could be identified:

#### Article 2, Definitions:

11. "hazardous substance" means any substance which is considered to be dangerous under Directive 67/548/EEC; ...

#### Article 4, Prevention:

1. In order to promote the prevention of waste Member States shall encourage, in particular:

(a) vehicle manufacturers, in liaison with material and equipment manufacturers, to limit the use of hazardous substances in vehicles and to reduce them as far as possible from the conception of the vehicle onwards, so as in particular to prevent their release into the environment, make recycling easier, and avoid the need to dispose of hazardous waste;

#### Article 6, Treatment:

3. Member States shall take the necessary measures to ensure that any establishment or undertaking carrying out treatment operations fulfils at least the following obligations in accordance with Annex I: ...

(b) hazardous materials and components shall be removed and segregated in a selective way so as not to contaminate subsequent shredder waste from end-of-life vehicles;

#### Article 8, Coding standards / dismantling information:

3. Member States shall take the necessary measures to ensure that producers provide dismantling information for each type of new vehicle put on the market within six months after the vehicle is put on the market. This information shall identify, as far as it is needed by treatment facilities in order to comply with the provisions of this Directive, the different vehicle components and materials, and the location of all hazardous substances in the vehicles, in particular with a view to the achievement of the objectives laid down in Article 7.

As can be seen from available documents, legislative work related to the ELV Directive in the last years in terms of hazardous substances focussed on the adaptations of Annex II to technical and scientific progress. In this context, the need to prolong or remove exemptions from this Annex were analysed in the study "Heavy metals in vehicles" (Ökopol, July 2001). There were two adaptations of Annex II so far, and the third one is scheduled for the years 2007 and 2008. In addition, legislative work on the review of 2015 targets is in progress, and the type-approval directive has recently been amended . O

On the other hand, it can be seen from the quotations above that Directive 2000/53/EC derives some limited obligations from the classification of substances as dangerous according to the criteria of Council Directive 67/548/EEC. In view of these legal obligations, it could be of relevance that additional substances are expected to be classified under GHS, compared to the current situation, cf. Table V.3 of Part I and Annex I to this study .

### V.2.1.3. Suggestions how to minimise potential effects of the GHS

In order to minimise potential effects related to additional classification under GHS, it is proposed to exempt from the reference to classified substances those hazard classifications (classes and categories / types / divisions) which are newly introduced by the GHS , in accordance with **Solution 1**, cf. Part I of this study. The respective classifications are listed in Table VI.1 of Part I.

With regard to the reclassification of current entries in Annex I to Directive 67/548/EEC, the GHS Regulation will provide for conversions for CMR and respiratory sensitisers on the basis of equivalent criteria. It is planned to carry them over to Annex VI to the GHS Regulation. Non-harmonised, but classified CMRs can easily be reclassified by using the conversion table in Annex VII.

## V.2.2. Legislation on electrical and electronic equipment

- **Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment**
- **Directive 2002/95/EC of the European Parliament and the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment**

<http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32002L0096:EN:HTML>

[http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l\\_037/l\\_03720030213en00190023.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_037/l_03720030213en00190023.pdf)

Directive 2002/96/EC (“WEEE-Directive”) aims at preventing the generation of electrical and electronic waste and to promote reuse, recycling and other forms of recovery in order to reduce the quantity of such waste to be eliminated. Its provisions apply to numerous categories of electrical and electronic equipment (EEE). The only provision relating to classification and labelling legislation is given in Article 11 where it is stated that producers should provide information on the location of dangerous substances and preparations in EEE to treatment facilities.

In view of these legal obligations, it could be of relevance that additional substances are expected to be classified under GHS, compared to the current situation. It is proposed to exempt from the reference to classified substances and mixtures those hazard classifications which are newly introduced by the GHS.

### V.2.2.1. Abstract of the legislation

Directive 2002/96/EC (“WEEE-Directive”) is based on Article 175(1) of the Treaty. It aims to prevent the generation of electrical and electronic waste and to promote reuse, recycling and other forms of recovery in order to reduce the quantity of such waste to be eliminated, whilst also improving the environmental performance of economic operators involved in its management.

This Directive applies to the following categories of electrical and electronic equipment:

- large and small household appliances;
- IT and telecommunications equipment;
- consumer equipment;
- lighting equipment;
- electrical and electronic tools (with the exception of large -scale stationary industrial tools);
- toys, leisure and sports equipment;
- medical devices (with the exception of implanted and infected products);

- monitoring and control instruments;
- automatic dispensers.

Member States are to encourage the design and production of electrical and electronic equipment which take into account and facilitate dismantling and recovery, in particular the reuse and recycling of waste electrical and electronic equipment. They are to minimise the disposal of waste electrical and electronic equipment (WEEE) as unsorted municipal waste and are to set up separate collection systems for WEEE. In the case of electrical and electronic waste, Member States are to ensure that, as from 13 August 2005, the return of contaminated waste presenting a risk to the health and safety of personnel may be refused. Other provisions relate to take-back systems and to charges for the return of such waste.

Producers must make provision for the collection of waste that is not from private households. Member States must ensure that all waste electrical and electronic equipment is transported to authorised treatment facilities.

By 31 December 2006 at the latest, a rate of separate collection of at least 4 kg on average per inhabitant per year of waste electrical and electronic equipment from private households must be achieved. A new target rate to be set at a later date is to be achieved by 31 December 2008.

### **Treatment and recovery**

Producers of electrical and electronic equipment must apply the best available treatment, recovery and recycling techniques. Such treatment is to include the removal of fluids and selective treatment in accordance with Annex II to the Directive. Waste treatment and storage must be in conformity with Annex III to the Directive.

Establishments responsible for treatment operations must obtain a permit from the competent authorities. They are encouraged to participate in the Community eco-management and audit scheme (EMAS). With a view to minimising the disposal of WEEE as unsorted municipal waste and to facilitating its separate collection, Member States shall ensure that producers appropriately mark electrical and electronic equipment put on the market after 13 August 2005 with the symbol shown in Annex IV to the WEEE-Directive.

Treatment operations may also be undertaken outside the Member State concerned, or even outside the Community, subject to compliance with Council Regulation (EEC) No 259/93.

Producers must set up systems for the recovery of waste electrical and electronic equipment collected separately. Defined rates of recovery by an average weight per appliance are set by the WEEE-Directive, to be met by 31 December 2006.

By 13 August 2005, producers must provide for the financing of the collection, treatment, recovery and environmentally sound disposal of waste electrical and electronic equipment. In the case of products placed on the market later than 13 August 2005, each producer is responsible for providing financing in respect of his own products.

### **Information**

Users of electrical and electronic equipment in private households must have access to the necessary information on the requirement not to mix this type of waste with unsorted municipal waste and to ensure separate collection, collection and take-back systems, their role in the recovery of waste, the effects of such waste on the environment and

health, and the meaning of the symbol which must appear on the packaging of such equipment (a crossed-out wheeled bin).

For each new type of electrical or electronic equipment, producers must provide, within one year after it is placed on the market, information on its reuse and treatment. Such information is to identify the components and materials present in the equipment and the location of dangerous substances and preparations. Such information must be communicated to reuse centres and treatment and recycling facilities. Producers of electrical and electronic equipment placed on the market as from 13 August 2005 will be identifiable by a mark on each appliance.

### **Reporting and penalties**

Member States are to draw up a register of producers and keep information on the quantities and categories of electrical and electronic equipment placed on the market, collected, recycled and recovered in their territory. Every three years, they must also send a report to the Commission on the implementation of this Directive. The first such report will cover the 2004 -2006 period. The Commission is then to publish a report on the same subject within nine months after receiving the reports from the Member States.

Member States are to determine the penalties applicable to breaches of this Directive.

### **Directive 2002/95/EC**

The use of hazardous substances in this type of equipment is further regulated by **Directive 2002/95/EC** on the use of certain hazardous substances in electrical and electronic equipment. It covers the same scope as the WEEE -Directive on waste electrical and electronic equipment (except for medical devices and monitoring and control instruments). It also applies to electric light bulbs and luminaires in households.

From 1 July 2006, lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBBs) and polybrominated diphenyl ethers (PBDEs) in electrical and electronic equipment must be replaced by other substances. However, as it is not always possible to completely abandon these substances, the Commission provides for a tolerance level of 0.1% for lead, mercury, hexavalent chromium, polybrominated biphenyls (PBBs) and polybrominated diphenyl ethers (PBDEs), and a tolerance level of 0.01% for cadmium. In addition, certain uses specified in the Annex to the Directive are tolerated.

On 6 June 2005 the Commission proposed reviewing the provisions of the Directive, in order to adapt the list of exempt uses so as to take account of technical progress.

### **V.2.2.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS**

With regard to classification and labelling provisions, the following links could be identified:

#### **Directive 2002/96/EC, Article 3, Definitions:**

(l) "dangerous substance or preparation" means any substance or preparation which has to be considered dangerous under Council Directive 67/548/EEC(13) or Directive 1999/45/EC of the European Parliament and of the Council ;  
...

#### **Directive 2002/96/EC, Article 11, Information for treatment facilities:**

1. In order to facilitate the reuse 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 reuse and treatment information for each type of new EEE put on the market within one year after the equipment is put on the market. This information shall identify, as far as it is needed by reuse centres, 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 preparations in EEE. It shall be made available to reuse centres, 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).

#### Annex II to Directive 2002/96/EC, Selective treatment for materials and components of waste electrical and electronic equipment in accordance with Article 6.1

1. As a minimum the following substances, preparations and components have to be removed from any separately collected WEEE:

- components containing refractory ceramic fibres as described in Commission Directive 97/69/EC of 5 December 1997 adapting to technical progress Council Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances(2), ...

In Directive 2002/95/EC, no further reference to classification and labelling provisions is made. Instead, it is referred to defined substances, cf. Article 4, Prevention:

1. Member States shall ensure that, from 1 July 2006, new electrical and electronic equipment put on the market does not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE). National measures restricting or prohibiting the use of these substances in electrical and electronic equipment which were adopted in line with Community legislation before the adoption of this Directive may be maintained until 1 July 2006.

As can be seen from the quotations above, it is only Article 11.1 of Directive 2002/96/EC to derive legal obligations from the classification of substances as dangerous according to the criteria of Council Directive 67/548/EEC. In this connection, it could be of relevance that additional substances and mixtures are expected to be classified under GHS, compared to the current situation, cf. Table V.3 of Part I and Annex I to this study.

### **V.2.2.3. Suggestions how to minimise potential effects of the GHS**

In order to minimise potential effects related to additional classification under GHS, it is proposed to exempt from the reference to classified substances and preparations (GHS terminology: "mixtures") those hazard classifications (classes and categories / types / divisions) which are newly introduced by the GHS, in accordance with **Solution 1**, cf. Part I of this study. The respective classifications are listed in Table VI.1 of Part I.

With regard to the reclassification of current entries in Annex I to Directive 67/548/EEC, the GHS Regulation will provide for conversions for CMR and respiratory sensitisers on the basis of equivalent criteria. It is planned to carry them over to Annex VI to the GHS Regulation. Non-harmonised, but classified CMRs can easily be reclassified by using the conversion table in Annex VII.

### V.2.3. Legislation on Batteries and Accumulators

- **Council Directive 91/157/EEC of 18 March 1991 on batteries and accumulators containing certain dangerous substances**
- **Proposal for a Directive of the European Parliament and the Council on batteries and accumulators and spent batteries and accumulators, 2002/0282 COD**

<http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31991L0157:EN:HTML>

[http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003\\_0723en01.pdf](http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003_0723en01.pdf)

The legislation on batteries and accumulators was examined because the wording of the title Council Directive 91/157/EEC contains the term “dangerous substances”. However, the legislation does not reveal a link to classification and labelling provisions. Therefore, the GHS will have no effect, either.

#### V.2.3.1. Abstract of the legislation

Council Directive 91/157/EEC is based on Article 95 of the Treaty. It prohibits, with effect from 1 January 1993, the placing on the market of:

- manganese alkaline batteries designed for prolonged use in extreme conditions and containing more than 0.05% by weight of mercury;
- any other alkaline battery with a mercury content of more than 0.025% by weight.

Directive 98/101/EC tightened up these standards sharply as of 1 January 2000, the date on which Member States prohibited the marketing of batteries and accumulators containing more than 0.0005% of mercury by weight. The same applies to appliances incorporating such batteries and accumulators.

Button cells and batteries composed of button cells with a mercury content of no more than 2 % by weight shall be exempted from this prohibition. Member States must draw up programmes aimed primarily at reducing the heavy-metal content of batteries and accumulators.

Under these programmes, Member States must encourage the separate collection of batteries and accumulators with a view to their recovery or ultimate disposal. The batteries and accumulators, or the appliances in which they are incorporated, must be marked in such a way as to indicate separate collection and recycling requirements and heavy-metal content.

In July 2006, the Conciliation Committee approved a joint text for a new Directive which would repeal the current legislation on batteries and accumulators, i.e. Directives 91/157/EEC, 1993/86/EEC and 98/101/EC.

**V.2.3.2. Analysis of the links to classification and labelling provisions and anticipation of the potential effects of the GHS**

Neither Council Directive 91/157/EEC and subsequent amendments nor the joint text for the new Directive as approved by the Conciliation Committee in July 2006 reveal a link to classification and labelling provisions according to Directive 67/548/EEC . The issues raised pertain mainly to the content of heavy metals such as mercury, lead and cadmium in batteries and accumulators.

Since no reference is made to classification criteria in the legislation, the GHS have no effect, either.

**V.2.3.3. Suggestions how to minimise potential effects of the GHS**

None.

# Annex I - Studies & Statements on GHS Hazard Classifications

## I. Physical Hazards

Basic information related to physical hazards is provided by the documents ECB1/75/01 -Part A. rev.1 and ECB1/75/01 -Part C2.

### I.1. Explosives (Chapter 2.1 GHS)

1. The EU system covers substances, whereas the GHS covers substances as packaged and pyrotechnic articles. The GHS classification comprising 6 divisions corresponds to class 1 of UN/ADR.
2. The EU system examines the ease of initiation by mechanical and thermal stimuli whereas the GHS is primarily concerned with the effects of initiation.
3. The EU classifies on the basis of (some of) the intrinsic properties of the material whereas the GHS finally classifies as affected by the containment (package).
4. The GHS has more tests and identifies more properties than the EU system. The GHS has detonation and deflagration tests.
5. EU risk phrase *R3* covers classified unstable substances whereas the GHS does not classify them within Divisions 1.1 to 1.6, but as *unstable explosive*.
6. The GHS system gives precedence to a classification as *Organic Peroxide* or *Self-Reactive Substance or Mixture*, explosive properties being considered a secondary hazard, whereas the EU will always give precedence to explosive properties, cf. Table I.1 below.
7. Further references to the EU test series A.14 is necessary, in order to maintain the current scope of substances which are classified under Directive 67/548/EEC.
8. In the GHS, probably most unintentional explosives (i.e. those that give a positive in a Series 2 test, but not in a Series 6 test) may not be classified, although they could have explosive properties (unpackaged) in some use settings (e.g. workplace). This issue was recognised at UN level, cf. UN documents ST/SG/AC.10/C.3/2005/36 and ST/SG/AC.10/C.4/2005/5: Explosive properties are considered so important that they should always have priority even if the substances or mixtures are assigned to other classes. For this reason a test series for explosive properties should be implemented in the GHS for all substances which might present an explosive hazard, i.e. test series A.14 according to Dir 67/548/EEC.

<b>EU</b>	<b>Explosive (E) R2, R3</b>	<b>Oxidising (O) R7</b>
<b>Identification by</b>	<b>Testing</b>	<b>Chemical Structure</b>
<b>GHS</b>	<b>Explosives</b>	
	<b>Organic Peroxides Type A, Type B</b>	
	<b>Self-Reactive Substances and Mixtures Type A, Type B</b>	
<b>RTDG (Transport)</b>	<b>Class 1 – Explosives</b>	
	<b>Class 5 – Oxidising Substances and Organic Peroxides Division 5.2 – Organic Peroxides Type A, Type B</b>	
	<b>Self-Reactive Substances and Mixtures Type A, Type B</b>	

Table I.1: Explosive properties: Conversion from EU *Explosive* and *Oxidising R7* to the GHS hazard classes *Explosives*, *Organic Peroxides* and *Self-Reactive Substances and Mixtures*

Further reading

- A.K. Brown, GHS - EU Explosives Comparison, July 2005

**I.2. Flammable Gases (Chapter 2.2 GH S)**

The EU system has test A .11 and classifies into a single hazard level (F+; R12) whereas the GHS classifies into two hazard categories.

**I.3. Flammable Aerosols (Chapter 2. 3 GHS)**

1. The GHS classifies into two hazard categories.
2. Two types of aerosol are characterised: spray aerosols and foam aerosols.

#### I.4. Oxidising Gases (Chapter 2.4 GHS)

The EU system and the GHS are approximately equivalent in coverage.

#### I.5. Gases under Pressure (Chapter 2.5 GHS)

1. This hazard classification has not existed in the EU legislation. It is based on hazards related to physical state, and not to the intrinsic properties.
2. Corrosive gases are not covered; criteria are needed.

#### I.6. Flammable Liquids (Chapter 2.6 GHS)

1. The GHS classifies into four hazard categories. GHS category 1 -3 cover the EU categories of danger *Extremely Flammable (F+; R12)*, *Highly Flammable (F; R11)* and *Flammable (R10)*, cf. Table I.2 below. GHS hazard category 1 covers effectively the same substances as the EU category *Extremely Flammable (F+)*.

EU Classification; R-phrase	EU Criteria	Flammable Liquids – Subcategory	GHS Criteria
Extremely Flammable F+, R12	$T_{fl} < 0\text{°C}$ and $T_{b,i} > 35\text{°C}$	category 1	$T_{fl} < 23\text{°C}$ and $T_{b,i} > 35\text{°C}$
Highly Flammable F, R11	$T_{fl} < 21\text{°C}$	category 2	$T_{fl} < 23\text{°C}$ and $T_{b,i} > 35\text{°C}$
Flammable R10	$21\text{°C} < T_{fl} < 55\text{°C}$	category 3	$23\text{°C} < T_{fl} < 60\text{°C}$
None	None	category 4	$60\text{°C} < T_{fl} < 93\text{°C}$

Table I.2: *Flammable Liquids* – Comparison of Categories ;  
 $T_{fl}$  = flash point,  $T_{b,i}$  = initial boiling point

2. There are some small differences in the limiting values for flash points between the EU categories of danger and the GHS hazard categories. Differences in the flash point limiting values are likely to have very little effect; they can probably not be distinguished from measurement errors.
3. For GHS hazard category 3, the escape clause in Note 2 which is based on combustibility is different to that in 2.2.5 of Annex VI of Directive 67/548/EEC.
4. The GHS has a further escape clause for viscous liquids in Note 3 that is contained in the EU land transport regulations. Some mixtures which are classified with EU *R10* will probably become declassified.

### **I.7. Flammable Solids (Chapter 2.7 GHS)**

1. The EU system has a test A10 and classifies into a single hazard level, whereas the GHS has a very similar test and classifies into two hazard categories.
2. The range of intrinsic properties and substances covered by the two systems are very similar.

### **I.8. Self-Reactive Substances and Mixtures (Chapter 2.8 GHS)**

1. The GHS hazard class covers thermally unstable substances and mixtures, capable of exothermic decomposition, such as initiators and blowing agents.
2. The GHS also covers explosive properties: Any self-reactive substance or mixture that possesses explosive properties will be defined as *Self-Reactive Type A or Type B* substance or mixture.
3. The EU system classifies GHS Type A and Type B substances and mixtures as *Explosive (E)* by testing.

### **I.9. Pyrophoric Liquids (Chapter 2.9 GHS)**

1. The EU system subsumes pyrophoric liquids under the category of danger *Highly Flammable (F)* and attributes to them risk phrase R17, cf. Table I.3 and I.4 below.
2. The EU system and the GHS have the same tests and criteria.

### **I.10. Pyrophoric Solids (Chapter 2.10 GHS)**

1. The EU system subsumes pyrophoric solids under the category of danger *Highly Flammable (F)* and attributes to them risk phrase R17, cf. Table I.3 and I.4 below.
2. The EU system and the GHS have the same tests and criteria.

<b>EU</b>	<b>Highly Flammable (F) R17</b>	
<b>Self-ignition time</b>	<b>5 min</b>	<b>hours or days</b>
<b>GHS</b>	<b>Pyrophoric Liquids</b>	<b>Self-Heating Substances and Mixtures (large amounts)</b>
	<b>Pyrophoric Solids</b>	
<b>RTDG (Transport)</b>	<b>Class 4, Division 4.2 Packaging Group I</b>	<b>Class 4, Division 4.2 Packaging Group II</b>
		<b>Class 4, Division 4.2 Packaging Group III</b>

**Table I.3:** Pyrophoric and self-heating properties: Conversion from E U *Highly Flammable (F)* to the GHS hazard classes *Pyrophoric Liquids*, *Pyrophoric Solids* and *Self-Heating Substances and Mixtures* (correspondence not clear)

### **I.11. Self-Heating Substances and Mixtures (Chapter 2.11 GHS)**

1. This GHS hazard class (2 subcategories ) is not covered by the current system of classification and labelling. It is sometimes stated that EU risk phrase *R17* might be applicable to oxidative *Self-Heating Substances and Mixtures*, cf. Table I.3 above and Table I.4 below.
2. In general, this hazard class has particular relevance for storage of substances classified as self-heating, particularly in bulk phase. It covers many substances, such as ingredients of washing powders, charcoal, coal, fine particles of Iron(II)oxide etc.

### **I.12. Substances and Mixtures which, in Contact with Water, Emit Flammable Gases (Chapter 2.12 GHS)**

1. The EU system and the GHS are the same, but the GHS classifies into three subcategories and the EU only has a single hazard level, namely *Highly Flammable (F)*, with risk phrase *R15*, cf. Table I.4 below.

<b>EU</b>	<b>Highly Flammable (F)</b> <b>R11</b> <b>“Highly flammable”</b> <b>Liquids</b>	<b>Highly Flammable (F)</b> <b>R11</b> <b>“Highly flammable”</b> <b>Solids</b>	<b>Highly Flammable (F)</b> <b>R15</b> <b>“Contact with water liberates extremely flammable gases”</b>	<b>Highly Flammable (F)</b> <b>R17</b> <b>“Spontaneously flammable in air”</b>
<b>GHS</b>	<b>Flammable Liquids (Cat. 2)</b>	<b>Flammable Solids</b>	<b>Substances and mixtures which, in contact with water, emit flammable gases</b>	<b>Pyrophoric Liquids</b> <b>Pyrophoric Solids</b>

Table I.4: Conversion from EU *Highly Flammable (F)* to various GHS hazard classes (GHS *Self-Reactives* not included)

### I.13. Oxidising Liquids (Chapter 2.13 GHS)

1. GHS classifies into three subcategories which will cover substances and mixtures classified in the current EU system as *Oxidising (O)*, *R8*, cf. Table I.5 below.
2. GHS category 1 corresponds also to EU risk phrase *R9*.

<b>EU</b>	<b>Oxidising (O) R9 Explosion</b>	<b>Oxidising (O) R8 Spontaneous ignition</b>			<b>Oxidising (O) R8 Mean pressure rise time less than or equal to reference mixture</b>
<b>Reference mixture (1:1)</b>	none	none	50% perchloric acid and cellulose	40% aqueous sodium chlorate solution and cellulose	65% aqueous nitric acid and cellulose
<b>GHS</b>	<b>Category 1 Hazard Statement assumes explosion</b>	<b>Category 1 Spontaneous ignition Hazard Statement assumes fire</b>	<b>Category 1 Mean pressure rise time less than reference mixture</b>	<b>Category 2 Mean pressure rise time less than or equal to reference mixture</b>	<b>Category 3 Mean pressure rise time less than or equal to reference mixture</b>

**Table I.5:** Liquid substances and mixtures: Conversion from EU *Oxidising (O)* to GHS hazard class *Oxidising Liquids* on the basis of testing criteria. The mean pressure rise time is the mean of the measured times for a mixture under test to produce a pressure rise from 690 kPa to 2070 kPa above atmospheric. The sample-to-cellulose ratio is always 1:1 (by mass)

#### I.14. Oxidising Solids (Chapter 2.14 GHS)

1. The GHS will permit differentiation between 3 subcategories, whereas the EU system has one criterion and two risk phrases (*R8*, *R9*) with no criteria to permit differentiation.
2. The GHS may classify more substances.

### **I.15. Organic Peroxides (Chapter 2.15 GHS)**

1. The EU classifies such substances and mixtures as *Oxidising (O)* or *Explosive (E)*, cf. Table I.1 above. The classification as EU *Oxidising (O)* is based upon chemical structure.
2. The GHS classification is based upon chemical structure and on tests and criteria.
3. GHS hazard class *Organic Peroxides* also covers explosive properties. An organic peroxide that possesses explosive properties will be classified as *Organic Peroxide Type A or Type B* substance or mixture.
4. In contrast, the EU system classifies GHS *Type A and Type B* substances and mixtures as *Explosive (E)* (by testing) and, in the case of organic peroxides (chemical structure deciding), as *Oxidising (O)*.
5. Both the EU system and the GHS have escape clauses for the classification which is based on the percentage of available oxygen (slightly different figures). The GHS will cover slightly less due to the available oxygen clause. However, this effect is considered to be negligible as most substances in commerce significantly exceed the figures.

NB: Organic peroxides are not oxidisers, but energetically unstable substances.

### **I.16. Corrosive to Metals (Chapter 2.16 GHS)**

1. This would be a new classification – the EU has no equivalent criteria.
2. There are a limited number of substances concerned.

## II. Health Hazards

Basic information related to health hazards is provided by the documents

- European Commission: Technical Assistance to the European Commission on the Implementation of the GHS (Ökopol, 2004)  
[http://europa.eu.int/comm/enterprise/reach/ghs\\_en.htm](http://europa.eu.int/comm/enterprise/reach/ghs_en.htm)
- DG ENTR, Comparison between EU and GHS Criteria, Human Health and Environment, June 2005  
[http://europa.eu.int/comm/enterprise/reach/docs/ghs/ghs\\_comparison\\_classifications.pdf](http://europa.eu.int/comm/enterprise/reach/docs/ghs/ghs_comparison_classifications.pdf)

### II.1. Acute Toxicity (Chapter 3.1 GHS)

1. Both the EU system and the GHS take account of different routes of uptake, i.e. oral, dermal and inhalation.
2. In the GHS, the LD<sub>50</sub> / LC<sub>50</sub> ranges of the individual categories do not always coincide with the ranges of the corresponding EU categories of danger, cf. Table II.1 below (oral and dermal route of uptake). For example, the current EU category *Very Toxic* (T+) for the oral route of uptake ranges from 0 • LD<sub>50</sub> • 25 mg/kg, while GHS category 1 ranges from 0 • LD<sub>50</sub> • 5 mg/kg and category 2 from 5 • LD<sub>50</sub> • 50 mg/kg. The EU category *Toxic* (T) ranges from 25 • LD<sub>50</sub> • 200 mg/kg for the oral route while GHS category 3 ranges from 50 • LD<sub>50</sub> • 300 mg/kg.

#### 1. Acute Toxicity - Oral

<b>EU</b>	<b>T<sup>+</sup> R28</b>		<b>T R25</b>			<b>Xn R22</b>	
<b>LD<sub>50</sub> (*)</b>	≤ 5	5-25	25-50	50-200	200-300	300-2000	2000-5000
<b>GHS</b>	<b>Cat. 1</b>	<b>Category 2</b>		<b>Category 3</b>		<b>Category 4</b>	<b>Category 5</b>

## 2. Acute Toxicity - Dermal

<b>EU</b>	T <sup>+</sup> R27	T R24			Xn R21	
<b>LD<sub>50</sub></b>	≤ 50	50-200	200-400	400-1000	1000-2000	2000-5000
<b>GHS</b>	<b>Category 1</b>	Category 2	Category 3		Category 4	Category 5

Table II.1: Category ranges for acute oral and dermal toxicity under EU legislation and the GHS

- The number of substances classified in a defined category is more or less proportional to the respective LD<sub>50</sub> / LC<sub>50</sub> range. For the example of the oral route of uptake, this means that GHS *category 1 and 2* will comprise more classified substances than EU *Very Toxic*, and GHS *category 3 (or 2 and 3)* will comprise more substances than EU *Toxic*.
- For the evaluation of the toxicity of a mixture, the GHS provides for two different methods: the GHS / ATE method and the GHS / LD<sub>50</sub> method. In general, it will be the decision of sectors which method they will favour: The GHS / ATE method will presumably be simpler and least expensive. For this reason, it will probably be used most commonly. However, each enterprise will need to consider inter alia the availability of data for the ingredients of their mixtures, the cost of testing which will generally be higher for mixtures with many components, whether use of animals should be avoided for business / political reasons and whether the result given by the least costly GHS / ATE method predicts the classification with sufficient precision.
- The application of the GHS / ATE method and the GHS / LD<sub>50</sub> method may lead to different classification results for the same mixture, as is shown in detail for one-component mixtures in the Förster / Wiertulla study. Unfortunately, it cannot be predicted if the classification of a multi-ingredient mixture as derived by one of the GHS calculation approaches will deviate from the most closely corresponding classification as derived from the EU conventional calculation method, cf. Annex II, Part A of Directive 1999/45/EC – available studies provide conclusive answers for one-component mixtures only. At least from a theoretical point of view, it is quite probable that migration of individual multi-ingredient mixtures to lower or upper toxicity ranges may occur under GHS. This is confirmed by the Monte-Carlo simulation performed in the context of the RPA impact assessment (May 2006).

6. The GHS uses formula 3.1.3.6.2.3 for the calculation of the classification of a mixture in case there is insufficient knowledge about the classifications of its ingredients ( $C_{\text{unknown}} > 10\%$ ). This formula will classify the more severe the less the classifications of the ingredients are known.
7. Apart from the classification of a substance or mixture, the conversion of the reference to a particular EU category to a (a) defined GHS category (ies) in a particular downstream act is crucial. For the example of the oral route of uptake, it will then be of relevance if the reference to EU *Very Toxic* is shifted to GHS category 1 or to GHS category 1 and 2 in future. In the former case, less substances and mixtures will probably be caught compared to the current situation, cf. above. In the latter case, the opposite could occur in theory. A related situation may arise for *Toxic*: Will the reference to *Toxic* be replaced by GHS category 3 or by GHS category 2 and 3? In the former case, a wider LD<sub>50</sub> range is covered, due to the upper limit being LD<sub>50</sub> = 300 mg/kg body weight. In the latter case, this trend is even more pronounced because the lower LD<sub>50</sub> limit would be lowered from 25 to 5 mg/kg bw. As a consequence of both cases, more substances and mixtures could potentially be caught. The situation and the underlying reasoning for the other routes of uptake are similar, though not completely the same as for the oral pathway.
8. In December 2005, the German delegation reported on recent work related to the application of the additivity formula for the calculation of the toxicity of gas mixtures at the UN SCE GHS meeting. Starting point of the analysis is that the additivity formula is said not to be applicable to gas mixtures. Indeed, classification only begins at gas concentrations which are far above human fatal intoxications: Use of the GHS additivity formula will only lead to safe values for gas mixtures in case the rat LC<sub>50</sub> is more than one order of magnitude lower than the human intoxication concentration which is very seldomly the case. This suggests, however, that the formula itself does not fail, but that the cut-off concentrations are too low which have been set for the classification of gaseous substances. In so far, a solution to the problem would be to use higher cut-off concentrations for gas substance classification under GHS, cf. the UN document below.

#### Further reading

- ECB documents CAL-TASK1-2/015, CAL-TASK1-2/029, CAL-TASK1-2/030
- R.-U. Förster, M. Wiertulla, Classification of substances and preparations – comparison of the EU and the Globally Harmonised System. November 2005
- Genevieve Hilgers, Comparison of criteria for the classification of substances between the Global Harmonisation and EU systems, August 25, 1999
- G.H. Holland, Verification of a Mathematical Method for the Estimation of the Acute Ingestion Hazard of Detergent Preparations, *Toxic. In Vitro* Vol. 8, No. 6, 1994
- ENV/JM/HCL(2006)3/REV1: Draft Issue Paper On Toxic Gas Mixtures

## **II.2. Skin Corrosion / Irritation (Chapter 3.2 GHS)**

1. For *skin irritation*, it was stated that the EU and the GHS criteria are equivalent. However, it has been stated in another source that more substances might be classified under GHS compared to the current situation. This would be due to higher mean values for erythema/eschar or oedema.: Whereas the EU legislation requires a mean value of  $\bullet 2$  for

the classification with R38, the GHS will require a mean value between 2.3 and 4 for the classification as *skin irritant / category 2*.

- For *skin corrosion / irritation*, more mixtures will probably be classified under GHS compared to the current legislation. This will partly be due to lower concentrations limits under GHS, resulting in a bigger interval for ingredient concentration to be considered for the classification of the mixture, cf. Table II.2 below:

EU category of danger	EU concentration limit	Corresponding GHS hazard classification	GHS concentration limit
Corrosive (C), R35	5%	Skin corrosion, category 1A	3%
Corrosive (C), R34	10%	Skin corrosion, cat. 1B and 1C	5%
Irritant (Xi), R38	20%	Skin irritation, category 2	10%

**Table II.2:** Concentration limits for the classification of mixtures containing *skin corrosive or skin irritant* substances

- Another potential driver for the classification of additional mixtures for the hazards *skin corrosion / irritation and serious eye damage / eye irritation* is the calculation method used under GHS. This effect was demonstrated by Eeckhout et al. who applied the EU CCM and the GHS standardised approach to the following formulations: 100, 38, 20 and 40 for laundry powder detergents, laundry liquid detergents, all purpose cleaner/acid liquid cleaner and hand dishwashing liquids respectively. The outcome was firstly that the EU CCM better reflected real testing results and secondly that numerous additional detergents were classified under GHS or saw a more severe classification, respectively. For example, for skin irritation category 2 (R 38) the average number of detergents subject to classification was shown to rise by 42%, cf. Table II.3 below. Of course, there are also other examples, e.g. the average number of detergents subject to *serious eye damage / eye irritation* category 2 (=R36) would fall by 11% under GHS. However, the feature of down-classification has obviously minor weight than up-classification. In the formulations considered, only surfactant ingredients have been taken into account. This means that the calculations may underestimate the effect of the GHS on detergent products.

Classification	Laundry powder detergent		Laundry liquid detergent		All purpose cleaner / acid liquid cleaner		Dishwashing liquid		Average	
	Based on EU CCM	GHS	Based on EU CCM	GHS	Based on EU CCM	GHS	Based on EU CCM	GHS	Based on EU CCM	GHS
1. • Skin corrosion, Cat. 1A (= R35, R34)	0 %	5 %	0 %	13 %	0 %	0 %	0 %	0 %	0 %	4.5 %
• Skin corrosion, Cat. 1B and IC (=R38)	22 %	94 %	84 %	87 %	15 %	95 %	87,5 %	100 %	52 %	94 %
2. • Irreversible effects on the eye (=R41)	85 %	100 %	97 %	100 %	40 %	100 %	97,5 %	100 %	80 %	100 %
• Irritant to eyes, Cat. 2A (=R36)	15 %	0 %	3 %	0 %	25 %	0 %	2,5 %	0 %	11 %	0 %
• Irritant to eyes, Cat. 2B (=R36)	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %

Table II.3: Comparison of the EU and the GHS classification for 198 detergent products

Further reading

- Genevieve Hilgers, Comparison of criteria for the classification of substances between the Global Harmonisation and EU systems, August 25, 1999
- Genevieve Hilgers, Impact of GHS standardized approach of skin/eye irritation/corrosion on AISE products, March 2001

### II.3. Serious Eye Damage / Eye Irritation (Chapter 3.3 GHS)

1. For *serious eye damage / eye irritation*, it was stated that the EU and the GHS criteria are equivalent. However, it has been stated in another source that several additional and more conservative criteria (factor 2 or 3) could be the reason for an increased number of classified substances compared to the current situation:
  - *Serious eye damage / eye irritation category 1* presents several additional and more conservative criteria vs. the Xi, R41 criteria: in case three animals are tested, iritis scores higher than 1.5 will trigger a classification in the GHS while only a score equal to 2 would trigger a classification in the EU system;
  - *Serious eye damage / eye irritation category 2* also presents several additional and more conservative criteria vs. the R36 criteria:
    - Ø corneal opacity score of  $\geq 1$  would trigger a classification in the harmonized system while only a score of  $\geq 2$  and  $< 3$  would lead to classification in the EU system ;
    - Ø conjunctival redness score of  $\geq 2$  would trigger a classification in the harmonized system while only a score of  $\geq 2.5$  would lead to classification in the EU system contrary to the EU system, the harmonized system indicates that when there is a pronounced variability among animal responses, this information may be taken into account in determining the classification;
  - Contrary to the EU system, the GHS criteria for *serious eye damage / eye irritation* do not cover the case where more than 3 animals would be tested;
  - Contrary to the EU system, a decision tier approach is given as an example of the approach to be used to classify substances. In this tier approach, several factors should be considered before testing is undertaken. Contrary to the EU system, skin irritation data related to historical human or animal experience can trigger the classification of the substance as *eye irritant category 2* (equivalent of R36) even though a lot of data show that there is not always a direct link between skin and eye corrosivity / irritation;
  - Contrary to the EU system, in the decision tier approach a clear reference to SAR for *serious eye damage / eye irritation* and *skin corrosion* is made to classify substances for these hazards, but not to avoid classification;
  - Persistence of the effect (at least 24h in the EU) is not specified in the GHS.
2. For *serious eye damage / eye irritation*, more mixtures will probably be classified under GHS compared to the current legislation. This will partly be due to lower concentration limits under GHS, resulting in a bigger interval for ingredient concentration to be considered for the classification of the mixture, cf. Table II.4 below:

EU category of danger	EU concentration limit	Corresponding GHS hazard classification	GHS concentration limit
Irritant (Xi), R41	10%	Serious eye damage, category 1	3%
Irritant (Xi), R36	20%	Eye irritation, category 2 A	10%

**Table II.4:** Concentration limits for the classification of mixtures containing substances which have *irreversible effects on the eye* or are *irritant to eyes*

- Another reason for additional mixtures to be classified for the hazards *skin corrosion / irritation and serious eye damage / eye irritation* is the calculation method used under GHS, cf. point 3 under II.2, Skin Corrosion / Irritation.

#### Further reading

- Genevieve Hilgers, Comparison of criteria for the classification of substances between the Global Harmonisation and EU systems, August 25, 1999
- Genevieve Hilgers, Impact of GHS standardized approach of skin/eye irritation/corrosion on AISE products, March 2001

#### **II.4. Respiratory or Skin Sensitisation (Chapter 3.4 GHS)**

- The EU and the GHS criteria are equivalent.
- The number of classified substances will not change under GHS.

#### Further reading

- Genevieve Hilgers, Comparison of criteria for the classification of substances between the Global Harmonisation and EU systems, August 25, 1999

#### **II.5. Germ Cell Mutagenicity (Chapter 3.5 GHS)**

- With regard to the mutagenicity hazard, the GHS will not change the classification criteria.

#### **II.6. Carcinogenicity (Chapter 3.6 GHS)**

- The GHS classification criteria are identical to those applied by Directive 67/548/EEC, cf. Annex I to this study. Guidance on how to interpret the data for potentially carcinogenic substances and derive a particular classification is still under development at UN level. The overall conclusion to be drawn is that the GHS will classify the same kind and number of substances and preparations (GHS terminology: “mixtures”) as are currently classified.

#### Further reading

- UN document ST/SG/AC.10/C.4/2005/2

### **II.7. Reproductive Toxicity (Chapter 3.7 GHS)**

1. As to reproductive toxicity the situation is similar to that for carcinogenicity: The GHS classification criteria are identical to those applied by Directive 67/548/EEC, cf. Annex I to this study. Guidance on how to interpret the data for potentially reprotoxic substances and derive a particular classification is still under development at UN level.
2. Following the presentation of the scientific issue paper on reproductive toxicity potency ST/SG/AC.10/C.4/2005/3 (OECD) at the UN SCE GHS meeting in July 2005, the GHS Subcommittee took note of the fact that the available scientific knowledge on this issue does not allow a general revision of the existing classification criteria.

#### Further reading

- UN document ST/SG/AC.10/C.4/2005/3

### **II.8. Specific Target Organ Toxicity<sup>13</sup> / single exposure (Chapter 3.8 GHS)**

1. Due to higher cut-off values for substance classification for all routes of uptake, the GHS will probably classify additional substances and mixtures.

#### Further reading

- ECB document ECBI/24/03 Add.1

### **II.9. Specific Target Organ Toxicity<sup>14</sup> / repeated exposure (Chapter 3.9 GHS)**

1. For *STOT (repeated exposure)*, the GHS criteria for the oral and the dermal route are twice as stringent as the current EU criteria for *R48* so that the number of substances and mixtures classified for this hazard will probably increase compared to the current situation: as indicated in section 15 of ECB document GHS/011/2005, classification as *STOT* after repeated exposure via the oral route will already be triggered when effects are observed in a 90 days study as per <10mg/kg/day (Category 1) and <100 mg/kg/day (Category 2) in the frame of GHS, but only as per <5 mg/kg/day (T, R48) and <50 mg/kg/day (Xn, R48) under the current EU system.

#### Further reading

- ECB document GHS/011/2005
- ECB document ECBI/ 56/04 Rev.1

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<sup>13</sup> Please note that the previous name of this hazard class was “specific target organ systemic toxicity” (STOST). The attribute “systemic” was deleted because this hazard class also covers local effects, cf. UN SCE GHS session July 2006.

<sup>14</sup> idem

## II.10 Aspiration Hazard (Chapter 3.10 GHS)

1. There are strong indications in the GHS criteria that more substances will be classified under GHS: all hydrocarbons with viscosities between 7 cSt and 20.5 cSt at 40°C, which are currently not classified, will be Category 1 under GHS. This includes quite a large number of lower viscosity mineral oils. In addition a large number of hydrocarbon and mineral oil based preparations (e.g. engine oils and industrial oils) and heavy gas oil will be in Category 1.
2. There is also a second difference - the EU criteria have an escape clause such that substances with a surface tension above a certain value need not be classified, even if they meet the other criteria. There is no such escape clause in the GHS criteria. However, there is some information that industry do not generally avail themselves of the surface tension clause and so this may not be significant.

### Further reading

- CONCAWE's Responses to questions from DG ENTR regarding aspiration hazards under GHS, January 2006
- Communication on Aspiration Toxicity versus EU Harmful R65, UK, January 2006

## III. Environmental Hazards

Basic information related to health hazards is provided by the documents

- DG ENTR, Comparison between EU and GHS Criteria, Human Health and Environment, June 2005  
[http://europa.eu.int/comm/enterprise/reach/docs/ghs/ghs\\_comparison\\_classifications.pdf](http://europa.eu.int/comm/enterprise/reach/docs/ghs/ghs_comparison_classifications.pdf)
- Ian Malcomber, Environmental GHS for Beginners. Presentation held at a CEGIC Classification Workshop by 3<sup>rd</sup> October 2005 (Brussels)

### III.1. Hazardous to the aquatic environment (Chapter 4.1 GHS)

1. The classification under GHS reflects the current EU system: Both systems use two hazards, *acute aquatic toxicity* and *chronic aquatic toxicity*, with similar classification criteria. With regard to *acute category 1*, *chronic category 1 and 2*, the GHS will classify approximately the same substances as the current EU system does (N/R50; N/R50-53, N/R51-53). It may happen, however, that the classification may change for individual substances and mixtures, cf. points 4-9 below.
2. Generally, the EU system combines the acute with the chronic toxicity, cf. combination of R-phrases, whereas the GHS puts them in separate hazard categories.
3. The concentration limits for the classification of mixtures are the same for the EU system and the GHS.

4. Endpoints: In the EU, the testing criterion is 72h E<sub>r</sub>C<sub>50</sub> while under GHS, the testing criterion will probably be 72 OR 96h E<sub>r</sub>C<sub>50</sub> for algae (provided exponential growth in the control vessel). The growth rate alone may alter some individual classifications.
5. Bioconcentration: In the EU, the bioconcentration potential cut-offs of log K<sub>OW</sub><3 and BCF<100 become log K<sub>OW</sub><4 and BCF<500. This means that some substances may no longer require classification.
6. Bioconcentration: In contrast to the EU system, bioconcentration will be used for ALL substances, and not only for substances with acute toxicity > 10 mg/l. This means that some previously non-classified substances may require classification.
7. Degradation: Under GHS, inherent test data cannot be used to declassify. Since declassification based on inherent data has not commonly been applied in the past, the effect is likely to be small only.
8. Escape Clause: Under Directive 67/548/EEC applied to substances with acute toxicity >10mg/l, under GHS applied at >1mg/l. This means that some previously classified substances may no longer need classification under GHS.
9. Mixtures: Using the summation method, the introduction of M<sub>i</sub>-factors is to reflect the toxic contribution of components <1 mg/l. In this connection, the introduction of M<sub>i</sub>-factors in the summation method might lead to some mixtures being either classified or more severely classified than they are currently. For example, highly toxic substances could drive an environmental classification at concentrations even below 0.25 %.

### Future Development

The Sub-Committee of the Experts on the Globally Harmonised System of Classification and Labelling of Chemicals (UNSCGH) is responsible for the technical aspect related to the health and environmental hazards. With regard to physical hazards, the Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG) is responsible for updating the GHS. The main functions of the parent committee, the Committee of Experts on the Transport of Dangerous Goods and the Globally Harmonised System of Classification and Labelling of Chemicals (UNCETDG/GHS) are to coordinate strategic and policy issues, to give formal endorsement to recommendations of the sub-committees and to provide the mechanism for channelling these to the UN ECOSOC. Future revisions of the GHS document will get formal adoption by UN ECOSOC on a biennial basis<sup>15</sup>.

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<sup>15</sup> GHS ST/SG/AC.10/30/Rev. 1, 2005, 1.1.3.2

## Annex II – Evaluation of Annex I to Directive 67/548/EEC

A. The following table is taken from the RPA / London Economics impact assessment report :

<b>R-Phrase</b>	<b>Description</b>	<b>No. Annex 1 Substances</b>	<b>No. New Substances in Annex 1</b>
R42	May cause sensitization by inhalation	77	14
R43	May cause sensitization by skin contact	568	409
R48	Danger of serious damage to health by prolonged exposure	118	104
Carcinogen Cat 1		188	1
Carcinogen Cat 2		650	14
Carcinogen Cat 3		134	12
Mutagen Cat 1		0	0
Mutagen Cat 2		176	3
Mutagen Cat 3		77	18
Reprotox Cat 1		17	9
Reprotox Cat 2		66	22
Reprotox Cat 3		105	80
R28	Very Toxic (Oral)	43	2
R26	Toxic (Oral)	150	6
R22	Harmful (Oral)	527	282
R27	Very Toxic (Dermal)	34	1
R24	Toxic (Dermal)	80	7
R21	Harmful (Dermal)	161	33
R41	Serious damage to eye	234	229
R36	Significant damage to eye	350	63
<b>Total Number of Substances Listed in Annex 1</b>		<b>3366</b>	<b>1045</b>

*Source: ECB (2006)*

B. A similar evaluation for R39 (all routes of uptake) and R48 (all routes of uptake) gives the following results:

R39, all routes of uptake	11 substances on Annex I in total
R48, combined with R20, R21 and / or R22	163 substances on Annex I in total
R48, combined with R23, R24 and / or R25	74 substances on Annex I in total