Final Report

"The potential impact on industrial competitiveness of restrictions on certain CMR 1A and 1B substances in articles" - Scoping study for the application of art. 68.2 of REACH to CMR substances requiring priority action”

13 November 2013

Revised 21 November 2013

Contract n° 30-CE-0533337/00-95 under Framework Contract ENTR/29/PP/2010/FC - Lot 1

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A report submitted by ICF International

In association with AMEC

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List of acronyms

ACEA	European Automobile Manufacturers Association
B2B	Business-to-business
BDO	Butanediol
CAAGR	Compound average annual growth rate
CBI	Centre for the Promotion of Imports from developing countries, an Agency of the Netherlands Ministry of Foreign Affairs
CEPE	Association of paints, printing inks and artists' colours in Europe
CFL	Compact fluorescent light bulbs
CMR	Carcinogenic, mutagenic and reproductive toxicant
CoRAP	Community Rolling Action Plan
CPV	Concentrated photovoltaic
CR	Chloroprene rubber
DALY	Disability Adjusted Life Years
Danish EPA	Danish Environmental Protection Agency
DDAC	Didecyldimethylammonium chloride
DINP	Diisononyl phthalate
ECHA	European Chemicals Agency
EC SCCS	European Commission Scientific Committee on Consumer Safety
EPI	Emulsion Polymer Isocyanates
ETAD	Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers
EuPIA	European Printing Ink Association
EVA	Ethylene-Vinyl Acetate Adhesives
FEFCO	European Corrugated Packaging Association
GaN	Gallium nitride
GPS LNA	GPS Low noise amplifier
HAA	Hydroxyl alkyl amide
HICP	Harmonised indices of consumer prices
HLG on KET	High-level group on key enabling technologies
HUD	U.S. Department of Housing and Urban Development
HWPW	Hardwood/plywood
IA	Impact assessment
IDC	International Data Corporation
IPBC	Iodopropynyl butylcarbamate
IR	Infrared
JAS	Japan Agricultural Standards
KET	Key enabling technologies
LCD	Liquid-crystal displays
LED	Light emitting diode
MDF	Medium density fibreboard
MDI	Methylene diphenyl diisocyanate
MMSA	Methanol Market Services Asia
MF	Melamine formaldehyde

MS	Member States
NSRL	No Significant Risk Level
OSB	Oriented Strand Board
OSHA	Occupational Safety and Health Administration (Part of the US Department of Labor)
PA	Protected Access
PB	Particleboard
PBT	Polybutylene terephthalate resins
PF	Phenol-formaldehyde
PRF	Phenol resorcinol formaldehyde
PUF	Polyurethane foam
PV	Photovoltaic
PVC	Polyvinyl chloride
PW	Plywood
RAC	Committee for Risk Assessment
RAR	Risk Assessment Report
RCR	Risk characterization ratios
RF	Resorcinol formaldehyde
RIVM	National Institute for Public Health and the Environment of the Netherlands
RMO	Risk management option
SEA	Socio-economic analysis
SiC	Silicon carbide
SiGe	Silicon germanium
SME	Small and medium enterprise
SML	Specific Migration Limit
SVHC	Substances of very high concern
TURI	Toxic Use Reduction Institute
UF	Urea-formaldehyde
UVCB	Unknown or Variable Composition, Complex Reaction Products, or Biological Materials
VCSEL	Vertical-cavity surface-emitting laser
WEEE	Waste Electrical and Electronic Equipment
WHO	World Health Organisation

Executive summary

Substances that are carcinogenic, mutagenic or toxic to reproduction (CMRs) are of specific concern to the Commission and Member States (MS) due to the long term and serious effects that they may exert on human health and the environment.

The European Union has established REACH (Regulation EC No.1907/2006) to provide an integrated system for the registration, evaluation, authorisation and restrictions of chemicals[1] in the EU. By placing the burden of proof for the safety of chemicals produced and placed on the market on industry, the provisions of the legislation aim to:

- Increase the protection of human health and the environment, including the promotion of alternative methods for the assessment of hazards of substances;
- Improve transparency between all actors;
- Enhance the competitiveness of the European chemical industry, encouraging innovation; and
- Preserve the integrity of the internal market.

"Restrictions" under REACH enable the Commission and the MS to initiate measures to address risks posed by substances at EU level. A standard procedure to prepare and adopt a restriction proposal is outlined in Articles 69 to 73 of REACH. However, specific conditions are also established under Article 68, with Article 68.2 setting specific rules to address risks related to substances classified as CMR category 1A and 1B[2] on their own, in mixtures or in articles, which could be used by consumers and for which restrictions can be proposed by the Commission. If Article 68.2 is used, the standard procedure does not apply and is replaced by a faster procedure with reduced scientific scrutiny and no legal requirement for an assessment of the socio-economic impacts of the restriction.

In principle, all substances[3] manufactured or imported in quantities of one tonne ore above, whether manufactured, imported, placed on the market in the EU, or used on their own or in mixtures must undergo registration under REACH.

Now that the first two registration deadlines for pre-registered substances have passed (for substances having the most hazardous properties[4] and those supplied in quantities greater than 1000 and 100 tonnes per annum) and substances have been notified under the CLP Regulation (for classification and labelling purposes), a more complete picture of the substances registered in the EU market can emerge, including details on where they are used. All CMRs manufactured or imported above one tonne per year should have been registered by the first registration deadline of November 2010. It is possible that CMR potentially present in articles have not been registered because their

[1] In principle, it does not cover radioactive substances, under conditions specified in Article 2(1)(b) of REACH substances for re-exportation or in transit, non-isolated intermediates, the carriage of dangerous substances and dangerous substances in dangerous mixtures by rail, road, inland, sea or air and waste as defined by Directive 2006/12/EC.

[2] CMR category 1A: known to have carcinogenic, mutagenic, toxic for reproduction potential for humans, classification largely based on human evidence. CMR category 1B: presumed to have carcinogenic, mutagenic , toxic for reproduction potential for humans, classification largely based on animal evidence

[3] Obligation does not apply, for example, to polymers or to some substances listed in Annex IV, for which sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties (water, glucose); or listed in Annex V, for which registration is deemed inappropriate or unnecessary and their exemption does not prejudice the objectives of REACH (certain substances occurring in nature under certain specified conditions)

[4] The first registration deadline was for CMRs at or above 1 tonne/year and for substances very toxic to aquatic organisms (R 50/53) at or above 100 tonnes/year as well as other phase-in substances above 1000 tonnes/year. The second registration deadline was for substances at or above 100 tonnes/year and less than 1000 tonnes/year.

tonnage is below 1 tonne per year. CMRs no longer used in the EU could also still be present in the articles, i.e. from historic uses of a substance or imports of non-EU manufactured articles. Hence, there is a need to improve the Commission's and the European Chemicals Agency's (ECHA) knowledge of CMRs in consumer articles.

Study objectives

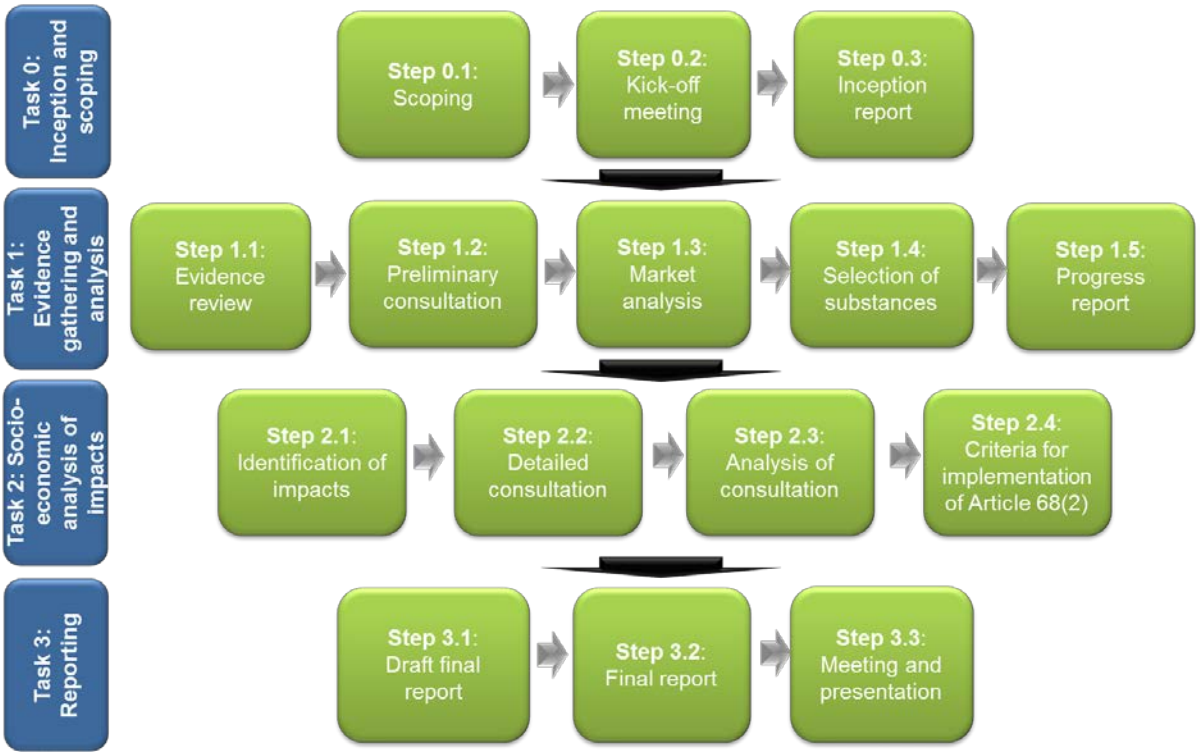
ICF International and AMEC were commissioned to undertake this study on "The potential impact on industrial competitiveness of restrictions on certain CMR 1A and 1B substances in articles - Scoping study for the application of article 68.2 of REACH to CMR substances requiring priority action" between December 2012 and November 2013. The objectives of the study were threefold:

- To collect and analyse information on CMR substances potentially present in articles, looking at uses, market information, market players, and possible alternatives;
- To provide a scoping assessment of the socio-economic impacts of a potential restriction for a short list of 13 CMR substances in articles; and
- To provide advice on the factors to consider before deciding to implement an Article 68.2 simplified restrictions procedure for CMR substances in articles.

Approach

After an initial project scoping, the approach consists of two analytical tasks, followed by a reporting task which brought together the study findings, as shown in Figure 1. The analytical tasks correspond closely to two rounds of consultation with industry (companies and trade associations) and other interested stakeholders (testing bodies, consumer representative organisations and Member State Competent Authorities) which was used to inform the analysis.

Figure 1 Summary of approach

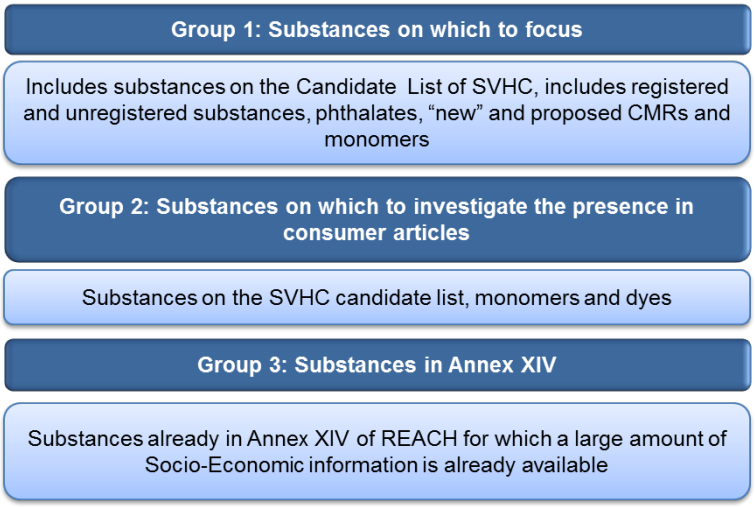


Source: ICF/AMEC

In Task 1, an initial list of 43 CMR substances identified by ECHA from information in the registration dossiers as possibly present in articles was screened to identify 13 substances to be taken forward for

a scoping socio-economic analysis (SEA) (Task 2). Screening in Task 1 removed those substances found not to be used in the production of consumer articles in the EU or present in consumer articles via other means (i.e. in imported consumer articles or as impurities from intermediate production processes). Each identified substance use and related supply chain were subjected to a market analysis, identifying the quantities of each substance present in the EU, the sources of the substance, the leading market players, plus any details of historic uses and the alternatives currently available on the market. The exposure route of the substance from article to consumer was also considered at this stage to determine the exposure potential of each article. The 43 substances selected by ECHA and the Commission are summarised in Figure 2.

Figure 2 Groups of substances considered within the scope of this study



Source: ICF/AMEC

Evidence for the market analysis and subsequent screening was sourced from an extensive review of the literature, which included chemicals databases, registration dossiers, industry studies, risk reduction strategies and completed socio-economic analyses, and journal articles. Supplementing this evidence base was a first round of consultation with relevant stakeholders. The intention of this consultation was to fill gaps in our developing knowledge of the substances and their prevalence in consumer articles. Consultation also helped identify sources of in-depth information on the socio-economic value of these substances in specific uses. A summary of stakeholders responding to the consultation exercise in Task 2 is provided in Figure 3 below. An additional 79 company, 13 industry association and 15 Member State competent authority responses were also received in Task 1 of the study.

Taking into account the guidance produced by ECHA on the impacts, stakeholders and methods to consider when producing a full SEA, scoping SEAs of the 13 selected substances were undertaken in Task 2. Detailed follow-up consultation with industry stakeholders assessed the costs and benefits of the possible restrictions on one or more uses. In each case, stakeholders were asked to present evidence supporting their judgements and, where possible, quantify the relevant impacts. In particular, stakeholders were encouraged to elaborate on the costs to industry (i.e. from retrofitting alternatives, relocating production or changing production processes), and on competitiveness and innovation impacts. The stakeholders contacted in Task 2 are summarised in Table 1.

Table 1 Summary of stakeholder responses to consultation in Task 2

Organisation Type		Number of stakeholders contacted	Number of stakeholders providing responses
Industry Representations	Manufacturers of CMR substances	14	10
	Downstream users (formulators, article manufacturers, etc.)	38	14
Individual companies	Manufacturer/importer of CMR substances	28	17
	Downstream users (formulators, article manufacturers, etc.)	53	20
	Chemical suppliers / distributors	6	5
Public authorities and regulators		3	2
Other stakeholder groups (Trade unions, consumer representations)		2	1
Grand total		**144**	**69**

Source: ICF/AMEC Consultation

The purpose of Task 2 was to use the findings of the scoping SEAs to establish a set of possible criteria that the Commission could use to identify whether an Article 68.2 simplified procedure should be considered for restrictions on CMR substances in consumer articles, and is preferable to a standard Article 69 procedure. Further, the criteria considered should determine the most appropriate scope of any restrictions, and should begin to think about how the developed criteria could be used in the long term, to help in prioritising CMR substances in articles for an Article 68.2 restrictions procedure. This report constitutes the final task of the study.

Findings of substance screening and market analysis (Task 1)

The screening and selection of substances in this task proved challenging. In some cases, a paucity of data made it difficult to establish whether a substance is still used inside or outside the EU, where use/production in the EU had potentially ceased, and therefore whether the substance is present in imported articles in any discernible quantity to pose a concern to human health. Potential alternatives for a substance in a specific use were easier to identity based on documentary evidence and the responses of industry stakeholders. However, quantities of the substance produced, used or imported into the EU were much harder to ascertain. Whether an identified alternative is suitable for a given use was also a difficult to confirm.

Selection of substances was guided by the need to take forward those substances contained in articles in significant volumes and those which have the greatest potential for consumer exposure from their use. It was also agreed to take forward to Task 2 at least one substance from each group and anticipated substances with positive and negative impacts to be representative of the factors any decision criteria will need to cover. A summary of those substances taken forward is provided in Table 2, with explanations of what was known regarding consumer exposure, the availability of substitutes, identified uses of high economic value and rationale for taking forward.

Table 2 Summary of substances selected for Task 2

Substance	Consumer exposure	Substitutability*	Economic value	Rationale for taking forward
Group 1: Substances on which to focus				
1B Non-registered phthalates				
DHNUP	Cannot be excluded	Yes	High (Construction)	Presence in imported articles and availability of alternatives.
1D "new" or proposed "new" CMRs				
Gallium arsenide	No	Limited	High (Critical uses - semiconductors)	Taken forward to Task 2 as a negative example where negligible potential for consumer exposure exists from use in articles.
Dihexyl phthalate	Cannot be excluded	Yes	Medium (PVC articles)	Consumer exposure cannot be excluded and the substance has a wide range of different uses and associated socio-economic values
Formaldehyde	Yes	Yes for some uses	High (widespread)	Provides the opportunity to assess a wide range of impacts in the SEA and is an example where use of Article 68.2 could be difficult due to the complexity of supply chains and its uses. Scope is limited to an examination of specific uses, highlighting a specific range of impacts.
Group 2: Substances on which to investigate the presence in consumer articles				
2A Individual substances				
TGIC	Yes	Yes, for some uses	High (Electronics)	Wide range of consumer articles containing the substance and possible technical performance issues surrounding alternatives.
o-Anisidine	Yes	Yes for some uses	Medium (aesthetics/ performance)	Consumer exposure possible and varied socio-economic value of use in articles, plus potential for imports.
Boric acid & Borax dehydrate	Cannot be excluded (mainly mixtures)	Limited	High (critical uses)	Consumer exposure possible and limited substitutability. As both substances have similar uses, both were assessed together in SEA, avoiding duplication in analysis
2B Monomers				
Ethylene thiourea	Cannot be excluded	Yes, for some uses	Medium (vulcanised rubber)	Large number of consumer articles containing the substance and limited availability of alternatives.
2C Dyes				
Direct Black 38	Yes	Yes	Medium (aesthetic properties in textiles)	Consumer exposure possible and more available information than other dyes.
Group 3: Substances in Annex XIV				
Bis(2-ethylhexyl) phthalate	Yes	Yes	Medium (PVC articles)	High potential for consumer exposure, particularly in minors and the socio-economic value of alternative substances and materials.

Substance	Consumer exposure	Substitutability*	Economic value	Rationale for taking forward
Dibutyl phthalate (DBP)	Yes	Yes	Medium (toys, rainwear, cookware)	Potential for consumer exposure from EU-produced articles and imports, plus the socio-economic impacts.
Tris(2-chloroethyl) phosphate	Yes	Yes	Medium (Flame retardant)	Although use is decreasing as a flame retardant and exposure appears mostly through indoor environment rather than direct consumer contact with the articles, substance introduces interesting issues for scoping SEA.

**Denotes whether identified alternatives are both economically and technically feasible in most uses, including whether there is current market acceptance of their use. A more specific analysis of individual uses and available substitutes can be found in the relevant chapters of the main report.*

Source: ICF/AMEC

Findings of Task 2

The results of the scoping SEAs showed that there is a wide range of factors which could be considered when determining the most appropriate restrictions procedure for CMRs present in consumer articles. They may differ from one case to another and are substance-specific and situation-specific as detailed further on. A summary of the factors identified by substance-specific scoping SEAs are presented in Figure 3 on the next page.

Categories of factors included consideration of availability and economic/technical feasibility of alternatives, the characteristics of relevant supply chains in terms of the types of businesses and their complexity, potential trade implications and critical uses in highly innovative sectors or those of high safety or economic importance.

Regarding human health and environmental factors, whether the substance in the article has potential for consumers exposure in a particular use was found to be important. Another element to be considered is the presence of a threshold (specific concentration limits defined in Annex VI of CLP, or no effect levels agreed by scientific committees). Other elements to be considered are whether the substance is bound within the article, is present in such low quantities that would make monitoring not possible, or compliance with already existing restrictions.

Proposed Decision Criteria

Although Article 68.2 establishes a simplified restrictions procedure for CMR 1A and B present in consumer articles, there is no guidance on under which circumstances or on which substances and uses in articles could be restricted by this simplified procedure (as opposed to adopting a standard restrictions procedure for consumer articles under Article 69 of REACH) and which CMR substances in articles should be made subject to Article 68.2.

In situations where under Article 68.2 a restriction of a CMR in articles might be adopted, there is likely to be no SEA or similar information gathering exercise and so the amount of information available to the Commission may be limited. The decision process must therefore be able to function based on different sources of available information or provide a series of either/or questions to ensure it is flexible for use in assessing different substances and uses in articles.

Figure 3 Substance-specific consideration identified from the scoping SEAs

Consideration/substance (a shaded block in the substance column denotes a positive response)	DHNUP	Gallium arsenide	Dihexyl phthalate	Formaldehyde	TGIC	o-Anisidine	Boric acid & Borax dehydrate	Ethylene thiourea	Direct Black 38	Bis(2-ethylhexyl) phthalate	Dibutyl phthalate (DBP)	Tris(2-chloroethyl) phosphate
Economic and technical												
Are there technically suitable alternatives to EU article producers (in sufficient quantities and if so, are these alternatives affordable in most cases?)?	■	■		■		■	■	■	■			■
If certain uses are already subject to authorisation, is a restriction on the substance in consumer articles necessary to cover imported articles?			■							■	■	■
Is the supply chain complex, making it difficult to be confident that the key uses and users can be identified and hence to estimate the main socio-economic impacts via a simplified restriction?			■	■		■				■	■	
Is EU use negligible (or will it be in certain uses after the sunset date for substances in Annex XIV), meaning that impacts on EU firms are likely to be negligible?									■	■	■	
Could a restriction potentially introduce technical barriers to trade?			■	■								
Is the industry (article producers or importers/suppliers) comprised mainly of SMEs, potentially indicating disproportionate costs (for substances still used in the EU)	■								■			
Are the markets that involve use of the substance quickly moving / innovative, meaning potential presence in different types of articles?		■					■					
Are there critical uses of the substance for which it would be necessary to introduce derogations from any restriction?		■										■
Health and environmental												

Consideration/substance (a shaded block in the substance column denotes a positive response)	DHNUP	Gallium arsenide	Dihexyl phthalate	Formaldehyde	TGIC	o-Anisidine	Boric acid & Borax dehydrate	Ethylene thiourea	Direct Black 38	Bis(2-ethylhexyl) phthalate	Dibutyl phthalate (DBP)	Tris(2-chloroethyl) phosphate
Is there genuinely potential for consumer exposure to the substance in the article (necessary to demonstrate justification for the restriction?)		■		■		■			■			■
Is there potential for co-benefits of a restriction on the substance in other than the consumer area (e.g. reduced worker exposure to CMRs, even if use is shown to be 'safe' in CSRs and even if risk to consumers is likely to be small)?								■				
If phased out in the EU or on the way to being phased out, is there the suggestion, that the substance is being replaced elsewhere, hence limiting the health benefits of a restriction?	■								■			■
Are other uses of the substance already restricted and is there a need for additional restriction to close the remaining gaps?						■			■			
How much uncertainty is there regarding the extent of current use and exposure to the substance and what level of evidence is sufficient to make a decision on restriction?									■			
If the substance is an intermediate, is there knowledge of which substances are derived from it, the products in which they are used and the extent to which they can lead to exposure to the substance from articles (e.g. through decomposition)?						■						
Does the substance have a threshold[5] for effects, meaning the scope of a restriction may need to be limited?			■							■	■	

[5] A threshold is the dose or concentration limit of a substance which is likely to induce an adverse human health effect. Presence of a CMR below an established threshold would indicate that human health is not adversely affected.

With a clear rationale established for a restrictions procedure, the following criteria are focussed on determining whether the Article 68.2 simplified procedure is the most appropriate. A set of draft criteria have been developed and are presented in the decision tree shown in Figure 4.

The purpose of the **first criterion** presented in the middle column of the decision tree is to establish that the relevant substance is present in consumer articles, based on the use of the substance in the production process, any direct use within the article or the degradation of other substances found within the article. Where this cannot be confirmed or refuted from existing information sources, including chemical dossiers and available literature, then consultation with industry stakeholders (producers, article manufacturers, and importers) may be required. If uncertainty remains, greater evidence gathering and data gathering exercise, through an Article 69 procedure is recommended. If it can be reliably proven that the substance is not used or contained in consumer articles then the restrictions process should be ruled out at this stage.

Having confirmed that the substance is contained in consumer articles, the ***second criterion*** asks whether the presence of the substance in a consumer article presents the possibility for ongoing health concern to EU citizens. In such a case, the Commission could take rapid action to mitigate the harm. An emergency simplified restrictions procedure could then be followed, indicated by the broken line in the figure. By ruling out this emergency procedure, the remaining criteria are focussed on determining whether an Article 68.2 simplified procedure is the most appropriate or whether other restrictions procedures (i.e. Article 69) should be considered.

Once the presence of a substance in an article is confirmed, the ***third criterion*** assesses the likelihood of consumer exposure to the substance based on technical grounds. A substance can be bound within a specific material and unlikely to be released during normal consumer use. This was found to be the case with boron compounds found in borosilicate glass as the boron is chemically bonded within the glass material. In the case of gallium arsenide used in semiconductors, the electronic compounds were found to the encapsulated within the consumer electrical article and therefore exposure to the substance is highly unlikely in normal use. In both cases, consumer exposure can be ruled out on technical grounds. When evaluating the likelihood of consumer exposure from a substance in an article, consideration should also be given to the existence of threshold effects. The presence of the substance in articles below a threshold could indicate that the dose or concentrations to which a consumer is exposed is insufficient to induce an adverse human health impact. Where this threshold has been determined for a given substance, any proposed restriction should take this into account and could be a reason for not proceeding with a restrictions procedure at this point in the decision tree.

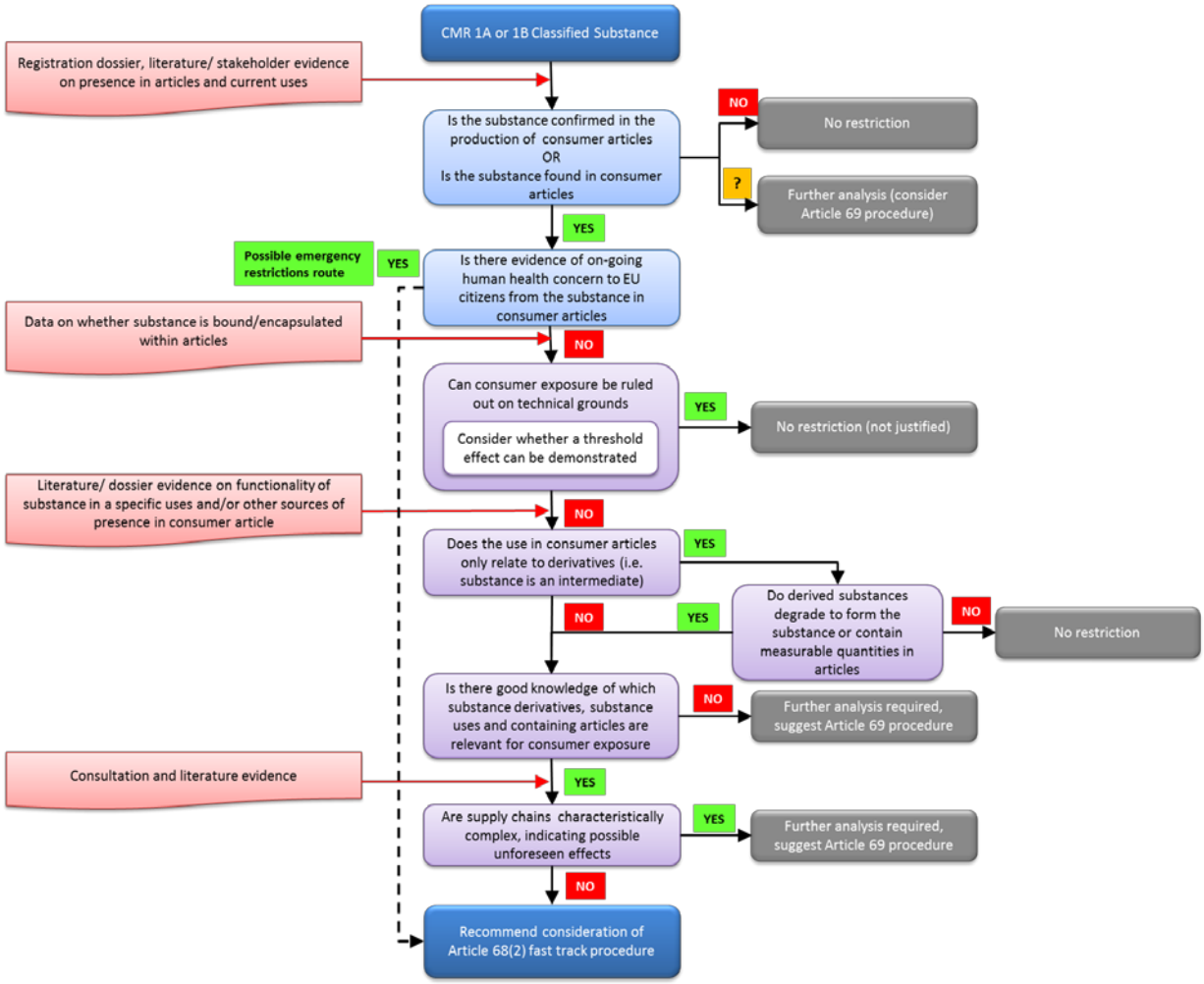
The ***fourth criterion*** is used to consider cases where the CMR of concern is found to be present in the article as an impurity. For this reason, the box to the right asks whether the presence of the substance in articles comes from the use of a derivative of the substance or intermediate in the production process. If this is the case, the presence of the substance in the article as a by-product or from the breaking down of the derivative in the article should be present in measurable quantities.

If the substance is not an intermediate or is found to be present in the articles in sufficient quantities, then the ***fifth criterion*** in the middle column of the flow chart asks whether there is sufficient knowledge of the identified uses, derivatives of degradation and articles containing them for the Article 68.2 procedure to be confidently considered. If there is insufficient information available to make informed judgments, then an Article 69 restriction should be considered to allow more time to investigate uses and human health impacts more thoroughly. At this stage some knowledge of the potential quantity of the substance contained in articles, whether the main source of use is from EU production or imported articles, as well as some indication of how exposure occurs (inhalation, dermal exposure, etc.) should be known to the decision maker.

The decision tree concludes with the ***sixth criterion*** by considering the complexity of the supply chains within which the substance is present. The more complex the supply chain, the greater the potential for unforeseen effects from a simplified procedure. For example, a simplified procedure might miss particular uses or propagate misunderstandings of the technical nature of how a substance is used in the article. Where the supply chain is relatively straightforward and decision maker is confident

the supply chain is complete and understood from the evidence available, then it is recommended that the Article 68.2 simplified procedure is considered. Where the decision maker is still uncertain about the supply chain, Article 69 should be considered.

Figure 4 Deciding whether a substance is appropriate for an Article 68.2 restriction



Source: ICF/AMEC

Once the Article 68.2 route is deemed the most appropriate restrictions procedure, guided by the above criteria, consideration should focus on the scope of any restriction, for example, whether the restriction should apply to all consumer articles containing that substance, a sub-set of articles or whether derogations should apply to specific uses. Figure 5 presents a decision tree to assess the scope of an Article 68.2 restriction.

The ***first criterion*** relates to the detectability and traceability of the substance under consideration, necessary if the restriction is to be effective at reducing consumer exposure. Although this criterion does not help the decision maker differentiate between an Article 68.2 or 69 restriction procedure, it could help define the most appropriate scope of the restriction, by eliminating those uses where the presence of the substance would be difficult to measure and monitor in articles.

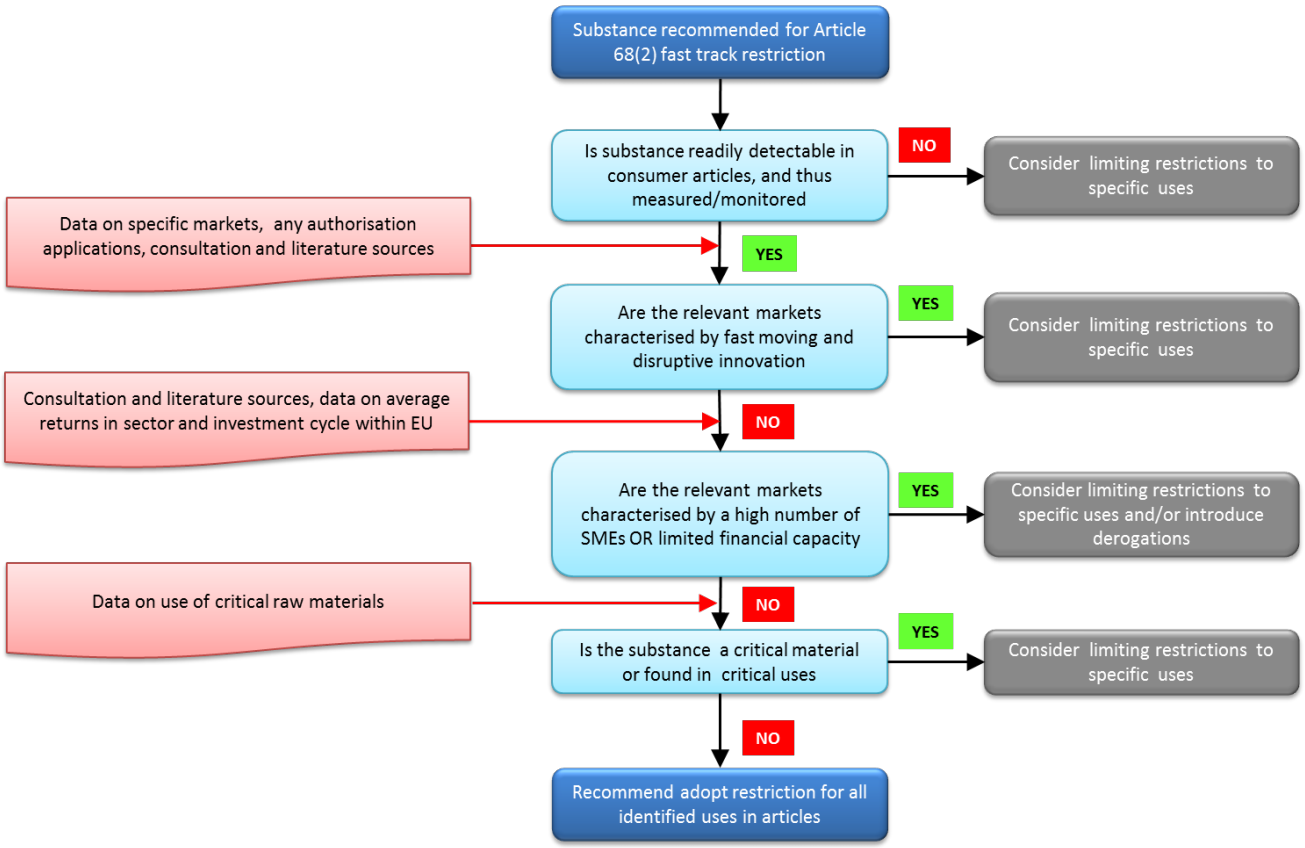
The ***second criterion*** assesses whether the relevant markets for the article are characterised by fast moving and disruptive innovation. If the market is characterised as such, then a restriction has the potential to slow down or prevent future innovation and product development, which would potentially put EU industry at a disadvantage to non-EU industry.

The ***third criterion*** addresses whether the affected industry has the financial capacity and capability to make the necessary changes to production processes, invest in new machinery and switch to

alternatives following the adoption of a restriction. The presence of a high number of small and medium enterprises (SMEs), EU manufacturers making low average returns or manufacturer's mid-way through their investment cycle may be indications of limited capacity to adjust to a restriction. However, if a phase out by EU industry has already taken place or is ongoing, this criterion may become obsolete as investments and changes to production have already taken place.

The ***fourth criterion*** assesses whether the substance is a critical material or has critical uses of strategic and/or economic importance to the EU. Criticality in a given use should be considered and critical material lists should be consulted at this stage. If the substance falls in this category, it should be ruled out for an Article 68.2 restriction, but may merit further investigation under an Article 69 procedure.

Figure 5 Determining the scope of an Article 68.2 restriction



Source: ICF/AMEC

1 Introduction

Substances that are carcinogenic, mutagenic[6], or toxic to reproduction[7] (CMR substances) are of paramount concern to the European Union (EU), especially given the long term and serious human health effects they can cause. CMR classifications of substances may lead to their identification as substances of very high concern (SVHC), restrictions under REACH[8] and the need to apply for authorisations under REACH. The Classification Labelling and Packaging of substances and mixtures (CLP) regulation[9] classifies CMR substances and mixtures into three categories depending on the available scientific evidence of the hazard to human health:

- ***CMR 1A*** is applied to substances *known* to be carcinogenic, mutagenic or toxic to reproduction based on human studies (epidemiological data).
- ***CMR 1B*** classification is applied to substances *presumed* to be carcinogenic, mutagenic or toxic to reproduction based on animal studies.
- ***CMR 2*** is applied to substances *suspected* to be carcinogenic, mutagenic or toxic to reproduction based on evidence obtained from human and/or animal studies, the data for which are not sufficiently convincing to place the substance in categories CMR 1A or CMR 1B.

REACH provides the possibility for the Commission to restrict the manufacture, use or placing on the market of any substance, with justification, including those classified as CMR. REACH provides a streamlined process for restricting articles that contain CMR substances, as laid out in Article 68.2 of the regulation. Specifically, Article 68.2 provides rules to address risks related to substances classified as CMR 1A and 1B on their own, in mixtures or in articles, that could be used by consumers and for which restrictions to consumers are proposed by the Commission. A ban on CMR substances in articles would apply to all companies placing articles on the market in the European Economic Area (EEA), even if they purchase them outside of the EEA. Restriction procedures can be initiated by the Member States (MS) and/or the Commission and they are concluded with a final decision by the Commission. The Commission is the authority that decides to add new or amend existing entries in REACH Annex XVII, which lists the restricted substances and each restricted use.

REACH has not only allowed for the possibility of extending the CMR-specific restriction approach to articles containing the substances, it has also expedited the process. For example, REACH Article 68.2 allows the Commission to place restrictions on CMR substances, bypassing the need for a high degree of scientific scrutiny and socio-economic impact analysis. Specifically, the Commission can follow a simplified procedure using Article 68.2 of REACH to amend Annex XVII to restrict consumer use of a substance on its own, in a preparation, or in an article which meets the criteria for classification as CMR 1A or 1B. The process of restriction under Article 68.2 could, in some cases, take less than a year.

ICF International has undertaken a project with the support of AMEC to inform the Commission's understanding of the potential impact on industrial competitiveness of restrictions on certain CMR 1A and 1B substances in articles. The project team is providing support to develop considerations and elements for possible criteria for the application of Article 68.2 to restrictions of CMR 1A and 1B in consumer articles.[10] Such criteria should

[6] Substances causing genetic defects.

[7] Substances which may damage the fertility or the unborn child.

[8] REACH is the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation EC No 1907/2006).

[9] Regulation EC No 1272/2008

[10] As agreed during the inception phase of this project.

place the emphasis on those substances which represent the greatest hazard (for instance due to their potency or other intrinsic properties), and on those that raise the greatest concern due to intensive use of substance / material combinations which may have the potential to lead to consumer exposure.

1.1 Study objectives and research questions

DG Enterprise (DG ENTR) and the European Chemicals Agency (ECHA) provided the project team with a list of 43 CMR substances[11] potentially found in articles. The project's core objective was to investigate these substances, specifically through:

- Collecting and analysing information on articles potentially containing one of the 43 CMR substances, looking in particular at uses, market information, market players, and possible alternatives;
- Providing a scoping assessment of the socio-economic impacts of a short list of 13 selected CMR substances.

The Commission and ECHA agreed that the project's aim is not to prioritise among the 13 substances those that are best candidates for the Article 68.2 procedure but rather to take the set of these 13 substances as an example representing different possible scenarios that can be expected when looking at CMR substances in articles. The Commission would like to learn, from the substance scoping analyses, which elements need to be considered before deciding on the implementation of an Article 68.2 procedure in lieu of the Article 69 full restriction. Therefore, this report includes considerations for development of draft criteria to implement Article 68.2 to CMR 1A and 1B in consumer articles.

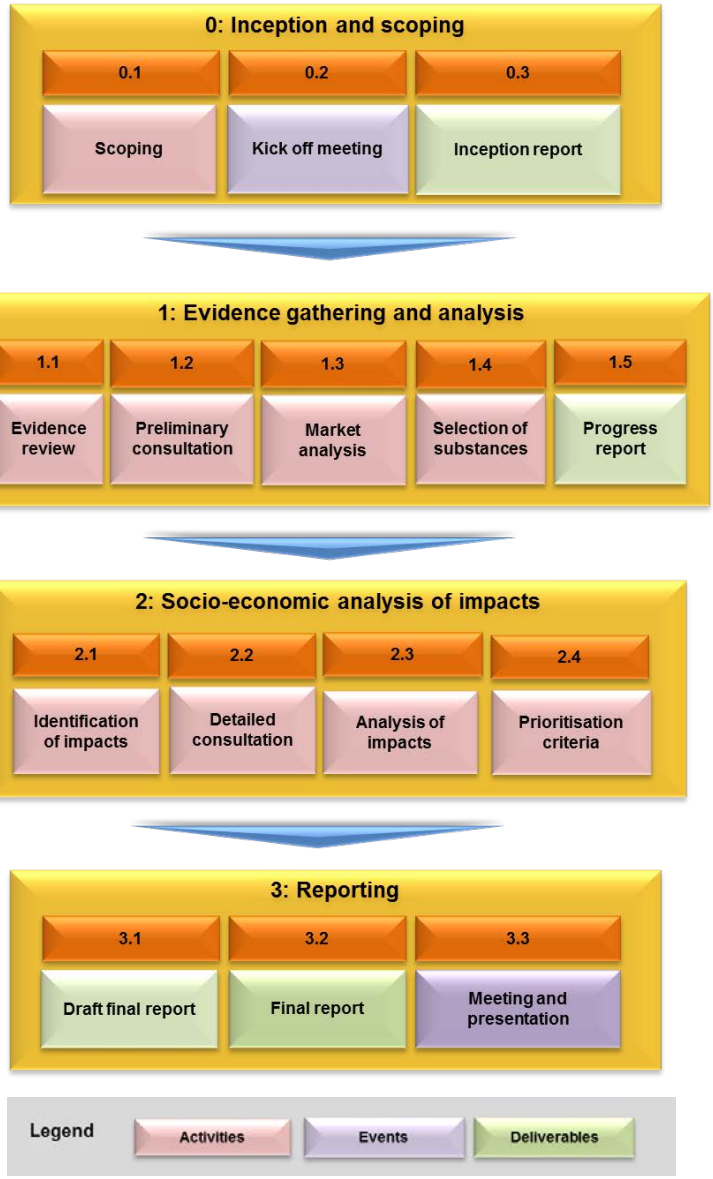
1.2 Summary of methodological approach

The approach to the study, summarised in Figure 1.1, involved:

- Rapid identification of relevant information sources for the substances concerned and their use/presence in articles;
- Targeted consultation with regulators, manufacturers, importers, downstream users and wider supply chains;
- Considered and transparent treatment of evidence to expose and address identified data gaps and other uncertainties that arose during the work; and
- Scoping and review of the socio-economic impacts of restrictions of 13 CMR substances, triangulating quantitative and qualitative information to identify the main impacts, consistent with the principles of the REACH Socio-economic analysis (SEA) guidance (ECHA, 2008) and the Commission guidelines on impact assessment (IA) (EC, 2009).

[11] A list of 44 substances was submitted but a duplicate substance was discovered during evidence review, leaving a final list of 43 substances.

Figure 1.1 Detailed project workflow



Source: ICF/AMEC

1.2.2 Overview of Methodology for Task 1: Evidence gathering and analysis

1.2.2.1 Step 1.1 Evidence Review

This sub-task included a rapid data assembly exercise in order to pull together relevant information on the 43 CMR substances, their uses, potential presence in consumer articles, likely consumer exposure to the substances, associated volumes and available alternatives. The literature and database sources identified in the inception report were reviewed first and supplemented with additional documents provided by the Commission, ECHA and Member State competent authorities, and identified through web searches. A standard form was used to systematically and consistently record all information of relevance to the study by substance and source. Based on this evidence review process, a gap analysis was performed to identify where data gaps existed and provide a mapping of data requirements

to stakeholders to whom requests were made. This also provided an early indication of where supplementary data research and literature scanning were required.

1.2.2.2 *Step 1.2 Preliminary Consultation*

The first round of consultation ran in parallel with the evidence review exercise. The data gaps identified during the evidence review informed the consultation process; new documents and reports identified during the consultation fed into the evidence review. In order to improve stakeholder participation and the collection of relevant data, a straightforward online survey was developed for distribution to a wide range of stakeholders. The targeted stakeholder groups include chemical producers, importers, formulators, product manufacturers, traders and distributors as well as Member State competent authorities, testing bodies and research institutes. In total, 171 EU organisations and 33 non-EU organisations were contacted[12] and 111 survey responses were received during the Task 1 consultation process.

With more detailed consultation planned for Task 2, the Task 1 survey focussed on collecting the basic key informational requirements of the study which included:

- Organisational and contact details of the respondent;
- The activities undertaken and industry sector in which the organisation is classified;
- The use of CMR substances in production processes and/or contained in articles;
- The material (wood, plastic, leather) and intended use of the article (i.e. by adults, children, home or leisure, etc.);
- The technical function of the chemical substance in the article (i.e. the properties given to the article);
- Whether the article is manufactured and/or imported into the EU;
- The quantities of the substance found in articles (i.e. the concentration or quantity used in production); and
- Whether possible consumer/environmental routes to exposure can be excluded or not, detailing the reasons.

The results of the survey were analysed and fed into the sub-tasks that followed to:

- Provide an evidence base on which to build more detailed analysis and determine if consumer exposure should be considered or could be ruled out;
- Identify issues that needed to be addressed in those sub-tasks;
- Inform the selection of substances for further analysis under Task 2; and
- Identify stakeholders that should be targeted for more detailed follow-up consultations during Task 2.

1.2.2.3 *Step 1.3 Market analysis*

This task collated the information collected so far and provided analyses for the 43 CMR substances. The market analysis 'triangulated' the information, data and evidence gathered from stakeholder consultation and the evidence review. Triangulation of the evidence is particularly important given the propensity for different sources to contradict each other. The team therefore focussed on the most recent publications and primary evidence to draw the most up to date and reliable conclusions on the uses of substances in consumer articles in

[12] A complete list of organisations contacted during Task 1 is provided in Annex 2.

each market. Fiches were developed for each substance, which were included in the Progress Report annexes. They summarised:

- The production profile of the substance: quantities and economic value;
- The market profile of the substance: nature of use, alternatives and substitution, affected supply chain;
- The uncertainties and gap analysis.

1.2.2.4 *Step 1.4 Selection of Substances for Task 2*

The selection of the substances to be taken through to Task 2 was based on a screening of the available evidence against the following criteria:

- Whether the substance is used in the production of, or is contained in, articles placed on the EU market; and
- Whether consumers using the relevant article are potentially exposed to the substance contained in the article.

The approach was intended to ensure that a representative selection of substances was assessed from each group and that an equally representative range of article uses was included. Consideration was also given to the following, based on discussion with DG ENTR, DG ENV and ECHA at the inception meeting:

- Uses in toys were included in the analysis, and were brought to the attention of DG ENTR unit responsible for toy safety;
- Substances found to be used in food contact articles were excluded because separate requirements exist, including a positive list of approved substances and specific migration limits[13] (SML) applicable to such uses; and
- A representative range of economic and technical issues associated with substitution was elaborated in the Task 2 analyses, so that the emerging judgment criteria that were developed were as useful as possible. The analysis includes, among others:
  - A negative example of a substance in an article which does not have potential for exposure of consumers;
  - An example of where consumer exposure is thought to be greatest from mixtures, but consumer exposure from articles should not be discounted;
  - Substances associated with high numbers of imported consumer articles; and
  - Substances with highly complex uses in consumer articles.

Following agreement with the Commission, the 13 substances presented in Table 1.1 were selected out of the initial set of 43 to undergo scoping analyses in Task 2:

Table 1.1 List of substances selected for Task 2

Substance	EC Number	CAS Number
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	271-084-6	68515-42-4
Gallium arsenide (GaAs)	215-114-8	1303-00-0

[13] Migration limits tackle food contact materials which must not transfer their components into the foods in unacceptable quantities. Migration limits for plastic materials: (1) Overall Migration Limit - 10mg of substances/dm² of the food contact surface for all substances that can migrate from food contact materials to foods; (2) SML for individual authorised substances fixed on the basis of a toxicological evaluation.

Substance	EC Number	CAS Number
Dihexyl (Di-n-hexyl) phthalate	201-559-5	84-75-3
Formaldehyde	201-559-5	84-75-3
1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione (TGIC)	219-514-3	2451-62-9
2-Methoxyaniline (o-Anisidine)	201-963-1	90-04-0
Boric acid	233-139-2	10043-35-3
Disodium tetraborate decahydrate; borax decahydrate	215-540-4	1330-43-4
Ethylene thiourea;imidazolidine-2-thione;2-imidazoline-2-thiol (ETU)	202-506-9	96-45-7
Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (CI Direct Black 38)	217-710-3	1937-37-7
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7
Dibutyl phthalate (DBP)	201-557-4	84-74-2
Tris(2-chloroethyl) phosphate (TCEP)	204-450-0	121-14-2

Source: ICF/AMEC

1.2.3 Overview of methodology for Task 2: SEA of impacts

This task built on the evidence and body of work conducted in Task 1 to provide an initial scoping SEA of the 13 selected substances. The purpose of this scoping SEA was to identify the main impacts from a potential ban for each of the assessed CMR substances in consumer articles, and screen these impacts across the different stakeholders to provide an overview of the socio-economic impacts of restriction, indicating data gaps and uncertainties where appropriate.

One objective of this analysis was to identify key information that should be included in a scoping SEA, to decide if a procedure according to Article 68.2 (without a full SEA) is appropriate.

1.2.3.1 Step 2.1 Identification of main impacts

Evidence from Task 1 was drawn together to provide an overview of the current situation with regard to the use of the selected CMR substances in articles, in order to identify the impact categories[14] and stakeholders affected by a possible restriction on the use of the substances in consumer articles. The analysis for this sub-task was based on stakeholder feedback and market data and focused on the following elements per substance:

- Expected developments in the use of chemical substances in articles;
- Supply chains that are likely to have to respond to a restriction; and
- The effects on the identified supply chains e.g. downstream users and consumers.

[14] The impact categories include operating costs and conduct of business; competitiveness, trade and investment; competition and the internal market; innovation and research; distributive impact.

1.2.3.2 Step 2.2 Detailed consultation

In this sub-task, we deepened and extended the initial consultation undertaken in step 1.2. During the initial consultation, several organisations indicated the possibility to provide additional data if given more time. These offers were followed up to obtain as much data as practicable where the organisations hold data relevant to the substances selected for Task 2. In addition, companies were identified through contact with trade organisations, ECHA's REACH dissemination portal, internet searches, and through contact with known manufacturers identified in Task 1.

In order to screen impacts against different stakeholder groups, further follow-up consultation was carried out via telephone interviews using tailored telephone survey questions, covering items such as:

- Locations of manufacturing sites and tonnage of manufactured substance, trends (consultations were used to compare with the information found in ECHA's registration database);
- Annual releases to the environment and risk reduction techniques;
- Specific tonnage of substance import into and export out of the EU for the substance on its own, in preparations, and in articles;
- Tonnage of companies' own use of the substance for manufacture of preparations or articles with indications of trends over recent years;
- The sales value of the substance according to use categories (these data are confidential);
- Tonnage of companies' production of other substances that may be used as alternatives to the substance in question;
- The likely response of their company, wider industry, and downstream users to a restriction on the substance use in consumer articles;
- The anticipated economic impacts of a restriction on their companies' activities, downstream users, and wider industry.

Representatives of downstream users were also asked questions, focusing on:

- Quantities of substances used, trends;
- Details of the extent of the substance in preparations or articles for consumer use;
- Perspectives on the technical and economic feasibility of available alternatives;
- Work already undertaken by their company, or other companies in the industry to replace the substance;
- The likely response of their company/industry to restrictive measures on the substance use in consumer articles;
- The anticipated economic impacts of restrictive measures on their companies' activities, upstream manufacturers and wider industry.

1.2.3.3 Step 2.3 Analysis of impacts

In this step, a scoping SEA was conducted for each of the 13 substances. The methodology and parameters of these SEAs are explained in further detail in Section 3.2 of this report. The key types of information sought/used was consistent with those considered in the SEA process for a restriction via Article 69 of REACH, though there was more reliance on literature sources due to the available resources for the project and number of substances to be assessed.

It was beyond the scope of this study to conduct comprehensive toxicological and willingness to pay analyses on the substances in articles. This study therefore applies a qualitative approach in discussing these issues for the substances under assessment.

1.2.3.4 Step 2.4 Prioritisation criteria

As agreed with DG ENTR, DG ENV and ECHA following the Progress Report, the scope of this step was to provide considerations for the development of draft criteria to implement Article 68.2 for CMR 1A and 1B substances in consumer articles.[15] The methodology and outcomes for this step are further detailed in Section 5 of this report.

1.3 Difficulties encountered and resolved

Throughout the project, the project team looked ahead to anticipate and mitigate risks to the study work programme and of the analysis to be conducted. Table 1.2 below presents the key difficulties encountered and how they were addressed.

Table 1.2 Difficulties encountered and resolved

Risks and difficulties encountered	Mitigation strategy	Results
Task 1 – Risks of confusion between substances during their analysis and discussion	A coding system was developed with one specific code per substance.	As a result of this coding system, no confusion of substances was encountered during this project.
Task 1 – Difficulties in identifying named contacts in individual businesses relevant to the specific substances	To reach a representative number of stakeholders the team adopted a top-down approach for the distribution of the surveys. EU chemicals and industry umbrella associations were contacted first in order to identify the most relevant SMEs and businesses to prioritise. These were then contacted directly or through the industry associations.	A questionnaire for the first phase of consultation was circulated to many industry associations. Industry associations then circulated the survey to companies and SMEs who are part of their REACH- or substance-specific working groups. As a result we received answers from businesses we did not directly contact.
Task 1 – Difficulties to reach out towards stakeholders and have access to relevant data	A teleconference with DG ENTR, DG ENV and ECHA was organised to agree on a new strategy with regard to our outreach towards the stakeholders. It was decided to put more emphasis on contacts in non-EU countries, especially those importing many articles into the EU.	As a result of this meeting, ICF used staff in its Beijing, China office to contact Chinese stakeholders. The team also made contact with organisations in Vietnam, India, Turkey, and Cambodia. The survey response rate increased from 11 responses on 20 March 2013 to 111 responses in May 2013.
Task 2 – Risks of coordination issues with stakeholders providing information on multiple substances	The following management techniques were used to mitigate this risk: appointment of one responsible consultant for each substance and	As a result the stakeholders have been able to provide input on different substances in a structured and systematic way. In addition workshops or phone

[15] The original terms of reference specified the development of criteria for prioritisation of CMR substances based on the potential impact restrictive measures would have on the markets associated with the uses of the substances in articles and relative to the effects on human health and the environment.

Risks and difficulties encountered	Mitigation strategy	Results
	appointment of one responsible consultant within the ICF and the AMEC team to ensure coordination.	conferences were organised with stakeholders and ICF/AMEC, allowing input on a variety of substances in one meeting.
Task 2 – Difficulties contacting stakeholders and obtaining access to relevant information	In order to ensure participation in the consultation the stakeholders who participated in the first round of consultation were prioritised. The list of stakeholders was then refined and supplemented based on the contacts with the industry, literature reviews and web-based researches.	As a result a large number of relevant stakeholders have been contacted and many of them provided us with insights and confidential data on the use of specific substances in consumer articles.

Source: ICF /AMEC

1.4 Structure of the remaining report

This Final Report presents the results of the study:

- Part 2 presents the key output of Task 1 with a summary of the substances selected for Task 2 of the study[16].
- Part 3 presents the results of Task 2. The purpose of conducting the scoping SEA is set out, together with a description of the approach used to assess the socio-economic evidences. The detailed stakeholder consultation is presented together with a list of all the contacted stakeholders.
- Part 4 presents the scoping SEAs developed by the project team for the 13 substances selected for Task 2. As agreed with the Commission, the different scoping SEAs follow the same structure and present a table summarising the relevant impacts by stakeholder group, impact category and supply chain – if applicable. Section 4.2 includes a high level summary focusing on:
  - Direct and indirect economic impacts;
  - Wider social/consumer impacts;
  - Health and environmental impacts;
  - Administrative and other impacts.
- Finally, Parts 5 and 6 focus on the considerations and recommendations for the development of draft criteria to implement Article 68.2 to CMR 1A and 1B in consumer articles.

[16] Annex 4 provides the more detailed summary tables for the 13 substances that were selected for Task 2.

2 Overview of Task 1 and outcomes

The 43 CMR substances listed by the Commission and ECHA have been split into three groups identified by DG ENTR and ECHA as of particular interest:

- Group 1: **Substances on which to focus**. Several of these substances are on the SVHC Candidate List[17] and this group includes registered CMR substances, registered and unregistered phthalates, "new" and proposed new CMRs, and monomers.
- Group 2: **Substances on which to investigate the presence in consumer articles**. These include several individual substances on the SVHC Candidate List, several monomers, and several dyes from a study realised by the National Institute for Public Health and the Environment of the Netherlands (RIVM).
- Group 3: **Substances in Annex XIV**. This group includes four substances already listed in Annex XIV. These substances already included a large amount of information in SEA present in the Annex XV dossier for restriction prepared by Denmark and DG ENTR (Danish EPA, 2011) noted that no additional data collection was needed. Therefore, these substances were not a substantial focus during the consultation process. Evidence review tasks were completed and a small amount of consultation with relevant industry groups was performed.

Table 2.1 presents the 13 substances that were selected for inclusion in Task 2 and the key reasons why they were selected. Substances selected for Task 2 needed to cover a range of scenarios as to the potential for consumer exposure as well as socio-economic issues (i.e. valuation of direct and indirect economic impacts from identified uses, different industry sector impacts including those on small and medium enterprises (SMEs), and differing degrees of substance substitutability). The selection covers substances contained in articles in significant volumes and substances which pose the greatest potential for consumer exposure from their use.

The following points are highlighted in relation to the selection:

- At least one substance was selected from each of the three groups;
- A negative example of a substance in an article which has very low potential for consumer exposure (gallium arsenide) was included for completeness ;
- Boric acid and disodium tetraborate decahydrate (borax dehydrate) are used in many of the same articles, and consumer exposure to them is often greatest from mixtures. They were therefore analysed as a pair.
- Numerous phthalates were identified as possible candidates for further analysis. However, as many of the uses, identified alternatives, and socio-economic impacts are common to each, only the two most commonly used phthalates from Group 3 were included under Task 2 (DEHP and DBP);

[17] A substance may be proposed as a SVHC if it meets one or more of the following criteria (listed in REACH Article 57):

- It is carcinogenic CAT 1A/1B;
- It is mutagenic CAT 1A/1B;
- It is toxic for reproduction CAT 1A/1B;
- It is persistent, bioaccumulative and toxic according to the criteria set out in REACH Annex XIII;
- It is very persistent and very bioaccumulative according to the criteria set out in REACH Annex XIII;
- Substances that give rise to an equivalent level of concern to the previous categories, e.g., endocrine disruptors; such substances are identified on a case-by-case basis.

- TCEP is included as a non-phthalate Group 3 substance and uniquely used as a flame retardant;
- Despite its complexity, formaldehyde was included in Task 2. However, the scoping SEA analysis for this substance was limited to make a scoping analysis feasible within the project timescale and resources;
- Substances related to articles imported in to EU in large volumes have been proposed to better understand the presence of substances in the EU and their supply chains. Substances found in toys, cookware and clothing therefore feature prominently.

Table 2.1 Summary of selected substances based on market and consumer exposure criteria and identified substitutes for consideration in Task 2

Substance	CAS No.	Details of consumer exposure	Substitutability, socio-economic value of industry and use	Rationale for taking forward to Task 2
Group 1: Substances on which to focus further information gathering in Task 1				
1B Non-registered phthalates				
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP) 1B-02	68515-42-4	Mixtures are the only confirmed exposure route for consumers for EU-produced goods (i.e. in adhesives, coatings, sealants). Residual concentrations possible in Polyvinyl chloride (PVC) articles imported (known high consumption in third countries) or through use as a plasticiser in EU production (unconfirmed). Occupational risk has been reported	No longer manufactured in the EU, but used in large volumes in third countries, potential consumer exposure expected from imports of articles as current exposure inconclusive. Potentially significant socio-economic value in construction sector. Other phthalates identified as alternatives	Presence in imported articles and availability of alternatives.
1D "new" or proposed "new" CMRs				
Gallium arsenide 1D-02	1303-00-0	Substance used in the manufacture of semiconductors where exposure to workers is greatest. No known consumer exposure to substance as any residues in semiconductor parts are sealed within article.	Possible critical use in semiconductor manufacturing should make an interesting case for SEA. No information on alternatives currently available	Taken forward to Task 2 as a "negative" example where negligible potential for consumer exposure exists from use in articles.
Dihexyl phthalate (DnHP) 1D-03	84-75-3	Used in mixtures as a plastisol in the manufacture of plastic articles (air filters, battery covers in automotive), including dip moulded articles (tool handles, baskets/buckets). Mixtures containing substance are used in toys (emollient and plasticiser) and textile/plastisol prints in the EU. .	Consumer exposure confirmed in consultation, particularly where article breakdown (i.e. in wash) or inhaled (i.e. toys in child's mouth). Potential high socio-economic value for EU manufacturers of articles. No alternatives identified.	Consumer exposure cannot be excluded and the substance has a wide range of socio-economic value.

Substance	CAS No.	Details of consumer exposure	Substitutability, socio-economic value of industry and use	Rationale for taking forward to Task 2
Formaldehyde 1D-07	50-00-0	One or several uses indicate exposure to workers (industrial and professional uses) and consumers via articles (containing resins, treated textiles, wood and paper products such as sanitary and insulation products) and mixture (disinfectants, cosmetics, coatings, etc.) As such, consumers are likely to be exposed to small concentrations of the substance in their everyday lives. It has been reported that indoor and ambient air constitutes examples of exposure pathways.	Large number of uses and exposure routes, including natural concentrations makes this a complex substance to assess in SEA. Added to the complexity in the need to separate residual by-product concentrations (in plastics) from substantive article use. Also issue of co-existing non-article exposure from combustion and tobacco smoke.	Provided opportunity for assessment of a wide range of impacts in the SEA and demonstration of an example where Article 68.2 might not be the most appropriate to use due to complexity of substance and its uses. Scope was limited to examination of specific uses and highlighting a specific range of impacts.
Group 2: Substances on which to investigate and confirm/refute **the presence in consumer articles**				
2A Individual substances				
1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione (TGIC) 2A-01	2451-62-9	Several uses of the substance in consumer articles have been confirmed: (1) weather-resistant powder coated articles such as steel garden furniture, car parts, metal fencing, window and door frames, electrical equipment, refrigerators, washing machines and ovens; (2) inks in the printed circuit board industry, [e.g., two-part inks used for solder-masking]; (3) electrical insulation materials; (4) resin moulding systems; (5) laminated sheeting; (6) silk-screen printing coatings; (7) tools; (8) adhesives; (9) lining materials; and (10) stabilisers for plastics	Replaced by hydroxy-alkylamides (HAA) in many countries, including in powder coating in Europe. Use in high performance electronics may not be substitutable, in which case socio-economic value may be high. Many alternatives exist for most but not all uses.	Wide range of consumer articles containing the substance and possible technical performance issues surrounding alternatives.

Substance	CAS No.	Details of consumer exposure	Substitutability, socio-economic value of industry and use	Rationale for taking forward to Task 2
2-Methoxyaniline; o-Anisidine 2A-06	90-04-0	It has been reported that the substance is not intentionally used in articles but may occur as a residue in textile or leather articles. It has also been indicated that o-Anisidine may be a component in printed polymers and printed articles, especially printed aluminium foils. Restriction exists under Annex XVII, however some uses may not be covered by the restriction (in printed paper and aluminium foils)	Widely replaced in the EU by alternatives in the production of textile and leather articles and in the cosmetic sector(mixture) Aesthetic value and performance of textile/leather provides example of different socio-economic issues to other substances	Potential for consumer exposure and socio-economic value of use in articles, plus potential for imports.
Boric acid 2A-09	10043-35-3	The substance is present in numerous articles but greatest exposure to consumers can arise from certain products (mixtures) such as fertilisers and detergents that contain the substance (although it was banned via the CMR amendment 109/2012) these mixtures could still be present in households. Textiles and primary food packaging material have a potential for consumer exposure.	Little information on substitutes for boric acid per se, probably explained by the fact that, in general, borates do not appear to have viable substitutes with regard to their use in certain products (e.g. borosilicates). Lack of substitutes, indicates possible high socio-economic value from use.	Potential for consumer exposure and limited substitutability. As both substances have similar uses, both were assessed together in SEA, avoiding duplication in analysis
Disodium tetraborate decahydrate; borax dehydrate 2A-10	1330-43-4	Similar properties and uses to boric acid, however exposure more likely through mixtures (fertilisers, detergents, antifreeze, lubricants, brake fluids, etc.) Exposure from articles limited to technical textiles, construction products (insulation) and articles containing adhesives (paperboard products). Exposure can occur through inhalation or through ingestion by way of material transfers from via mixtures still present in households or brought from other non-EU countries	Information on alternatives is currently not available Wide range of uses, suggests interesting investigation of SEA value possible.	

Substance	CAS No.	Details of consumer exposure	Substitutability, socio-economic value of industry and use	Rationale for taking forward to Task 2
2B Monomers				
ethylene thiourea;imidazolidine-2-thione;2-imidazoline-2-thiol 2B-01	96-45-7	There may be a potential for consumer exposure (dermal and inhalation) through contact with articles containing the substance (e.g. present in neoprene products). Although the majority of ethylene thiourea is converted into other compounds during the rubber manufacture process, trace amounts could remain in some products, including neoprene apparel such as wetsuits and footwear. Therefore consumer exposure cannot be excluded.	Limited information appears to be available on alternatives to replace ethylene thiourea as an accelerator in rubber manufacturing. The SafeRubber project aims to develop a new, safe, multifunctional accelerator curative molecule which can replace thiourea-based accelerators in the vulcanisation process. Additionally, industry has indicated that viable alternatives, with similar properties, are already available or in the process of being developed.	Large number of consumer articles potentially containing the substance and limited availability of alternatives.
2C Dyes				
Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (CI Direct Black 38) 2C-01	1937-37-7	The substance is not registered under REACH but consultation suggests articles containing the substance are imported into the EU. There is a potential for dermal exposure through contact with articles dyed with the substance. Restriction affecting its use exists under Annex XVII, however some uses may not be covered by the restriction (e.g. paper)	There is relatively little information on specific alternatives to this substance Direct Black 22, which does not contain benzidine, may be used as an alternative	Potential for consumer exposure and more available information than other dyes.

Substance	CAS No.	Details of consumer exposure	Substitutability, socio-economic value of industry and use	Rationale for taking forward to Task 2
Group 3: Substances in Annex XIV [18]				
Bis(2-ethylhexyl) phthalate (DEHP) 3A-02	117-81-7	Used widely in plastic and rubber consumer articles, including toys[19]. Articles of PVC are most likely to contain substance, including plastic prints on garments, toilet bags, waterproof clothing, etc. Non-PVC use is mainly as a mixture in adhesives, sealants, paints and lacquers which may be used in production of consumer articles.	Alternatives such as Diisononyl phthalate (DINP) typically more expensive (by 10% or more). Alternative materials to PVC in toys and medical products should also be considered, posing interesting challenges for SEA.	High potential for consumer exposure, and the socio-economic impacts of using alternative substances and materials.
Dibutyl phthalate (DBP) 3A-04	84-74-2	Consumers are exposed to this substance, as noted in RAPEX mainly from plastic articles such as toys[19], rainwear and cookware. Several studies have detected the presence of DBP in humans, although diminishing. Oral is the main exposure route. Inhalation and environmental exposure are also relevant exposure pathways	There is no general direct substitute for all applications. Other phthalates can be regarded as the closest substitutes in terms of functionality Potentially replaced by other substances including DIBP, DINP, DINCH, GTA, DGD.	Potential for consumer exposure from EU-produced articles and imports, plus the socio-economic impacts.

[18] These substances cannot be used in the EU

[19] Substances in toys are not a focus for this study (because there are restrictions in place in Annex XVII for content in toys).

Substance	CAS No.	Details of consumer exposure	Substitutability, socio-economic value of industry and use	Rationale for taking forward to Task 2
Tris(2-chloroethyl) phosphate (TCEP) 3A-05	121-14-2	Substance found in articles treated with flame retardants. Household dust from textiles, carpets, timber, foams, etc. identified as main consumer exposure route. May be present in technical textile, protective clothing and foam articles. Actual exposure from direct article use is limited. Exposure in indoor environments from dust seems more likely to occur.	Uses within the EU have decreased substantially in recent years. Imported articles identified as possible major source of exposure, therefore raises interesting socio-economic issues for industry sectors concerned. Different to phthalates and with different exposure route suggest interesting case TCPP [Tris(2-chlorpropyl)phosphate] is the main substitute for TCEP as a flame retardant. As such, relevant industries have already substituted TCEP for TCPP in many applications.	Although use is decreasing as a flame retardant and exposure appears mostly through indoor environment rather than direct contact with articles, substance introduces interesting issues for SEA.

Source: ICF/AMEC Survey

3 Overview of Task 2

3.1 Introduction

This section summarises the approach taken to Task 2 and how the outcomes have contributed to achieving the study objectives. The objectives of the study relevant to Task 2 are:

- To provide an initial, scoping SEA of the substances selected for further analysis by the Commission and ECHA; to identify the main impacts for each of the assessed CMR substances in articles; and to screen these impacts across the different stakeholders to provide an overview of the socio-economic impacts of a possible restriction, indicating data gaps and uncertainties where appropriate.
- To develop considerations to help the Commission to develop draft criteria for implementation of Article 68.2 for CMR substances in articles.

The outputs of this task will not necessarily lead to any specific regulatory action; instead the purpose of this section, using the findings of the scoping SEAs, is to propose considerations and elements for the development of a set of criteria which will aid the Commission in their further work.

As summarised in Section 1 of this report, for the first task in the study, the team collected and analysed information on the uses of 43 CMR substances in the EU, from which 13 were selected for further investigation.

The purpose of this task was not to provide a full SEA of the use of the selected CMR substances. Rather, it was intended to present an analysis of available social-economic information on substance production and use in consumer articles, along with impacts of potential Article 68 restriction at a scoping level. Based on the “scoping SEAs” for 13 CMR substances, the project team has drawn conclusions on substance-specific findings for development of a set of criteria which the Commission may use to further develop their thinking on how to apply restrictions for CMR substances in articles via Article 68.2.

Taking into account the Commission’s guidelines on IA (EC, 2009) and the REACH guidance documents on SEA (ECHA, 2008), each scoping SEA is intended to provide:

- A brief overview of the use of the selected CMR substance within the EU and its presence in different types of articles, both produced in, and imported into, the EU, including potential trends in use (the baseline scenario);
- Most likely response by the supply chain (i.e. manufacturers, downstream users, consumers) to a possible ban of the CMR substance for incorporation into consumer articles in Europe (expected non-use scenario);
- Potential economic impacts on the supply chain and wider economic impacts (competition and competitiveness, innovation and R&D, etc.);
- Potential social impacts on the supply chain;
- Potential administrative costs; and
- Potential impacts on human health and/or the environment.

The scoping SEAs undertaken for each of the 13 CMR substances have been structured in accordance with the abovementioned points and conclude with a section on substance-specific considerations to take into account for the development of draft criteria to implement Art 68.2 to CMR 1a and 1B in consumer articles.

Evidence for the development of the scoping SEAs has been assembled from primary and secondary sources to provide a picture of the use and presence of CMR substances in articles in the EU and the socioeconomic implications resulting from a restriction. This

involved consultation with individual businesses, industry representative organisations, competent authorities both in EU MS and farther afield, including stakeholders in third countries. In addition, evidence has been gathered from published policy documents, REACH dossiers, risk assessments and risk reduction strategies, chemical databases and research articles. The approach to the consultation methodology is further elaborated in section 3.3.

3.2 Approach to assessing the socio-economic evidence

Evidence from Task 1, supplemented with additional stakeholder consultation feedback and literature review has been drawn together to provide an overview of the current situation and expected developments with regards to CMR substance use/presence in articles. This has allowed the determination of the anticipated responses to a potential restriction on use/presence in articles across the key stages in the supply chain, as well as the potential effects that the restriction could have on downstream users and consumers.

Categories of stakeholders considered in this analysis include:

- EU manufacturers or importers of substances;
- Downstream professional and industrial users;
- Formulators (mainly involved in producing mixtures of substances purchased from local manufacturers or importers. Mixtures from the first formulator can be used by a second formulator as a raw material for his own mixtures and, as such, several formulators can be involved until the end-use mixture is supplied);
- EU producers of articles;
- Importers of articles;
- Retailers i.e. businesses that sell articles to members of the general public;
- Consumers. Members of the public are not permitted to handle CMR substances or mixtures containing them. In the supply chain, they are only viewed as the buyers of final products.

For some of the substances with complex supply chains and several types of articles that could potentially contain the CMR substance, it was necessary to select a few uses/applications to focus on, based on considerations related to greatest potential for exposure of consumers or availability of reliable information (e.g. plastic traffic cones, toys, footwear and vinyl flooring in the case of DnHP).

Building on the response (non-use) scenarios in the event of a restriction developed for each of the supply chains considered, the project team identified the main impacts and stakeholders potentially affected by a possible restriction of each of substance in the various types of consumer articles. The analysis would be focussed on those stakeholders most affected by the possible restriction and would consider the nature and scale of the impacts, following the SEA principles in relation to the possible costs and benefits.

The main impacts were identified by a qualitative assessment. To this end, discussion and case studies of the effects of a ban on the substances in articles on different stakeholders have been developed to undertake qualitative appraisal of the different categories of impact, in accordance with the general principles of the Commission IA guidelines and REACH SEA guidance. The type of appraisal and evidence for the main impacts provided for each of the 13 substances is presented in Table 3.1. In some cases, it has been possible to derive indicative quantitative estimates of the impacts of a restriction.

It is important to note that it has been beyond the scope of this study to conduct comprehensive new research or toxicological and willingness to pay studies on substances in articles. This study has therefore mainly relied on literature research, and limited

consultation, with value transfer techniques to apply comparable and relevant values produced in other studies to substances under assessment in this context.

Table 3.1 Socio-economic assessment of impacts

Type of impact	Type of appraisal and evidence
Operating costs and conduct of business	Manufacturers and importers Assessment of the likely benefits and costs experienced by the supply chain, as compared to the reference scenario, using evidence on the costs of existing restrictions and benefits foregone with respect to the current market situation. Quantitative or qualitative according to data availability and identification of specific issues for SMEs. Consider range of potential impacts such as: ■ Product reformulation; ■ Product entry/withdrawal; ■ Supply chain re-engineering; ■ Fixed/operating costs of additional reporting requirements ■ Potential administrative burdens to companies. Downstream users and consumers Assessment of the anticipated supply chain response and the potential implications of these responses to change in consumer prices (based on judgements about scale of changes in costs and potential for cost pass-through and evidence on the additional costs of alternatives) Evidence on potential change in the range and availability of product choices in the retail environment. Also considered cases where critical raw materials are used.
Competitiveness, Trade and Investment	Appraisal of impacts (including avoided problems) in terms of external trade. Consideration of both trade in products and trade in inputs, with specific attention to the possible effects on the supply of critical raw materials.
Competition and the internal market	Qualitative appraisal of impacts (including avoided adverse impacts on the internal market) in terms of industrial structure of the market (highlighting particular impacts on SMEs), and associated competition issues.
Innovation and research	Qualitative appraisal of wider economic impacts in terms of innovation and research & development, including references to Key Enabling Technologies (KETs) and the impact of redirection of research activities towards regulatory compliance (as opposed to genuine search for market driven innovations).
Distributive/Equity	Consider distributional effects on economic operators in different sub-markets: those using alternative substances or supplying substitute articles; in specific regions; and with specific characteristics (e.g. large companies, SMEs)
Social impacts	Qualitative appraisal of the potential loss/gain of jobs along the affected supply chains (including the supply chain for alternative substances/articles); and the distributional impacts across specific MS regions and groups of economic operators (SMEs)
Administrative costs	Qualitative appraisal on the potential administrative burdens on competent authorities.
Environmental and health impacts	Commentary on potential changes in impacts, based on risk assessments and other sources of data on the (direct and indirect) effects on human health, and the releases to the environment (atmosphere, water, ground, etc.), insofar as these affect consumers

Source: ICF/AMEC

Drawing on the evidence-base of previous steps, for the economic based impact categories (first 5 of table above), an indication of the scale of the impacts across each of the substance's supply chains (substance producers/importers; EU article manufacturers/importers; and consumers) has been assigned in accordance with the following qualitative ranking:

✓ - Benefit or positive outcome;
- No or insignificant anticipated impact;
× - Cost or negative outcome;

This exercise has enabled a visual representation of the main impacts/benefits that could result in the non-use scenarios for each of the substances considered. A summary table with the categories of impact considered, along with a qualitative assessment of impacts for each stakeholder and supply chain, are presented at the end of each substance's specific section.

3.3 Stakeholder Consultation

In order to screen impacts against different stakeholder groups, further follow-up consultation (beyond that in Task 1) with industry actors and a cross-section of key market players, in terms of the different types and quantities of substances and their use/presence in consumer articles, has been carried out via the submission of a substance based questionnaire, telephone interviews and follow-up mail communication.

The aim was to obtain further market and technical information on:

- EU production and the sales value of substances according to use categories;
- How manufacturers/importers/distributors of substances and downstream products would react under the non-use scenarios (cease trading, use alternatives, etc.);
- Technical performance and cost of available substitutes (to estimate economic and technical feasibility of using alternatives);
- Supply chain constraints and upstream demands from users;
- The nature of the effects of restrictions on human health and related environmental factors (including how they compared to using alternatives).

In order to obtain this information, a simple and easy-to-complete survey questionnaire[20] for each of the substances analysed was developed for distribution to representative bodies and companies involved in manufacture, import, formulation and distribution of the 13 substances, stakeholders in the key sectors in which these substances are used/present in consumer articles (i.e. manufacturers of articles), and, where appropriate, the supply chains of identified key alternatives.

By tailoring survey questionnaires to the specifics of each substance the project team was able to target holders of potentially useful information, to guide the responder on specific substance considerations and to avoid any confusion/misinterpretation in the response process (i.e. mixing responses for different substances).

The survey questionnaire contained a high proportion of open questions supported by accompanying instructions and examples in order to enhance detailed and accurate completion of the survey. It also contained an indicative list of potential alternatives suggested in the literature or marketing material to help the responder in the consideration of potential impacts. The main objective of the Task 2 consultation phase was to gather information on:

[20] This was included as annex in previous reports.

- How and why the substance (and mixtures containing the substance) is used/present in articles and its importance to the business and its customers (i.e. in terms of sales, turnover, employees and locations).
- How the business and their customers would respond if there were a ban on some or all of the uses of the substances in consumer articles (i.e. economic, commercial, social and wider implications)
- How other substances or materials that are possible 'alternatives' to the substances compare in terms of performance, availability, cost and other impacts.

In order to encourage the provision of information, the questionnaire gave responders the possibility of responding either in a brief telephone interview or video conference or through a written submission replying to those questions for which they had information.

As consultation progressed, it became apparent that there was a need to contact additional stakeholders in order to cross-check, clarify or complete information that was being gathered. In many cases it was not consider necessary to send the questionnaire (generic in nature) at an advanced stage of the consultation and separately tailored telephone/email survey questions were prepared.

Relevant contacts for the distribution of the questionnaire and further follow-up were identified through contact with trade organisations, ECHA's REACH dissemination portal, internet searches, and through contact with known stakeholders identified through consultation. In this sense, the consultation exercise carried out under Task 1 enabled the project team to identify holders of potentially useful information, their location in the supply chain and the industry/product sectors concerned.

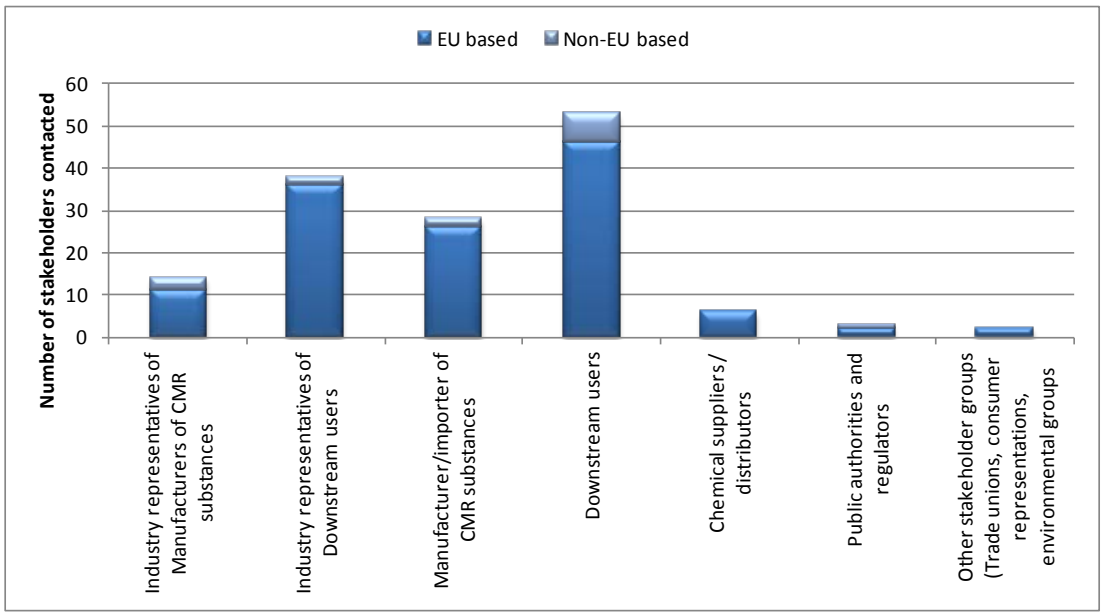
The consultation covered a wide array of upstream (chemical manufacturers, importers, distributors) and downstream (formulators, article manufacturers) stakeholders relevant for each of the substances, including representative industry associations. Added to that list were public authorities and regulators, trade unions, consumer representatives and environmental groups.

Nonetheless, the team identified difficulties in identifying named contacts in individual businesses in several cases, especially regarding the need to contact manufacturers of articles that could contain the selected substances. To reach a suitable number of stakeholders, the team adopted a top down approach to distribution of the surveys, and went on to contact representatives from chemical and industry user/working groups and associations, eventually contacting individual businesses. However difficulties remained regarding non-EU organisations, mainly article manufacturers, even where the team tried contacting alternative organisations such as trade bodies.

Overall, whilst much useful information has been obtained from many stakeholders, there were a number of cases where no information was provided by key stakeholder organisations, despite several telephone and written requests.

In all, 129 EU organisations and 15 non-EU organisations (Table 3.2) were contacted over a period between end of May 2013 to beginning of September 2013. A complete list of organisations contacted is provided in Annex 3.

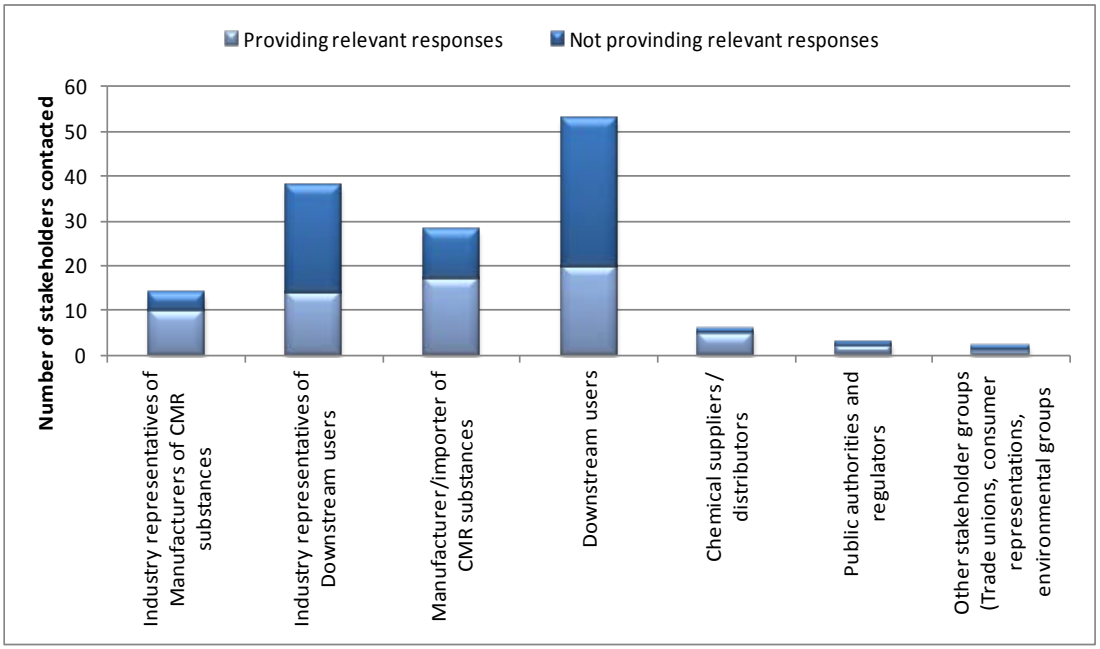
Figure 3.1 EU-based Stakeholders, Organisations and National Authorities Contacted



Source: ICF/AMEC Survey

As of 29 October 2013, 69 stakeholders (48%) had provided relevant responses. In general, companies opted for either scheduling a telephone interview to answer to particular questions or sending specific information through email communication. A summary of the stakeholders providing relevant responses received is provided below:

Figure 3.2 Summary of Stakeholder Responses to the Survey



Source: ICF/AMEC Consultation

Table 3.2 Count of stakeholder responses to the survey

Organisation Type		Number of stakeholders contacted	Number of stakeholders providing responses
Industry Representations	Manufacturers of CMR substances	14	10
	Downstream users (formulators, article manufacturers, etc.)	38	14
Individual companies	Manufacturer/importer of CMR substances	28	17
	Downstream users (formulators, article manufacturers, etc.)	53	20
	Chemical suppliers / distributors	6	5
Public authorities and regulators		3	2
Other stakeholder groups (Trade unions, consumer representations)		2	1
Grand total		**144**	**69**

Source: ICF/AMEC Consultation

As shown in Figure 3.2 and Table 3.2, the responders are predominantly individual companies involved in the manufacturing or import of CMR substances, with 61% of the companies contacted providing a relevant response. In contrast, although a larger number of downstream companies were contacted, fewer relevant responses were received from them, (38% of the total contacted). This was mainly due to the difficulty in targeting downstream users that could be actually impacted by a restriction (i.e. that the substance was of relevance to them). The same pattern emerged at the industry association level, with more representatives of manufacturers contacted providing relevant responses (71%) than those representing downstream users (37%).

Some stakeholders were contacted regarding several substances. An overview of the results of the consultation for each of the substances is provided in each substance's specific chapter in Part 4.

A review of literature sources was completed in parallel with the stakeholder consultation. The aim was to assemble the most relevant and recent published evidence on the use of the substances selected and the social and economic implications of a possible ban on certain uses of the substances in articles. Literature and database sources identified in Task 1 were reviewed first and supplemented with additional documents provided by responders to the consultation, the Commission, ECHA, Member State competent authorities, and through additional literature searches and review. A full list of referenced sources is provided in **Annex 1.**.

4 Substances analyses

4.1 Scoping SEA: 1,2-Benzenedicarboxylic acid, di-C7-11- branched and linear alkyl esters [DHNUP]

4.1.1 Introduction

This section covers the scoping SEA for **1,2-Benzenedicarboxylic acid, di-C7-11 – branched and linear alkyl esters (DHNUP; CAS No. 68515-42-4)** and follows the structure defined in the introduction, concluding with the identification of considerations and elements to help ECHA and the Commission in the development of criteria for application of Article 68.2 for CMR substances in articles.

4.1.2 Regulatory Status

Although DHNUP was pre-registered under REACH, with an envisaged registration deadline of 2010, according to ECHA's databases, DHNUP has not yet been registered.[21]

In January 2011, the Danish Environmental Protection Agency (Danish EPA) published an Annex XV dossier for identification of the substance as SVHC (Annex XV, 2011) and in May 2011, the Member State Committee published an agreement on the identification of DHNUP as a SVHC meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction 1B. This classification corresponds to classification as toxic for reproduction Category 2.

In June 2011, ECHA published a decision to include DHNUP in the Candidate List of substances for eventual inclusion in Annex XIV on the basis of its toxic to reproduction properties (ECHA, 2011). Annex XIV lists all substances subject to authorisation under REACH. The use and placing on the market for a use of substances listed on Annex XIV is prohibited from the time of the "sunset" date unless an authorisation has been granted for that use or unless an exemption applies.

4.1.3 Production and uses of 1,2-Benzenedicarboxylic acid, di-C7-11 – branched and linear alkyl esters (DHNUP) in articles

Phthalates are a group of chemical substances which have in common at molecular level a general structure of carbon chains. DHNUP is a phthalate ester that comprises a combination of high-medium weight, highly solvating ortho-phthalates and high weight, low migration ortho-phthalates (Environment Canada, 2009a). Several individual phthalates are classified as toxic to reproduction 1B (R1B) and are documented endocrine disruptors or are suspected of being endocrine disruptors affecting reproduction in human beings and animals.[22]

DHNUP is characterised by structural flexibility and is classified in the Annex XV SVHC dossier as an "Unknown or Variable Composition, Complex Reaction Products, or Biological Materials" (UVCB) substance. It is primarily used as a plasticiser in PVC, in foam production and as an adhesive or sealant. By suspending PVC in a plasticiser, the plastisol (which is a liquid suspension of PVC particles in a plasticiser) imparts enhanced properties of flexibility and durability to the PVC. Further, DHNUP benefits from compatibility with several polymer resins, including copolymer and homopolymer vinyl resins, nitrile, chlorinated and styrene-butadiene rubber, cellulosics, neoprene, polyurethane, acrylic latex, alkyd resins and rosin-

[21] According to records in ECHA's database on registered chemicals (http://echa.europa.eu/search-chemicals) as of 13 November 2013.

[22] See for instance Lowell Centre for Sustainable Production (2011), Phthalates and their Alternatives: Health and Environmental Concerns

modified polyester resins of maleic anhydride and glycerine. Products potentially containing DHNUP identified in this study include:

- Electrical and communication wiring/ insulation;
- Automotive sealants;
- Urethane, glass, and transmission adhesives;
- Roof coatings, barrier coatings, exterior trim, and tarps;
- Cement, caulk, and sealers; and
- High end luggage.

From the results of the first task of the study, it was confirmed that the applications of greatest potential for exposure of consumers relate to PVC products. High-molecular weight phthalates such as DHNUP are trapped with the polymer matrix (covalently bound), which leads to off-gassing over the decades of service life of products containing the substance. One study estimated that some manufactured articles do not reach landfills for as long as 30 years after having been fabricated) (Environment Canada, 2009a). Exposure levels are 8.7 µg/kg-bw per day for toddlers and 3.3 µg/kg-bw per day for adults (Environment Canada, 2009a) and may be further restricted on account of the external physical barriers posed by cables and wiring.

European phthalate manufacturers as a whole and the European Council for Plasticisers and Intermediates (ECPI) advised that DHNUP is not manufactured in or imported to the EU at present. (Annex XV SVHC Dossier, 2011) However, one EU-based electrical cable manufacturer stated that the substance was used in the production of certain cable types[23]. Further, DHNUP has been manufactured in, as well as imported into, a number of non-EU countries in recent years. Manufacturing in Canada was estimated at between 100 and 1,000 tonnes in 2006 and imports into Canada in the same year were between 10,000 and 100,000 tonnes. This reduction in the use of DHNUP in Canada occurred largely due to the decreased availability of the upstream plasticizer alcohols required for its synthesis. It is not known if the decline in DHNUP quantities in Canadian commerce is temporary or permanent therefore continued imports of articles containing DHNUP into the EU from Canada cannot be ruled out (e.g. as a component of sealants in EU car imports from Canada). (Environment Canada, 2009a). Information on use in other non-EU countries was unobtainable.

4.1.3.1 *DHNUP in articles*

Acknowledging that EU-manufactured PVC articles do not contain DHNUP, the focus of the analysis undertaken in this section was on quantifying the volume of DHNUP in articles potentially imported into the EU per annum. As this is a scoping study, analysis of the potential presence of DHNUP was confined to the following products, the imports of which may contain DHNUP:

- PVC insulated wire and cable;
- Water beds and air mattresses;
- Bathing equipment (swim-coats/wings/belts and pools); and
- Luggage items (bags, brief-/suitcases and similar items).

These articles were selected on the basis of their prevalence in the marketplace and the potential exposure of consumers to DHNUP via uses of the articles. As the presence of DHNUP in these products cannot be ruled out (given that phthalates are not regulated in China and other non-EU countries where the products in question are produced), it may be

[23] These suppliers, however, subsequently reported that they did not manufacture DHNUP, which suggests that the cables in question might have been produced using stock purchased in previous years.

argued that exposure to the substance could occur, although at low levels, primarily through migration from consumer products (e.g. through inhalation or skin contact).

4.1.3.1.1 PVC insulated wire and cable

Plasticised PVC is commonly used for electrical wire and cable insulation. Phthalates comprise the most frequently used plasticisers in this context. While the chance of consumer exposure to electrical wires and cables may not be high, it cannot be ruled out given the ubiquity of electrical wiring in modern homes.

The EU was estimated to have imported more than 471,000 tonnes of insulated wire and cable in 2011 (Danish EPA, 2012).The percentages imported from various countries are detailed in Table 4.1.

Table 4.1 Imports of insulated wire and cable to EU 27 in 2011

The position number in this column refers to data in the Eurostats database on external trade	2011 tonnes imported into EU 27	Articles	Largest exporters (2011)
Position 85442000	78,616	Co-axial cables, insulated	China (64%) Morocco (12%) Turkey (8%)
Position 85444210	25,859	Electric conductors, telecom., ≤1000 V, insulated	China (83%)
Position 85444290	170,856	Electric conductors, ≤1000 V, insulated, with connectors	China (66%) Tunisia (8%) Morocco (5%) Ukraine (5%)
Position 85444920	58,792	Conductors, Electric, <= 80 V, insulated, telecom.	China (49%) Turkey (11%) Tunisia (7%) Taiwan (7%) South Korea (7%)
Position 85444993	37,533	Conductors, Electric, <= 80 V, insulated,	Turkey (31%) Morocco (17%) Tunisia (14%) China (14%)
Position 85444995	99,590	Conductors, Electric, 80 V ≥, <= 1000 V, insulated,	Turkey (43%) Switzerland (19%) China (13%) Egypt (8%)
Total	**471,246**		

Source: Danish EPA, 2012.

A review of the available evidence and consultation findings indicates that a 0.1-10% concentration of DHNUP (by weight) in PVC articles is typical. On this basis, it is estimated that up to 23,000 tonnes of DHNUP may be entering the EU each year in the form of PVC insulated wire and cable (conservatively assuming an average concentration level around 5%).

Further, it can be assumed that only a proportion of these imports end up contributing to wiring and cables in homes and therefore contribute to consumer exposure, in cables and cords connected to home and office computers, home and office lights, office equipment, home appliances and cable television (coaxial cables). Of the cables listed in the table above, those for usage at 80 volts or less, plus coaxial cables, could be used by consumers

on a regular basis. However, conductor and telecom cables are not likely to be directly used by consumers. Taking into account these assumptions, approximately 175,000 tonnes of the imported cables might be used by consumers. Using the 5% content described above, this could amount to consumer exposure of more than 8,700 tonnes per year. However, this exposure is likely to be limited with limited handling and proper use of cables by consumers.

4.1.3.1.2 Waterbeds and air mattresses

Waterbeds and air mattresses (or inflatable mattresses) that are imported into the EU from third countries may contain traces of DHNUP, given that soft PVC is commonly used in manufacturing these articles. The potential of consumer exposure to DHNUP through these articles merits examination.

Consultees did not confirm or deny the presence of DHNUP in waterbeds and air mattresses, but did confirm that EU producers have switched to alternatives. The presence of these articles in imports is therefore unknown. The following is therefore provided as an estimation of the potential scale of DHNUP use.

Eurostat estimates that 8,400 tonnes of waterbeds and air mattresses were imported by EU MS in 2011, with nearly all (98%) of these imports arriving from China (Danish EPA, 2012). The extent to which these articles contain DHNUP is unclear. Substitution of PVC with emerging alternatives such as rubber and textile reinforced urethane plastic in the manufacturing of waterbeds and air mattresses in time may mean that the above figures are overestimates. Nevertheless, the analysis does demonstrate that even with small concentration of phthalates in articles, the volume of article consumption in European market is sufficient to indicate potential consumer exposure. Assessing whether an actual risk results from this exposure is outside the scope of this study.

4.1.3.1.3 Bathing equipment

Bathing equipment (the most commonly used types of which include swimsuits and wings, belts and pools used for bathing) constitutes another potential source of DHNUP phthalate exposure in the EU. As it is worn close to the skin and sometimes contains phthalates, there is some potential of exposure to DHNUP from imported bathing equipment, as it is confirmed that EU use has ceased.

Imports in 2001 are estimated at just over 200,000 tonnes (Danish EPA, 2012). Most of the imported articles (87%) came from China. The extent to which such articles may contain phthalates is difficult to estimate, however a study conducted by the Swedish Chemicals Agency in 2012 suggests that roughly 10% of such articles might be considered to include prints containing low phthalate concentrations (Swedish Chemical Agency, 2013). Assuming for simplicity that no more than 10% of this group of articles (i.e. 1% of the total import stock) are likely to contain DHNUP (rather than alternative phthalates such as DEHP) and that, where present, DHNUP is likely to appear in low concentrations of approximately 1% on the whole (as outlined in the subsections above), it may be estimated that the DHNUP content in bathing equipment imported by the EU is likely to amount to no more than 20 tonnes.

4.1.3.1.4 Luggage items

Luggage items such as bags and suitcases/ briefcases constitute a category of articles which may contain DHNUP, however confirmation of use and the relevant quantities used has been difficult to obtain. As late as 2010, use of DHNUP in the manufacturing of such items was registered outside the EU, not only in emerging markets but also in Canada (Annex XV SVHC Dossier, DHNUP, 2011). Nonetheless, of the 15,000 tonnes of such items imported by the EU in 2011, the great majority were imported from China (Danish EPA, 2012). We have been unable to quantify the amount of DHNUP imported via luggage articles. However, based on the illustrative example in relation to waterbeds and air mattresses it is possible that given the large volume of luggage (handbags, cases) sold in the EU per annum and imported, that only a small concentration of DHNUP in small proportion of products would be sufficient for consumer exposure to a quantity of DHNUP.

However if the concentration of DHNUP is low in these articles it is likely that consumer exposure will also be low.

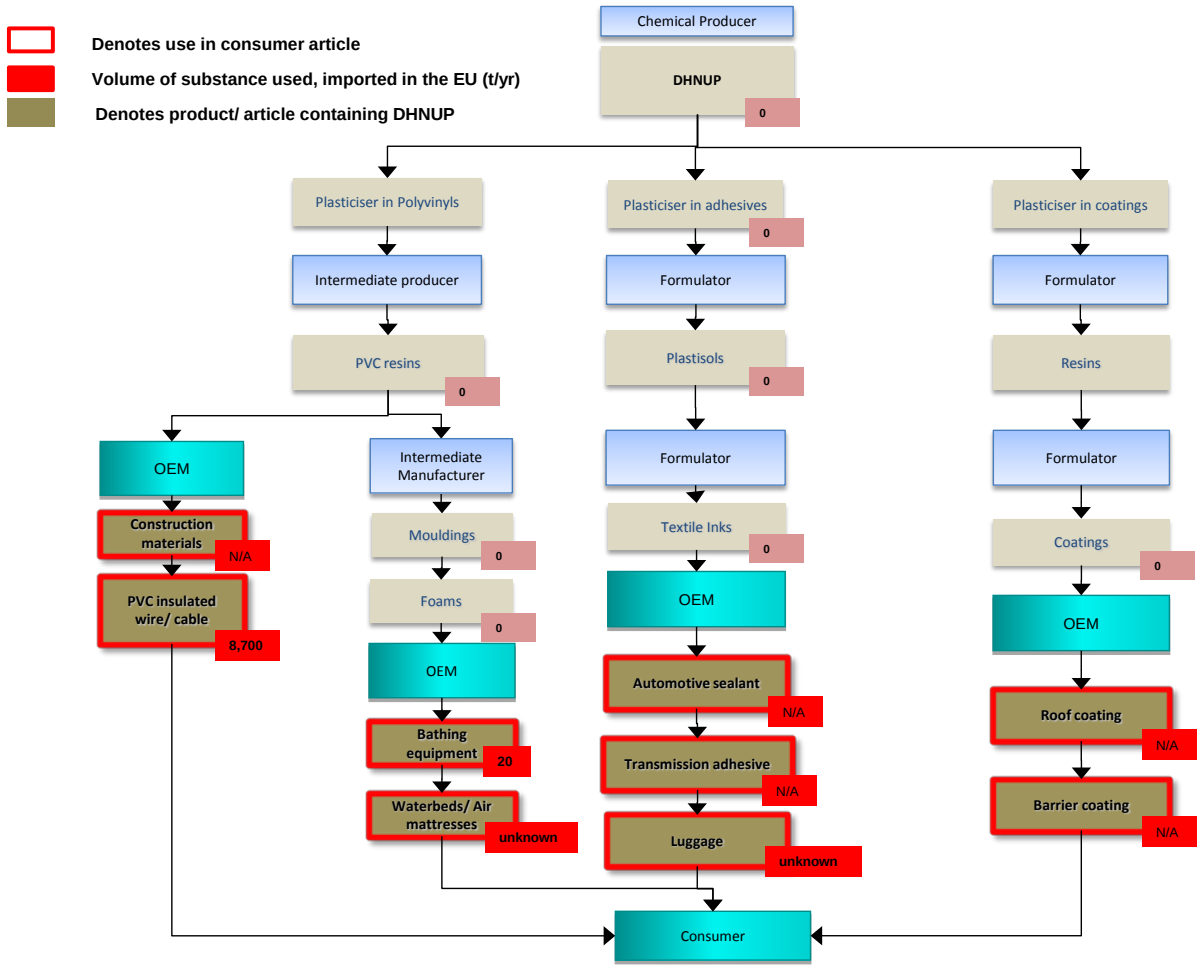
4.1.3.2 *Trends in DHNUP production and usage*

Phthalates accounted for just over 78% of the world consumption of plasticizers in 2012, down from approximately 88% in 2005; they are forecast to account for 75.5% of world consumption in 2018 (HIS Chemical, 2013). Regarding recent trends in commerce, Canadian consumption of linear phthalates in general, represented by C7-C11 phthalates as the majority market component, is expected to decrease at an annual average growth rate of −12.9% between 2005 and 2010 Worldwide consumption of linear phthalates is expected to decrease at an annual average growth rate of −22.9% for the same period. Plasticization of vinyl resins using high molecular weight plasticizers such as DHNUP represents the highest volume use of phthalate esters worldwide and 80–90% of worldwide plasticizer consumption in general (Environment Canada, 2009a).

4.1.4 Supply chains affected

Figure 4.1 illustrates the supply chain for DHNUP contained in consumer articles, identifying those stakeholders potentially affected by a restriction and summarising the volumes present in each use. The quantity of DHNUP estimated to be present in the EU is provided in the flow diagram, with the quantities embedded in imported articles highlighted in red.

Figure 4.1 Summary of supply chains of DHNUP



Source: ICF/AMEC Consultation

Upstream of those articles potentially containing DHNUP, the supply chain starts with the production of DHNUP which is known not to occur in the EU (shown by the muted colours in the diagram). Equally, the use of DHNUP by formulators of PVC resins and plastisols supplied to plastic manufacturers does not occur in the EU. Applications of DHNUP containing plastics are then shown in the four branches of supply chain diagram. Final products (articles) where consumer exposure cannot be ruled out populate the remaining branches of the supply chain. With zero quantities of DHNUP containing plastics being used in the EU, the diagram clearly highlights that any quantities of DHNUP found in articles come from imported products. Based on the analysis conducted above, it is estimated that about 25-30 tonnes of DHNUP per annum may enter the EU in imports. Waterbeds and air mattresses are excluded from this estimate due to the absence of quantitative information on the amount of DHNUP present in these articles.

4.1.5 Expected non-use scenario

During the preparation of the scoping SEA, a consultation exercise with industry was undertaken to ascertain anticipated responses to a restriction for DHNUP in consumer articles. Efforts were made to engage with European manufacturers and importers and non-EU manufacturers of consumer articles potentially containing DHNUP, as well as selected other stakeholders (e.g. research institutes and testing bodies). The results of this consultation are included in Table 4.2.

Table 4.2 Consultation exercise

	Type of industry/article	Stakeholders contacted	Valuable responses received
Trade/ industry associations	Textiles, inks, plastics, toys, construction, chemicals	9 European 3 International	2 European
Private companies	Manufacturers/ importers of phthalates, and formulators	5 all with EU representation	2 responses
Other stakeholders	Testing bodies, competent authorities	1 European 1 National	1 European 1 National

Source: ICF/AMEC Consultation

In the case of DHNUP, for which production and use has already ceased in Europe, it is clear that a restriction would simply legally enforce the phase-out activities that industry has already undertaken. A focus was therefore placed on non-EU manufacturers to confirm whether or not DHNUP is used in various production processes or if any restrictions exist in third countries. A lack of input received in this regard led to the conclusion that, although unlikely, continued use of DHNUP in consumer articles imported to the EU could not be ruled out. The remaining assessment has consequently relied to a large extent on literature sources, given the difficulties in consulting with third country stakeholders.

For each supply chain considered above, the probable responses of stakeholders to the proposed restriction are summarised in Table 4.3.

Table 4.3 Expected response of article supply chain to proposed restriction

Article supply chain	Response of EU industry	Alternative (if applicable)
PVC insulated wire and cable	Use already ceased, imports from outside the EU to continue	Switch to other phthalates (i.e. DIDP, DINP) outside EU
Waterbeds and air mattresses	Use already ceased, imports from outside EU to continue	Switch to other phthalates (i.e. DIDP, DINP) outside EU
Bathing equipment	Use already ceased, imports from outside EU to continue	Switch to other phthalates (i.e. DIDP, DINP) outside EU; Switch to citrates, sebacates, adipates, and phosphates as alternative to phthalates where bathing toys meant for children are concerned (Lowell Centre for Sustainable Production, 2011)
Luggage items	Use already ceased, imports from outside EU continue	Switch to other phthalates (i.e. DIDP, DINP) outside EU

Source: ICF/AMEC Consultation

4.1.6 Assessment of economic and social impacts

4.1.6.1 Screening of impacts

The first step in the SEA is a screening of the impacts and stakeholders potentially affected by the restriction. This ensures that the analysis is focussed on those stakeholders most affected by the proposed restriction and considers the nature and scale of the impacts, following the SEA guidelines produced by ECHA in relation to the possible costs and benefits. Categories of impact are shown in Table 4.4, along with a qualitative assessment of impacts.

With no production or use of DHNUP in the EU, it is not surprising to find that no direct impact is expected on EU industry. Nevertheless, a restriction which increases the costs of non-EU industry or imposes requirements on importers is likely to have a positive competitiveness impact on EU industry. Consumers are found to benefit on the one hand from mitigation of any risks to the environment and human health. However, a restriction on DHNUP in articles that is strictly enforced for imported articles would likely results in higher prices as non-EU manufacturers passed increased operating costs (to incorporate substitutes) on to consumers. Some manufacturers may stop manufacturing rather than use alternative substances, in which case, the choice of articles on the EU market is reduced. Each impact is assessed in greater detail in what follows.

4.1.6.2 Direct economic impacts

For DHNUP, no quantitative assessment of the impacts was possible because, as identified in the initial scoping, the costs of the restriction would only affect non-EU industry and EU consumers. Other impacts on, for example, competitiveness are also assessed qualitatively.

At present, DHNUP is neither commercialised nor used in the production of consumer articles in the EU. Alternatives are widely available and have already been substituted for DHNUP in production processes[24]. Consequently, an EU-wide ban on DHNUP would not result in job losses or increased operating costs for EU manufacturers.

On the other hand, a restriction on DHNUP in articles is likely to have a cost impact on importers and non-EU suppliers if they wish to continue to import the DHNUP-containing articles into the EU. Non-EU manufacturers would be pressed to integrate safer alternatives

[24] Confirmed by stakeholders: ref: ICF/AMEC consultation; see also Annex XV Dossier, DHNUP, 2011.

into their manufacturing processes. Such requalification of materials can be a costly and time-consuming process whereby performance of replacement products would have to be thoroughly tested and verified. Replacing DHNUP could also lead to other direct costs such as the costs of purchasing different processing and handling equipment or increased amounts of raw materials in order to achieve similar outcomes (to those achieved through the use of DHNUP). Indirect costs – such as those incurred on account of reduced efficiency associated with replacement products – could also potentially arise. All of these increased costs would be passed on to consumers in the form of higher prices.

In a similar vein, it is highly probable that EU importers would be required to demonstrate that imported products do not have a detectable content of DHNUP before they are marketed. This would necessitate adequate testing of replacement products and communicating safe use information to relevant authorities and consumers, which could eventually add to costs and drive up prices of some products imported into the EU.

4.1.6.3 *Indirect impacts*

Phthalate free production has been widely promoted in some industries (e.g. in the manufacture of toys) (Washington Toxic Coalition, 2008). Furthermore, CMR substances cannot be used in toys, via the generic ban on CMR substances: "CMR substances shall not be used in toys, components of toys or micro-structurally distinct parts of toys" in Regulation 2009/48/EC.

A restriction on DHNUP may induce non-EU producers to follow EU producers to such alternatives. This should provide greater certainty around the content of imported products, especially at a time when consumers are growing increasingly worried about the long term consequences of chemical exposure. A restriction should also provide certainty to producers of alternatives and encourage the further innovation of safer and more affordable substitutes in this and other uses.

For consumers, if EU-manufactured articles are perceived as safer compared to imports where non-compliance is higher following a restriction, consumers may be more confident to purchase EU produced articles and accept a small increase in price for the finished article.

4.1.6.4 *Wider social impacts*

As no changes in production are foreseen for EU manufacturers, employment is unlikely to be affected by a restriction on DHNUP. What is more significant is that if EU producers gain a competitive advantage or the restriction ensures a level playing field, employment should be expected to be maintained or expanded consistent with shifts in consumer demand.

An adverse impact could however affect SME importers as compliance with a restriction on DHNUP may require a large commitment of professionals knowledgeable in regulatory affairs, which small companies may lack. If SMEs cannot afford channelling resources into regulatory efforts, time and effort to implement product testing and undertake administrative requirements, smaller businesses may find it more difficult to compete.

Finally, as mentioned above, there are several potential outcomes wherein consumers are subjected to higher prices.

4.1.6.5 *Administrative costs*

To enforce the restriction, competent and border authorities of the MS responsible for market surveillance and testing of imports are expected to see an increase in workload. However, as their work includes testing for multiple substances in articles or mixtures, it is difficult to quantify the impacts of adding a single substance to their list of responsibilities. Additional administrative costs of compliance for EU importers were described above.

4.1.6.6 *Potential human health and environmental benefits (for consumers)*

Reported routes of exposure for consumers which may result in injury or illness include the oral ingestion of phthalate containing articles (e), or from breathing in phthalates contained in household dust as articles degrade or undergo off-gassing in the home (e.g. and old luggage equipment). Consequently, due to the high prevalence of mouth-to-hand contact, children are often more susceptible to exposure than adults. There is also some evidence to suggest that phthalates are ingested through the skin in the case of vinyl flooring (Carlstedt, Jönsson, and Bornehag, 2013). Despite this, much of the literature and evidence focusses in inhalation of dust in the air as the main exposure route.

Recognised as toxic to reproduction, phthalates such as DHNUP are known to be a contributing factor in infertility in unborn children and even, in some cases, in adults (Annex XV SVHC Dossier, DHNUP, 2011). The beneficiaries of a restriction on the use of DHNUP could thus include couples no longer requiring fertility treatment due to the restriction on, and therefore a reduced exposure to, DHNUP. The benefits should not only include the private costs to the couples concerned, but also the wider costs to their family and society (the social benefits). The benefits to include are:

- The medical cost of fertilisation treatment, which would have been incurred by the private individual, couple and/or the state healthcare provider. This includes the costs of consultation, treatment and any medicines prescribed;
- The lost earnings incurred by the couple in undergoing consultation and treatment, plus the loss of productivity the employer may have incurred from the absence of the couple;
- The wider intangible effects on close friends and family, related to their stress and well-being, which they would have a willingness to pay to avoid or to experience (i.e. birth of grandchild).

It may not be straightforward to quantify the net environmental impact. In essence, an ecological benefits assessment will depend on two components: (1) the extent to which ecological benefits are or may be ameliorated as a result of the ban; and (2) the monetary value that could be ascribed to the ecosystems protected. This could prove challenging given that ecological risk characterisations and assessments do not express effects in terms of 'impacts' that can be valued. The high degree of uncertainty noted above in relation to the quantities used/present in articles will make it difficult to quantitatively estimate any potential human health/environmental improvement in this context.

4.1.7 Overall conclusions on potential costs and benefits

The review of socio-economic evidence in relation to DHNUP indicates the absence of any substantial economic costs for EU industry due to the fact that DHNUP is neither produced nor used in the EU. However, if non-EU manufacturers incur costs to change their manufacturing processes to incorporate substitutes and/or importers must comply with testing practices to ensure DHNUP content below thresholds in the imported articles, costs associated with these activities will be passed on to consumers. Additionally, if non-EU manufacturers cease manufacture of some articles, rather than employ substitutes to DHNUP, consumers will have fewer choices in the marketplace. A restriction on imports containing DHNUP could generate human health and environmental benefits.

4.1.8 Substance-specific considerations for development of draft criteria to implement art 68.2 to CMR 1A and 1B in consumer articles

With regard to the potential choice of Article 68.2 as a risk management option (RMO) (compared to other forms of restriction), the following considerations arise from this case study:

- Given that, in 2011, ECHA published a decision to include DHNUP in the Candidate List of substances for eventual inclusion in Annex XIV and the substance is already being

phased out by industry, it may be difficult to justify a faster Article 68.2 restriction aimed at EU article manufacturers. However, if use of DHNUP were to re-emerge in the future before an Article 69 restriction were in full effect, Article 68.2 might be considered to maintain consumer protection and providing certainty for producers of alternatives;

- Given the above activities, there may be enough risk information in place to build a case for an Article 68.2 restriction on DNHUP in imported articles.
- Given the possibility of the prevalence of DHNUP in imported articles, an Article 68.2 or 69 restriction could level the playing field between EU manufacturers who have already sought out alternatives and incurred costs and the non-EU manufacturers who are selling articles at cheaper prices because they have not incurred these costs.
- DHNUP is used (or has been used) in both consumer articles and in industrial articles, especially in cables. Criteria should therefore take into account the extent to which there is clearly use in consumer articles like cables, and the extent to which these can be distinguished from industrial cables.
- A key point that remains unknown is the level of exposure to DHNUP by the final consumer. The potential for measuring/monitoring the presence of the substance in articles is therefore important to take into account in developing criteria. At present there is relatively little certainty on the degree of any risks to the consumer. Further research and testing would be required to assess the concentration of DHNUP in articles, and the associated exposure for the general public taking into account likely migration, as well as whether there is any “safe” threshold for exposure. Criteria may need to take into account whether there is a risk to consumers that needs to be addressed, as well as the uncertainties in the current level of knowledge on the risks. However, the extent to which a risk may need to be demonstrated in the context of an Article 68.2 restriction is as yet unclear. In setting out the wording of a potential restriction, it could be important to ensure that all of the articles entering the EU market are covered.

Table 4.4 Screening of relevant impacts by stakeholder group and impact category

✓ - Benefit or positive outcome
- No or insignificant anticipated impact
× - Cost or negative outcome

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
All identified consumer articles	Operating costs and conduct of business	No impact anticipated as production of DHNUP has ceased in Europe -	No impact anticipated as EU manufacturers of articles are already using alternatives to DHNUP in production lines. Some regulatory costs if there is a need to show DHNUP is not being used. -/×	Costs for non-EU manufacturers to implement substitutes could drive up prices of imports. If non-EU manufacturers do not demonstrate a regulatory-compliant level in articles, then importers may undertake testing before importing the article. ×	No impact anticipated as production of DHNUP has ceased in Europe and EU manufacturers of articles are already using alternatives to DHNUP in production lines. Some regulatory costs if there is a need to show DHNUP is not being used. -/×	Consumers may see higher prices on articles manufactured outside of the EU or more limited choices if non-EU manufacturers cease manufacture of articles rather than seek substitutes to DHNUP. ×
	Competitiveness, Trade and Investment	No impact anticipated as production of DHNUP has ceased in Europe -	No impact anticipated as EU manufacturers of articles are already using alternatives to DHNUP in production lines. Some regulatory costs if there is a need to show DHNUP is not being used. If imports cease or slow down, EU manufacturers may see increased business. -	Due to higher costs mentioned above, EU importers of articles may lose their competitive edge in a highly competitive EU market ×	No impact anticipated as EU manufacturers of articles are already using alternatives to DHNUP in production lines. Some regulatory costs if there is a need to show DHNUP is not being used. If imports cease or slow down, SMEs may see increased business. -/×	Greater certainty around chemical content in imported articles. Higher prices on imported products may induce substitution for what is locally produced. Choice may thereby restricted. ×/✓
	Competition and the internal market	No impact anticipated as production of DHNUP has ceased in Europe -	No impact anticipated as EU manufacturers of articles are already using alternatives to DHNUP in production lines. Some regulatory	Local manufacturers of articles who have already switched to alternatives would be advantaged if there higher prices on or cease of manufacture of some imported articles	No impact anticipated as EU manufacturers of articles are already using alternatives to DHNUP in production lines. Some regulatory costs if there is a need to show	N/A

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
			costs if there is a need to show DHNUP is not being used. -/×	×	DHNUP is not being used. -/×	
	Innovation and research	No impact anticipated as production of DHNUP has ceased in Europe -	No impact anticipated as EU manufacturers of articles are already using alternatives to DHNUP in production lines. Some regulatory costs if there is a need to show DHNUP is not being used. -/×	No impact on innovation and research as these activities not undertaken by this group -	No impact anticipated as EU manufacturers of articles are already using alternatives to DHNUP in production lines. Some regulatory costs if there is a need to show DHNUP is not being used. -/×	N/A
	Distributive/Equity	No impact anticipated as production of DHNUP has ceased in Europe -	No impact anticipated as EU manufacturers of articles are already using alternatives to DHNUP in production lines. Some regulatory costs if there is a need to show DHNUP is not being used. -/×	Larger impact on EU article importers than local manufacturers due to additional costs ×	No impact anticipated as EU manufacturers of articles are already using alternatives to DHNUP in production lines. Some regulatory costs if there is a need to show DHNUP is not being used. -/×	N/A

Source: ICF/AMEC Consultation

4.2 Scoping SEA: Gallium Arsenide [GaAs]

4.2.1 Introduction

This section covers the scoping SEA for **gallium arsenide (GaAs; CAS No. 1303-00-0)** and follows the structure defined in the introduction, concluding with the identification of considerations and elements to help ECHA and the Commission in the development of criteria for application of Article 68.2 for CMR substances in articles.

4.2.2 Regulatory Status

GaAs was registered by three companies as a full substance in the tonnage band 10 – 100 tonnes per annum.[25]

GaAs is The Committee for Risk Assessment (RAC) of ECHA has been tasked to evaluate new data on the toxicity to reproduction of GaAs, pursuant to Article 77.3.c in REACH. In its latest opinion, published in July 2013, the RAC confirmed its view to classify GaAs as a substance toxic to reproduction (category 1B) (ECHA RAC, 2013). In 2011, RAC had already adopted the recommendation to classify GaAs as carcinogen (category 1B) (ECHA News Alert, 2011).

4.2.3 Production and uses of Gallium Arsenide (GaAs) in articles

GaAs cannot be found naturally. It is manufactured from the raw materials arsenic (As) and gallium (Ga), often to levels of ultra-high purity. The compound GaAs is a semiconductor and is therefore used in the manufacture of devices that use semiconductors (Table 4.5 below presents a list of the main consumer devices using GaAs). Within the production process of semiconductor device, GaAs goes through 4 production steps before its integration within consumer devices:

1. Synthesis of polycrystalline raw material;
2. Single crystal ingot growing;
3. Wafer processing (cutting, polishing); and
4. Epitaxy[26].

In the first stages of ingot growing and wafer production, elemental Ga and As, plus small quantities of dopant material (carbon, silicon, tellurium, or zinc) react at extremely high temperatures (around 1200°C) to form ingots of doped single crystal GaAs. Different methods of ingot production are used in the semiconductor industry. The crystalline structure of each GaAs ingot is determined using x-ray diffraction and the ends of the single crystal ingot are cropped. In the third stage of production, the GaAs ingots undergo a series of manipulations to prepare GaAs wafers (US Department of Labor - OSHA, 2013). During this process a large quantity of GaAs is lost, mainly in the form of dust, which is then collected, treated and recycled. Depending on the quality of the lost material, it is either reused in the production process of GaAs wafers, selected for gallium recycling or treated as waste.

In a fourth step, the single-crystal GaAs wafers are used as substrates for the growth of very thin layers of the same or other III-V compound semiconductors[27] with different electrical conductivity or optical properties (the substrate determines the crystallinity and orientation of

[25] According to records in ECHA's database on registered chemicals (http://echa.europa.eu/search-chemicals) as of 13 November 2013.

[26] Epitaxy is the process of growing thin films of crystals, in which the substrate determines the crystallinity and orientation of the grown layer. A variety of epitaxial growth techniques are used in III-IV display and device production. The two most common techniques are Vapour Phase Epitaxy and Liquid Phase Epitaxy (US Department of Labor - OSHA, 2013).

[27] III-V compound semiconductors have at least one group III element and at least one group V element, e.g. GaAs.

the grown layer during this process). A variety of epitaxial growth techniques are used in the III-V semiconductor display and device production (US Department of Labor - OSHA, 2013). In the final production stage the encapsulated substrates or semiconductors based on GaAs are integrated into the fabrication process of electrical and optoelectronic components that will be further integrated into the manufacture of consumer or business to business (B2B) articles[28].

4.2.3.1 *GaAs in consumer articles*

The properties of GaAs and GaAs compounds are used to achieve very high performance attributes in a variety of products in which GaAs containing semiconductors are found. The key properties of GaAs or compound semiconductors based on GaAs are:

- High electronic speed – the mobility is 5 to 10 times higher than the one achieved with silicon – enabling transistors to operate at high frequency while being relatively insensitive to heat compared to silicon based transistors;
- High breakdown voltage enabling the creation of high power components; and
- *Direct band gaps* – enabling efficient generating of light (e.g., light emitting diodes (LED), semiconductor lasers including vertical-cavity surface-emitting laser (VCSEL).

When GaAs wafers are used as a substrate for the epitaxial growth of other complex III-V compounds, the complex multilayer structures that can be produced enable the creation of many new quantum electronic and photonic devices. The complex III-V compounds are grown on GaAs substrates rather than on other substances because the crystal lattice structure of GaAs minimises mechanical stress which improves the lifetime and performance of GaAs-based devices. At the end of the production process the GaAs substrate is removed from the finished semiconductor so that only residual quantities of GaAs remain in the final article using the new III-V compounds[29].

During the consultation process, stakeholders were asked to identify in which consumer articles GaAs components are used, a summary of which is provided in Table 4.5.

Table 4.5 Identified consumer articles based on GaAs

Applications	Consumer articles
Wireless applications	- Smartphones; - Computers and tablet devices; - Handsets; - Cable TV; - GPS; - WIFI connectivity.
Photonic applications	- All devices using red and infrared (IR) diodes emitters and photo-detectors: e.g. DVD/CD/Blue-ray players, remote controlled equipment, chargers for mobile devices; - Device interface; - Red, yellow and orange LED: backlighting of displays in many consumer devices; - IR LED and IR lasers: sensor technology in vehicles, security surveillance, mobile devices.
Solar applications	- Terrestrial and spatial solar panels.
Telecommunication and	- Computers and tablet devices;

[28] B2B articles purchased by businesses or governments and not by consumers. They are then among others used in developing the necessary infrastructure for the working of many consumer articles (e.g., fibre-optic communication infrastructure for data transmission purposes).

[29] Stakeholder consultation and READE, 2013.

Applications	Consumer articles
electronics applications	- Smart phones; - Handsets; - GPS.

Source: ICF/AMEC Consultation

It should also be stressed that GaAs substrates are also essential components of the infrastructures and technologies necessary for the working of the consumer devices identified (e.g. fibre-optic communications, radiofrequency components, base stations, satellites). In addition to the use of GaAs in the manufacture of consumer articles, it has important uses in numerous research and development (R&D) activities carried out by research institutes and universities for purposes such as energy efficiency and improved radio frequency performance applications.[30]

4.2.3.2 *Quantification of GaAs presence in articles*

Despite its use in a large variety of applications in many different consumer articles, the overall quantity of GaAs wafers produced on a yearly basis is relatively small. The stakeholder consultation enabled us to estimate the total production of GaAs ingots in the EU to be around 70 tonnes per year. As stated in the production process described above, GaAs ingots undergo a series of manipulation steps to prepare GaAs wafers. Each of the processing steps results in the removal of GaAs from the original ingot, mainly in the form of dust: between around 35% and 60% of the original ingot material is typically removed.[31] Depending on the quality of the lost material, the collected dust is either reused in the production process of GaAs wafers, selected for gallium recycling or treated as waste. The quantity of GaAs wafers manufactured in the EU is therefore smaller than for total ingot production, and is estimated to be around 40 tonnes per year. The worldwide production of GaAs wafers is estimated between 125 and 200 tonnes per year.[32] GaAs wafer manufacturers can also import GaAs ingots from outside the EU for wafer production inside the EU. No data are available on the total volume of imports of GaAs ingots or wafers to Europe.

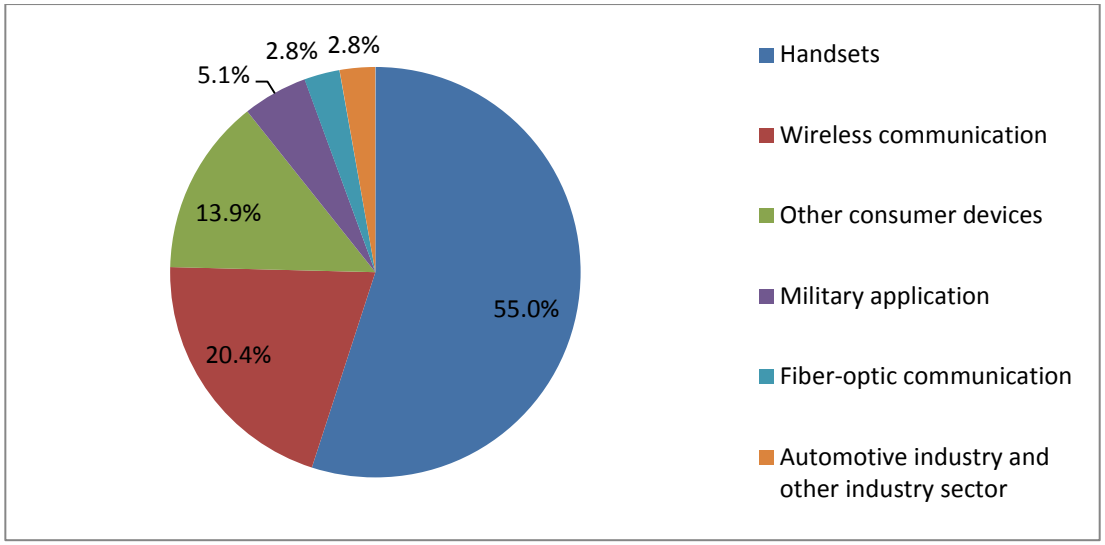
The quantities of GaAs wafers traded are therefore relatively small even though the size of the market is very important due to the high added value of applications in which the finished components are found. The size of the global market for devices containing GaAs was estimated at $US 5.2 billion in 2012 by Strategy Analytics, with a projected compound average annual growth rate of (CAAGR) of 3% for the period 2011-2016 (Highman, 2012). More optimistic projections forecast the market growth of GaAs containing devices at a CAAGR of 8% over the period 2011-2015 (TechNavio, 2013). This growth is driven by the demand for new generation smartphones and handsets (55% of the global market for GaAs) and wireless communication devices (20% of the market) (Highman, 2012). New developments in the photonic and solar cell industry also have the potential to contribute to the market growth in the coming years. Figure 4.2 presents a breakdown of current uses for GaAs devices by application.

[30] Example of leading EU research institutes in microelectronics developing research programmes based on GaAs include: Fraunhofer ISE and its research on solar cells (http://www.ise.fraunhofer.de/en); CEA-LETI (http://www-leti.cea.fr/) and IMEC (www.imec.be) and their research on III-V compounds for advanced Complementary Metal-Oxide Semiconductor technologies.

[31] Stakeholder consultation and Barron, 2012.

[32] Stakeholder consultation.

Figure 4.2 GaAs device market segmentation – 2011



Source: Highman, 2012.

Based on this analysis the present scoping SEA will focus on three different consumer articles which play a key role in the growth of the GaAs device market: smartphones, tablets and LEDs. Due to the limited scope of this SEA and the lack of available data, the remaining articles have not been considered in this study. They are however represented in the supply chain flow diagram presented in Figure 4.3.

- **Smartphones**: An average smartphone, weighing approximately 100g, typically contains the following GaAs containing devices: WIFI Protected Access (PA); cellular PA; and GPS Low noise amplifier (LNA). The surface of the dies containing GaAs compounds used for these devices being only a few mm^2 and less than 75µm thick, the total weight of GaAs in a smartphone is estimated by the consulted stakeholders to be around 2.5 mg. According to the latest results from the European Mobile Phone Tracker published by the International Data Corporation (IDC) in May 2013, a total of 31.6 million smartphones were sold in Europe during the first quarter of 2013. (IDC, 2013) If we expand this number to the whole year we reach a total projection of approximately 130 million new smartphones being sold in Europe in 2013. Assuming that each of these smartphones contains around 2.5 mg of GaAs this means that if smartphone sales stay static, every year approximately 325 kg of GaAs enter the EU market through the sale of smartphones.
- **Tablets:** A tablet computer weighting around 300g typically contains the same GaAs devices as a smartphone. The total quantity of GaAs present in a tablet is estimated to be around 8 mg by the different stakeholders consulted.[33] Tablet sales have been growing rapidly in recent years within the EU: for example in Germany the number of tablets sold in 2012 more than doubled compared to 2011 (from 2.1 million to 4.4 million) (eMarketer, 2013). Futuresource Consulting estimated the total number of tablets sold in the EU in 2012 at 35 million units (Murphy, 2013). If it is assumed that they all contain around 8 mg of GaAs a total of almost 300 kg of GaAs entered the EU market through the sales of tablets in 2012.

[33] Stakeholders' consultation – GAIT Team derived information.

- Based on the growth projections (Arthur, 2013; De Renesse and Weidinger, 2013) of the smartphone and tablet sales, the identified quantities are expected to significantly increase in the coming years.
- In addition to GaAs quantities found in consumer articles such as smartphones and tablets it is important to stress that GaAs compounds are also a key component of the infrastructure needed to enable the transfer of mobile data between consumer devices. As these infrastructures are not considered as consumer articles they are out of scope of this SEA.
- **LED chips:** GaAs is one of the basic components of certain types of LEDs dies (red, yellow and orange) and IR diodes (also referred to as IR LED) and lasers. Colour and IR LEDs chips are integrated in consumer articles for various purposes (Some examples include: for red, yellow and orange LED: backlighting of displays in electronic devices, lighting purposes, large screens, architectural displays, etc.; for IR LED: sensor technologies in vehicles, remote controls, movement sensors, etc.). The quantity of GaAs present in both colour LED chips (yellow, red and orange) and IR LED chips is extremely low and varies according to the specificity of the chip and its production process. For red, yellow and orange LED, the greatest proportion of GaAs is found in the substrate material which is removed from the thin-film LEDs during the production process and is therefore only present in the final chip as a residue. Additional GaAs is present in low quantities in the LED structure. In total this represents approximately 0.01% to 0.05% (by weight) of the final LED chips (Leis, 2012 and stakeholders' consultation). There exists no aggregated data about the total quantity of LED lamps produced within the EU and imported to the EU. However, Lighting Europe estimates that approximately 5 billion tonnes of LED lamps are imported into the EU every year. According to these estimations, at a concentration of GaAs of 0.01% w/w per LED die, this represents a total of 5 tonnes of GaAs entering the European market in LED lamps[34,35]. Despite consultation with the largest EU industry association (Lighting Europe), no estimates of the number of LED lamps produced within EU have been identified.

4.2.3.3 *Trends in GaAs production and usage*

The size of the global market for devices containing GaAs is expected to grow significantly in the coming years. According to the most conservative projections, based on a CAAGR of 3% between 2011 and 2016 the market size is expected to grow from around $US 5.2 billion in 2011 to over $US 6 billion in 2016 (Highman, 2012). The production and use of GaAs is expected to grow at an equivalent rate of 3% per annum.

4.2.4 Supply chains affected

Figure 4.3 illustrates the supply chain for GaAs contained in consumer articles, identifying the stakeholders potentially affected by a restriction and summarising the volumes present in the key consumer articles identified. The supply chain of GaAs based devices is extremely complex as it starts with the production of micro-scale chemical components and ends up with their integration in a large variety of products for many different purposes. The diagram and description presented here provides a simplified version of this complex supply chain.

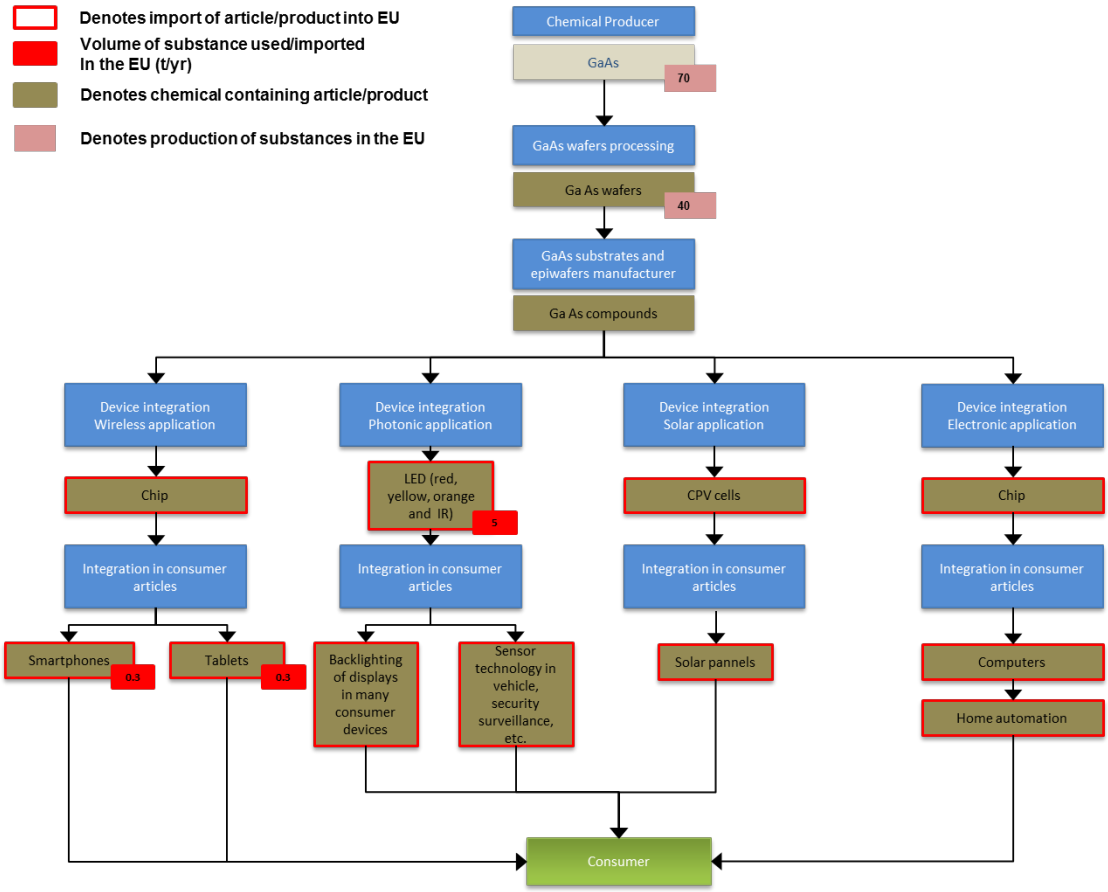
[34] Source: Stakeholder Consultation

[35] This represents a concentration of GaAs of 0.000005% w/w per LED lamp (in comparison with the concentration presented in the text, which are per LED die). These concentrations figure have been estimated based on the figures provided by the stakeholders and should be considered with caution as they are based on import estimations and not on aggregated data.

The supply chain of GaAs devices starts with the production of GaAs ingots and GaAs wafers. Four companies share the vast majority of the global GaAs ingots production. One of these is based in the EU and is a market leader in the manufacturing of both semiconducting and semi-insulating GaAs. This process of developing GaAs wafers based on GaAs ingots is undertaken either by the companies developing the ingots or by specialised companies. GaAs wafers developed in the EU do not only use raw materials produced within the EU raw materials are also imported from third countries (e.g. US, China, Japan). The GaAs wafers produced in the EU are then sold not only within the EU but also in the US and different Asian countries.

Manufacturers of GaAs substrates and epiwafers based in the EU import GaAs wafers from different part of the world (Europe, US and Asia) and export their encapsulated GaAs compounds to consumers worldwide. As illustrated in Figure 4.3Figure 4.3, GaAs compounds are integrated into devices for four key applications. These devices can take the form of among others chips, LEDs or Concentrated Photovoltaic (CPV) cells and are then integrated into larger modules before their final integration into consumer or B2B articles. It is important to stress that the supply chain of GaAs devices is organised at a global level and the mapping of the import and export flows of GaAs based devices is out of the scope of this analysis.

Figure 4.3 Summary of supply chains of GaAs



Source: ICF/AMEC Consultation

4.2.5 Expected non-use scenario

During the preparation of the scoping SEA, a consultation exercise with the industry across different stages of the supply chain was undertaken to ascertain anticipated responses to a

potential restriction for the use of GaAs in consumer articles. The results of this consultation are included in Table 4.6.

Table 4.6 Consultation exercise

Type of company	Stakeholders contacted	Valuable responses received
GaAs manufacturers	1 European (only 4 key players at global level)	1 EU companies
GaAs substrates and epiwafers manufacturer	6 EU companies 1 international technology association	4 EU companies 1 International technology association
Device integration	3 EU companies 4 trade associations	3 EU companies 1 Trade association

Source: ICF/AMEC Consultation

All the consulted stakeholders stressed that there currently exists no alternative to GaAs offering the same physical property package and which could be manufactured at an industrial scale with economically viable costs and within similar occupational health and environmental protection conditions. A ban on GaAs products would therefore affect all the players in the supply chain. These impacts will be discussed in the next section.

The consultation exercise enabled us to collect a considerable amount of information on the crucial underpinning role GaAs has in many technologies considered by the Commission as crucial for the upcoming societal challenges in the field of energy efficiency, transport, digital communication, etc. (EC, 2012a). Based on the output from the stakeholder consultation and additional literature review the section below will analyse the potential impact of a ban on GaAs on the different players identified in Figure 4.3. The analysis will focus on the micro- and nano-electronics and photonics industries as these industries are expected to drive the growth of the GaAs device market. Moreover they produce components feeding into final consumer articles used on a daily basis by European citizens (e.g. smartphones, tablets, LEDs).

However, as illustrated in Table 4.7, different stakeholders mentioned the emergence of potential future alternatives for specific GaAs applications. However it should be noted that, according to the consulted stakeholders, these alternative substances are, at the current stage of development, limited to specific purposes and have limited performance compared to GaAs.

Table 4.7 Potential alternatives to GaAs and their respective limitations

GaAs application and devices	Potential alternatives	Limitations
Radio Frequency application	Gallium nitride (GaN)	The market is currently very small and immature and the technology requires some years/decades to achieve market applicability. On the long term GaN could replace GaAs for some limited functionalities (e.g., high power and broad-band amplifiers, high power switches).
	Silicon (Si)	Silicon is a potential alternative for some GaAs components for high volume of production; however it cannot replace GaAs for specific very high performances (e.g., High intercept Low Noise Amplifiers).
	Silicon germanium (SiGe)	SiGe components could replace GaAs components for some limited functionalities (e.g., low-power amplifiers, mixers, switches and oscillators).

Power electronics	GaN	The market is currently very small and immature and the technology requires some years/decades to achieve market applicability.
LED	GaN	GaN has the potential to replace GaAs for specific functionalities but for others it is complementary to GaAs as they operate in different part of the spectrum; it will therefore not completely replace GaAs. GaN is adequate for blue/UV and possibly green LEDs. For longer wavelengths (e.g. red) the efficiency is too poor to compete with GaAs.
Wireless application	Silicon	Silicon has the potential to replace GaAs for some applications but the low-speed and frequency of operation of Silicon prevent any long-term substitution and could not function in 3G and 4G devices.
Photovoltaic (PV)	Silicon	Silicon based PV cells could replace GaAs cells but they are much less efficient (18-20%) than their GaAs concentrated PV counterparts under development (>40% currently and >50% with further band-gap engineering and development).
High power laser	CO2 lasers	The key component of modern solid state laser systems operating around 1 µm is a GaAs-based laser diode pumping a laser-fibre or laser-disk. The flexibility of such systems is indispensable for many industrial applications. In some applications replacement by CO2 lasers could be possible. This would result in less flexible machinery, increased energy consumption and higher prices.
Transport and mobility	GaN	GaN could represent an alternative for specific power components.

Source: ICF/AMEC Consultation.

GaN and Si represent the two main substances which could potentially substitute GaAs for certain applications. However, as will be discussed below, the cost associated with the use of these alternatives is considerable.

4.2.6 Assessment of economic and social impacts

4.2.6.1 Identification of main impacts

The first step in the SEA is a screening of the impacts and stakeholders potentially affected by the restriction. This ensures that the analysis is focussed on those stakeholders most affected by the proposed restriction and considers the nature and scale of the impacts, following the SEA guidelines produced by ECHA in relation to the possible costs and benefits. Categories of impact are shown in Section Table 4.8, along with a qualitative assessment of impacts.

Before going into more details about the different impact categories and in light of the previous sections it is important to stress that GaAs compounds and other III-V compounds based on GaAs are considered as key semiconductors for the upcoming societal challenges. GaAs compounds are crucial components of articles expected to greatly contribute to addressing challenges such as the e-society; transport and mobility issues; lighting; energy; and environmental challenges. A ban on GaAs in the EU would therefore not only have a very negative impact on high-tech EU businesses but it would also considerably damage the competitiveness and innovative power of the EU in crucial sectors of the economy. It would also jeopardise the achievement of the EU objectives as outlined in the EU Digital Agenda

for Europe[36], the KETs' communication[37], the European Space and Defence Agencies' strategies and the EU 20-20-20 targets for reductions in Greenhouse Gas emissions and improved energy efficiency by 2020 compared to 1990 levels.

The sections below analyse the social and economic impact that a ban on GaAs would have on the different actors in the supply chain.

4.2.6.2 Direct economic impacts

Out of the 9 respondents to our consultation who provided information on their total revenues, four companies indicated that more than 95% of their total revenues are directly dependent on the sales of GaAs substrates or on the sales of consumer articles containing GaAs substrates. For them, a ban on GaAs would most probably lead to an immediate closure of business as existing alternatives are not able to substitute GaAs at the current stage of development. This would result in a combined loss of turnover of almost € 250 million. Three other respondents would close down their facilities and R&D activities in Europe and relocate to other parts of the world, most likely in Asia, while the two last companies would encounter significant sales losses (around € 570 million for the two companies). The combined effect of a ban on GaAs for these 9 companies (i.e., 4 closures of businesses, 3 relocations and 2 significant sales losses) would represent an annual loss of almost € 900 million per year for the EU economy (expressed as turnover of these companies).

4.2.6.2.1 GaAs manufacturers

Four companies share the large majority of the production of GaAs wafers on a global scale. One of these is based within the EU and is a market leader in the manufacturing of both semiconducting and semi-insulating GaAs. For that company a ban on GaAs would mean a direct closure of business. The existing exemption for military purposes outlined in the REACH regulation would only represent a very small share of the company's business and would be too small for manufacturing GaAs to remain economically feasible. This could result in the loss of EU produced raw materials for EU downstream manufacturers. In addition this could lead to higher prices and lack of availabilities for downstream manufacturers and users. This could ultimately impact the security of supply of key materials for military as well as industry purposes. For non-EU manufacturers a ban could lead on one hand to a gain of market shares outside of Europe as one of their key competitors would have to stop its activities. On the other hand non-EU producers would face losses on the EU market as they would not be allowed to export their product to the EU anymore.

According to the consulted stakeholders, if a total ban on GaAs manufacturing is established within the EU, the whole supply chain is likely to relocate outside the EU along with the associated high-tech substances production and development. This would not only lead to important economic losses but also to a total dependency of the EU towards non-EU producers of high-tech components for integration within electronic devices. In addition, as already stressed GaAs wafers are used as substrate for the epitaxial growth of other complex III-V compounds, which are equally crucial as GaAs for meeting the key societal challenges ahead. As GaAs is essential for this process, a ban on GaAs would prevent EU semiconductors manufacturers to develop new III-V compounds. This would highly impact EU R&D and innovation efforts as well as the EU competitiveness.

4.2.6.2.2 GaAs substrates and epiwafers manufacturers

EU GaAs substrates and epiwafers manufacturers would likely face important loss of sales and additional costs (e.g., price of alternative substances, redesigning the manufacturing processes) if GaAs was banned in the EU. Without access to their basic raw materials, their

[36] More info at: http://ec.europa.eu/digital-agenda/en/our-goals

[37] More info at: http://ec.europa.eu/enterprise/sectors/ict/key_technologies/

manufacturing process or even business models would have to be completely redesigned based on the available alternatives. They will be dependent on the quantities and prices of the available alternative substrates. The potential alternatives introduced in Table 4.7 have strict limitations with regard to their physical properties in comparison with GaAs, and are at different stages of production, leading to in some cases considerably higher costs.

GaN is, for example, typically grown on a 100 mm silicon carbide (SiC) wafer, which costs around € 3000 per unit, whereas the price of similar GaAs wafers is around € 60. This results in a cost difference of a factor 50 at the current stage of development. Even without this very large price difference, there is currently no manufacturer able to supply enough GaN quantities to replace GaAs. Therefore only a medium to long term switch to this alternative is feasible. As noted by a stakeholder, economies of scale are likely to result in lower GaN prices in the future when the technology matures but this will require considerable R&D investment and is not expected to occur within the next decade. The price of silicon is lower (by a factor of 10) than that of GaAs but manufacturing costs are almost two times higher. Silicon is therefore only competitive for specific functions with a high volume of production.

In addition to the cost of the alternative substance, the costs of changing the manufacturing toolsets and processes to adapt to this new substance are considerable in the semiconductor industry. Different substances require different crystal growth, characterisation, testing and packaging equipment which represent an investment of several hundred million € per company. While managing their R&D budget to investigate alternatives to GaAs, EU companies also have to take the opportunity cost of these investments into account; non-EU companies rely on GaAs and therefore will not have to invest as much effort in the search for alternatives. According to stakeholders, in the case of a ban on GaAs, substrates and epiwafer manufacturers would have to stop their ongoing R&D programmes focusing on GaAs and switch their efforts to alternative technologies. This would result in the use of old technologies and missed innovation and development and represent an important loss of competitiveness for the EU at a global level[38].

Depending on their size and business model, EU GaAs substrates and epiwafers manufacturers will have three alternatives while facing the challenges of a potential restriction on GaAs:

- Change their production process to supply articles that contain GaAs in concentrations below the threshold established in any restriction;
- Relocate outside the EU; or
- Close their businesses.

Out of the 5 GaAs substrates and epiwafers manufacturers who responded to our consultation, two would completely cease their activities and three would relocate their manufacturing outside the EU.

4.2.6.2.3 Components and articles manufacturers

Further down the supply chain, companies integrating the GaAs based compounds into components which will then be integrated into consumer or B2B articles will face similar challenges as identified above: high dependency on non-EU providers; potential change in production processes; and loss of competitiveness regarding R&D and innovation. Faced with these challenges and depending on their profile, EU businesses will have the following options:

- In some cases EU components or articles manufacturers could be supplied by EU or non-EU suppliers for components containing quantities of GaAs below the likely established threshold. However there could be cost impacts associated with such a

[38] ICF/AMEC stakeholder consultation.

dependency on non-EU suppliers, but the magnitude of such impacts is difficult to determine based on the available data. Manufacturers producing similar components or articles outside the EU would therefore most probably increase their sales on the EU market and gain market share from their EU competitors as they would presumably be able to purchase components at lower costs.

- EU-based manufacturers could change their manufacturing process and use alternatives in the longer term. However, the cost associated with these changes is high: a substrates and epiwafers manufacturer estimated the cost of new crystal growth, characterisation and testing, fabrication and packaging equipment to be over € 100 million for one company only. Considering that the average annual turnover of the respondents is around € 170 million[39], these additional costs are highly significant.
- A third option consists of relocating specific business units or wholesale movement of production activities outside the EU. Based on the input from different stakeholders active in the lighting industry, the direct cost associated with the closure of a production line or business unit in Europe and its transfer outside the EU is estimated to be around € 20 million for one facility only[40]. This represents among others the cost associated with equipment transfer, ramp-up at new site, training at new site, etc. In addition, the potential loss of sales during the unavailability or the production line and the potential risk of intellectual property leakage at the new site need to be taken into account.
- Some EU component or article manufacturers might choose to completely cease their activity based on their dependence on GaAs. This will not only affect EU innovation capacity and competitiveness but could also lead to dependence on non-EU producers for military applications if EU producers of specific military and defence products cease their operations.

4.2.6.2.4 Consumers

Quantities of GaAs present in the majority of the final consumer articles containing GaAs are very low and could be below the potential threshold[41] set by a restriction. In this case, an EU ban on GaAs would not prevent European consumers gaining access to these products. However, the relocation of the manufacturing of all devices with any GaAs-based technology outside the EU is likely to raise the prices of these devices. Even though this cost impact is difficult to estimate, it can be argued that based on GaAs' crucial role in numerous articles used on a day-to-day basis by European citizens, they may be expected to continue to purchase these articles at elevated prices. The consumer would then be impacted by increased costs in the form of higher prices.

Nevertheless it is worth emphasising that – at the present time – if all consumer devices containing GaAs, in whatever proportion, are completely banned within the EU this would result in a society without smartphones, tablets, 3G and 4G networks, GPS connectivity, efficient lighting systems until alternatives to GaAs can be utilised.

4.2.6.3 Indirect economic impacts

Considering the crucial enabling role of GaAs for many new technologies and devices and its underpinning role in the value chain, a ban on GaAs will not only have a direct economic

[39] This figure does not take into account the respondent with the largest turnover as its profile is very different compared to the rest of the participants to the consultation. It is a European company, leader in global security solutions and systems with a turnover of more than € 5 billion.

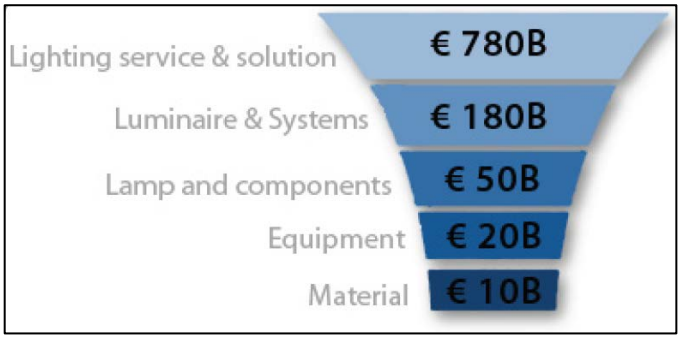
[40] ICF/AMEC stakeholder consultation.

[41] A potential threshold mentioned by the stakeholders would be quantities below 0.1% w/w of a substance in an article as outlined in Article 33 of the REACH regulation.

impact but also a very substantial indirect economic impact. A manufacturer of GaAs substrates and epiwafers estimated that the closure of one business unit following a ban on GaAs – resulting in a direct loss of € 10 to 20 million – is expected to affect the supply chain at a proportion of 30 to 100 times the direct economic impact, resulting in an indirect economic impact of up to € 2 billion for one production site only. These proportions have been confirmed by a recent study analysing the value added or "leverage effect"[42] of photonics technologies on the EU economy. They estimated the value added on the EU economy by the photonics market to be around 62 times the size of the EU photonics market (TNO, KTN and Technologia, 2011). If we consider that this proportion is a good indication of the impact of GaAs on the value chain and apply this proportion to the direct economic loss identified above (€ 900 million), this represents an indirect economic impact in the range of € 50 to 60 billion. However, this analysis may portray an over simplified version of the supply chain, as components may still be manufactured for EU companies, but outside Europe where assembly of the final product also takes place. It should also be stressed that GaAs is not the only component responsible for the value added by photonics technologies, these estimation represent therefore an order of magnitude.

The High-Level Group (HLG) on KETs set up by the Commission, illustrated the trickle-down effect of products based on these KETs by looking at the global photonics and micro- and nanoelectronics industries. It estimated that these two sectors feed into a full value chain worth up to € 780 billion worldwide.

Figure 4.4 Example of value chain of the micro- and nanoelectronics and photonics industry



Source: HLG on KETs, 2010.

Focusing on the EU economy, the working group on micro- and nanoelectronics within the HLG on KETs estimated, based on an inverted pyramid model, that the semiconductor industry provided the knowledge and technologies that generated around 10% of the EU GDP in 2009, equivalent to € 1,100 billion (HLG on KETs, 2010). With regard to the photonics industry, McKinsey recently estimated the market size of the European LED lighting market[43] to be around € 1 billion in 2011. They projected its size to grow up to € 14 billion by 2020 (McKinsey, 2012). This growth is expected to be mainly driven by fast LED price erosion and the upcoming regulation banning low-voltage halogen lamps which will contribute to an accelerated LED uptake in Europe. Regarding the whole photonics industry, the size of the EU market has been estimated to be around € 58.5 billion by an FP7 project (TNO, KTN and Technologia, 2011).

These different markets do not entirely depend on GaAs only and that many other components play important roles in their development. However, considering the crucial enabling role of GaAs described in the above sections, these numbers, even though they

[42] The leverage effect is the contribution of a technology to the value chain of an end product or service which would not be competitive without that technology.

[43] This number includes the full value chain: new fixture installations, lighting system control components and light sources replacements.

have to be treated with caution[44], illustrate the types of trickle-down effects that GaAs and similar semiconductors have on the EU economy.

4.2.6.4 Wider social impacts

4.2.6.4.1 Competitiveness and innovation

In the event of a ban of GaAs, given the lack of readily available alternatives, the EU industry would lose its capacity to innovate in a large variety of sectors (i.e., solar energy, efficient transport system, e-communication, health and environment). The competitiveness of the EU at a global level would be seriously damaged as the capability to develop further semiconductor devices will simply be lost for EU companies. The EU would for example lose its ability to develop new applications in the field of telecommunication, automotive radar, solid lighting and solar energy, among others. Considering the high added value of these devices this is of particular concern for the health of the EU economy.

The EU downstream users and consumers would become dependent on innovation in other parts of the world. This could have a large impact on the price of these innovations and their availability. Moreover, considering the important role of GaAs for innovation in the field of defence and space technologies, this dependency could have important political and strategic impacts for the EU as its access towards key technologies for its security and defence would entirely depend on third countries.

In addition, the stakeholders consulted estimate that the majority of R&D programmes based on GaAs would have to be stopped in Europe. This would represent an important loss not only for companies but also for universities, research institutes and the governmental institutions which have been financing these R&D programmes. This sudden end of R&D programmes would prevent semiconductor technological breakthrough and permanently damage the leadership position of EU companies in certain part of the photonics and micro- and nanoelectronics sectors. This would prevent the creation of new jobs and represent a major risk of intelligence leakage to other parts of the world. EU-based companies would lose their added value and their ability to compete and differentiate against other EU-based companies.

A restriction on the use of GaAs would also prevent the EU from achieving key objectives related to the Europe 2020 Strategies and in the following initiatives:

- KETs: The Commission clearly recognise the crucial role of semiconductors such as GaAs for ensuring the competitiveness of the European industry in the knowledge economy (EC, 2012a).
- Digital Agenda for Europe: Different actions of the Digital Agenda for Europe stress the crucial role of the micro- and nanoelectronics industry for the EU economy. Action 129 emphasises for example the crucial role of micro- and nanoelectronic components as essential differentiating building blocks of all innovative products and services including those necessary to address societal challenges such as health, security, safety, transport and energy.[45]

[44] As explained in the Photonics 21 report, there are different reasons why the results of their value added assessment need to be taken with caution: "*First, the method used to determine leverage is new, experimental and not scientifically validated. Second, the assessment of the dependency of the enabled manufacturing industries and final markets on photonics for their competitiveness is based on expert judgement. As this assessment involved mainly experts from the photonics area this might have led to a bias. Under these circumstances the reader is warned that the figures reported here on leverage need to be put into context. However, the researchers believe that the results provide a valid indication of the leverage of photonics to the European industry*."

[45] More info at: http://ec.europa.eu/digital-agenda/en/pillar-v-research-and-innovation/action-129-key-transformative-action-pooling-european-public-and

- Horizon 2020 Research and Innovation Programme: The EU Framework programme aims to strengthen the EU industrial leadership in innovation through key technologies, greater access to capital and support to SMEs.[46] As stressed by one of the stakeholders, a restriction on GaAs would directly affect many of the societal challenge listed in Horizon 2020 as it would imply a prohibition of R&D into very underpinning technologies that will drive innovation.

4.2.6.4.2 Impact on employment

The closure of EU-based companies and the relocation of others outside the EU, which are likely to result from a ban on GaAs, would have considerable impact on employment within the EU. For the 8 companies active in Europe, which provided information on employment during the consultation exercise, a ban on GaAs would represent a loss of more than 2 000 direct jobs. One of the key stakeholders active in the manufacturing of GaAs epiwafers estimated that the direct job losses could lead to a loss of 50 000 to 100 000 jobs down the supply chain (fabrication plants and end-user applications).

At a larger scale, the HLG on KETs estimated that approximately 500 companies are active in the micro- and nano-electronics industry (materials, equipment and semiconductors) employing directly 200,000 people and creating 1 million indirect jobs in Europe. Regarding photonics, the HLG on KETs estimated the number of active companies to be around 5 000, mostly SMEs, employing 300 000 people directly. It is estimated that around 2 million indirect EU jobs in the manufacturing sector depend indirectly on photonics products. Based on an expected global CAAGR of 13% for the micro- and nano-electronics industry and 8% for the photonics industry between 2008 and 2015, the number of related jobs is expected to continue to grow worldwide (HLG on KETs, 2011). These two sectors showed a rapid recovery after the recent economic crisis and are expected to strongly support the growth strategy defined by the Commission's Europe 2020 Strategy. As stated above, it is obvious that all these jobs do not entirely depend on the availability of GaAs and that other KETs are underpinning them. However, it does provide an indication of the scale of impact potentially involved.

The social return on investment on KETs such as photonics and micro- and nanoelectronics is substantial. Case studies showed that public investments in these technologies could generate a return in additional taxes and social security contributions up to more than fourfold the initial investment. A recent study demonstrated that during the period 1994-2010, the € 1.2 billion invested by public authorities (in Dresden) in micro- and nanoelectronics in the form of subsidies and grants resulted in a return in terms of taxes of € 2 billion and in terms of social security payment at € 3.9 billion (EC, 2012). A ban on GaAs would therefore not only result in important economic losses but also in considerable job losses and the loss of Member State taxation revenue over time.

4.2.6.5 Administrative costs

Administrative costs were not identified in consultation as a major impact, although some additional costs are likely for article importers into the EU to ensure compliance with any restriction (i.e. providing accreditation and product testing information) and for national authorities responsible for enforcement. In the latter case, it is unclear what costs are associated with the addition of single substance to current responsibilities.

4.2.6.6 Human health and environmental impacts

There is active debate about the toxicity to reproduction of GaAs and its carcinogenicity in policy, industrial and academic circles. The RAC of ECHA has been tasked to evaluate new data on GaAs toxicity to reproduction, pursuant to Article 77.3.c in REACH. In its latest opinion published in July 2013, the RAC confirmed its view to classify GaAs as a substance

[46] More info at: http://ec.europa.eu/research/horizon2020/index_en.cfm?pg=h2020

toxic to reproduction (category 1B). In 2011, RAC had already adopted the recommendation to classify GaAs and carcinogen (category 1B) (ECHA News Alert, 2011).

Stakeholders consulted for this assignment stressed that the risk of exposure for the users of final articles containing GaAs compounds is very low as in all device chips containing GaAs are encapsulated in such a format that there is no exposure risk. Moreover the quantities of GaAs present in final products are extremely low. The stakeholders did mention the minimal exposure risk during the production process of GaAs and the associated mechanical work (but these are assumed to be outside the scope of a proposed restriction related to consumer articles). Dust could be inhaled or ingested during this process. However, very high standards are applied during the manufacturing process and at the end-of-life to prevent any exposure. These standards are based on the following principles:

- Engineering control during the manufacturing process (e.g. wetted processes, local exhaust ventilation, etc.): According to a GaAs substrates and epiwafers manufacturer, environmental monitoring in establishments provides widespread evidence of airborne Ga and As being lower than 2µg/m^3.
- Efficient recycling in all manufacturing process in Europe.
- Specific waste management structure: Within the EU, waste containing GaAs components are subject to the Waste Electrical and Electronic Equipment (WEEE) Directive.[47]

Considering that the quantities of GaAs present in the majority of final consumer articles are below the likely established threshold, an EU ban on GaAs will not prevent European consumers' exposure to products containing very small quantities of GaAs. However there is a high chance that these imported products will not follow the high health, safety and environment standards currently in place in Europe. Moreover, over time, as a consequence of the move of R&D programmes and industries using GaAs out of Europe, the knowledge base of the EU on GaAs will decrease and the management of the waste containing GaAs components will become more difficult. Indeed with the regulation in place, waste containing GaAs components are highly monitored and recycling processes are in place ensuring that only minimal quantities of GaAs enter the environment.

4.2.7 Overall conclusions on potential costs and benefits

The review of socio-economic evidence on the production and use of GaAs revealed that a European ban on GaAs would have harmful consequences not only for the GaAs industry but also for the EU economy as a whole. Considering the crucial enabling role of GaAs for a large variety of technologies expected to play a key role to overcome the upcoming societal challenges in the field of energy, transport, communication, health and environment, the full socio-economic impact of a ban on GaAs would be so large and dispersed that it is very difficult to quantify. The economic impact of € 50 to 60 billion estimated in this analysis only represents a fraction of the full economic and social impact associated with a potential ban on GaAs. It implies a Europe without smartphones, tablets, solar panels, LED lighting, WIFI, 3G and 4G connections, and many more products.

4.2.8 Substance-specific considerations for development of draft criteria to implement Article 68.2 to CMR 1A and 1B in consumer articles

This section firstly includes consideration of issues that are important in determining whether Article 68.2 restriction is potentially most appropriate, compared to other forms of restriction. Following this, the identified socio-economic issues that it would be important to take into account in assessing the merits of a restriction are discussed.

[47] Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on WEEE.

With regard to the potential choice of Article 68.2 as a RMO (compared to other forms of restriction), the following considerations arise from this case study substance:

- As demonstrated, GaAs is a crucial enabling substance for many technologies in a variety of sectors of the EU economy. Moreover, it has an underpinning role in the value chain of these sectors and does only represent very limited risks of exposure to the final consumers. In the case of crucial substance, such as GaAs, the application of an Article 68.2 or Article 69 restriction may not be appropriate as it will not only affect the viability of many businesses based within the EU, but it will also affect the EU economy as a whole. *It is therefore suggested to account for critical uses and the socio-economic value that the substance generates in specific end-use applications. This could be done by considering the implementation of derogation procedures.*
- The quantities of GaAs compounds in final consumer articles are extremely low in absolute terms as well as on a proportional basis. Moreover, all device chips containing GaAs are encapsulated in such a form that there are extremely limited exposure risks for the final consumers. *In situations where substances are embedded within finished consumer articles and exposure risks are very limited, Article 68.2 or Article 69 restrictions may not be justifiable in terms of reducing the risks to consumers.*
- Considering the fact that the quantities of GaAs compounds present in final consumer articles are extremely low, if a restriction on GaAs establishes a minimum threshold for the presence of GaAs in articles, this might create a competitive disadvantage for EU companies. Indeed, the import of articles containing GaAs quantities below the threshold would still be authorised, while their development/manufacturing would be prohibited as these are based on compounds containing higher proportion of GaAs, resulting in concentrations in articles that are potentially above the threshold. EU companies would face additional costs in their manufacturing process (e.g., dependence on non-EU suppliers for specific components containing the substance in question) compared to their non-EU competitors. Moreover, EU companies would have the possibility to relocate outside the EU, causing an adverse impact on growth and employment. *The real impact and effectiveness of the establishment of thresholds based on Article 68.2 restriction procedure needs to be taken into account and evaluated.*
- If a complete ban is imposed on a substance present in consumer products with a very high value for EU consumers (e.g., smartphones), *the regulator should take the impacts of non-compliance into consideration, particularly regarding the presence of the substance in imported articles. Indeed, in these circumstances a restriction might not be effective.*
- As demonstrated in this scoping SEA, at the current stage of development, there are no alternatives able to replace GaAs in the vast majority of its uses. The potential use of alternative substances would create a considerable competitive disadvantage for EU companies as they would have to cope with:
  - The additional costs of the alternative substances;
  - Their limited availabilities;
  - The costs associated with the re-qualification of the manufacturing processes; and
  - The competitive advantage of their non-EU competitors still authorised to use GaAs.
- *Therefore any implementation of an Article 68.2 or Article 69 restriction procedure should carefully take into account the (lack of) availability of affordable, safer alternatives which offer comparative technical performance, which are market ready and supplied in sufficient quantities for use. At least an Article 69 restriction process might allow time for research and development of alternatives; whereas the Article 68.2 restriction could occur so quickly that there would be no time to consider and test use of alternative substances.*

Table 4.8 Identification of relevant impacts by stakeholder group, impact category and supply chain

✓ - Benefit or positive outcome;
- No or insignificant anticipated impact;
× - Cost or negative outcome

IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU SUBSTRATE AND EPIWAFER MANUFACTURERS	EU COMPONENT AND ARTICLE MANUFACTURERS	DOWNSTREAM USERS (CONSUMER)	SPECIFIC ISSUES FOR SMEs	EU ECONOMY
Operating costs and conduct of business	Significant impact: closure of business ×	Significant impact on cost of operations: loss of bias material, re-qualification of the manufacturing processes and investment in new toolsets. Depending on their size and business model EU based component manufacturers will have to relocate outside the EU or close their businesses. ×	Significant impact on cost of operations: dependency on non-EU providers and change in production process. Depending on their size and business model EU component and article manufacturer will have to adapt their business model and re-qualify their production process, relocate outside the EU or close their businesses. ×	N/A	The numerous high tech SMEs located in the EU will face very high difficulties to cope with the additional costs associated with a ban on GaAs. Many will have to cease their activities. ×	Large companies will have the possibility to relocate their production outside of Europe. This will not be the case of all high tech SMEs, which are very active in the GaAs supply chain, many of which will have to close. ×

IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU SUBSTRATE AND EPIWAFER MANUFACTURERS	EU COMPONENT AND ARTICLE MANUFACTURERS	DOWNSTREAM USERS (CONSUMER)	SPECIFIC ISSUES FOR SMEs	EU ECONOMY
Competitiveness, Trade and Investment	Significant impact: closure of business ×	Significant impact: the capacity of EU industry to develop new applications based on GaAs will be reduced in many crucial sector of the economy. Investment in R&D will cease and the closure of many businesses will strongly affect the trade flows within the EU and between the EU and third countries. ×	Significant impact: European companies would lose their leadership in many different innovative sectors (e.g., solar cells, RF and wireless applications) and will be strongly dependent on non-EU supply for critical components. ×	Limited impact for the consumers. They will still have access to consumer articles containing GaAs as the quantity of GaAs in the final article is likely to be below the established threshold in the EU. However the price of these articles might considerably increase as they will have to be imported from non-EU manufacturers. ×	Significant impact: Many SMEs will not be able to compete any more on the EU and world market. ×	Significant impact: the EU industry will lose its competitiveness to develop new applications based on GaAs in many crucial sector of the economy. Investment in R&D will cease and the closure of many businesses will strongly affect the trade flows within the EU and between the EU and third countries. ×
Competition and the internal market	Significant impact: closure of business ×	Significant impact: the EU industry's competitiveness will be reduced. Manufacturer will be dependent on the quantities and prices of substrate available from third countries. ×	Significant impact: the EU industry will lose its added value and its ability to compete and differentiate internally. Manufacturer will be dependent on the quantities and prices of components available from third countries. ×	Limited impact for the consumers. They will still have access to consumer articles containing GaAs as the quantity of GaAs in the final article is likely to be below the established threshold in the EU. However the price of these articles might considerably increase as they will have to be imported from	Significant impact: Many SMEs will lose their competitiveness. ×	Significant impact: the EU industry will lose its dynamic competitiveness and ability to differentiate itself in global markets. ×

IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU SUBSTRATE AND EPIWAFER MANUFACTURERS	EU COMPONENT AND ARTICLE MANUFACTURERS	DOWNSTREAM USERS (CONSUMER)	SPECIFIC ISSUES FOR SMEs	EU ECONOMY
				non-EU manufacturers. ×		
Innovation and research	Significant impact: closure of business ×	Significant impact: Europe's domestic capability to develop further compound semiconductor devices would be compromised. Ongoing R&D programmes and investment would be lost or relocated outside Europe. Loss of the opportunity to create high added value products based on GaAs In Europe and the opportunity of emerging businesses in sector such as energy, lighting and transport. ×	Significant impact: the capability to develop further GaAs based components and devices would be lost for Europe. Ongoing R&D programmes and investment would be stopped with associated lost. Loss of the opportunity to create high added value products based on GaAs and the opportunity of emerging businesses in sector such as energy, lighting and transport. ×	Consumers might not have access to the latest technologies based on GaAs as these would be developed in other part of the world ×	Significant impact: Many high-tech SMEs will face high difficulties and will be unable to invest in further R&D programmes. ×	Significant impact: There would be impacts on EU business' capacity to innovate in the affected technologies. There is also a chance that more research activities are relocated outside Europe, where it may be more difficult for associated industries to learn from and share the knowledge generated. There is also a high chance of knowledge leakage. ×
Macroeconomic and employment	Significant impact: closure of business ×	The entire supply chain of European companies using GaAs based technologies will change. Many will have to relocate outside the EU or close their businesses. A	The entire supply chain of European companies using GaAs based technologies will change. Many will	The entire supply chain of European companies using GaAs based technologies will change. Many will	Significant impact: Many high-tech SMEs, crucial for the competitiveness and innovative power of the EU will face high	Significant impact: Relocation of jobs outside the EU and Loss of employment: few thousands direct jobs and many more

IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU SUBSTRATE AND EPIWAFER MANUFACTURERS	EU COMPONENT AND ARTICLE MANUFACTURERS	DOWNSTREAM USERS (CONSUMER)	SPECIFIC ISSUES FOR SMEs	EU ECONOMY
		significant number of direct and indirect jobs will be lost. ×	have to relocate outside the EU or close their businesses. A significant number of direct and indirect jobs will be lost. ×	have to relocate outside the EU or close their businesses. A significant number of direct and indirect jobs will be lost. ×	difficulties. ×	in indirect supply chain. ×
Distributive/Equity	Significant impact: closure of business	All EU based substrate and epiwafer manufacturers will be equally affected. Non-EU manufacturers will not face these restrictions and increase their market share.	All EU based GaAs based components and article manufacturers will be equally affected. Non-EU manufacturers will not face these restrictions and increase their market share.	The price of articles containing GaAs components is likely to increase. Wealthy consumers will be able to purchase these articles while this might not be the case of poorer consumers.	N/A	N/A

Source: ICF/AMEC Consultation

4.3 Scoping SEA: Dihexyl (Di-n-hexyl) phthalate [DnHP]

4.3.1 Introduction

This section covers the scoping SEA for **Dihexyl (Di-n-hexyl) phthalate (DnHP; CAS No. 84-75-3)**. This section follows the structure defined in the introduction, concluding with the identification of considerations and elements to help ECHA and the Commission in the development of criteria for application of Article 68.2 for CMR substances in articles.

4.3.2 Regulatory Status

DnHP has not been registered under REACH as of November 2013.[48] In September 2013, Germany submitted an Annex XV report to have the substance listed as SVHC due to its CMR property of being toxic to reproduction. ECHA was receiving comments on the proposed through 17 October 2013. If DnHP is identified as an SVHC, it will be added to the Candidate List for eventual inclusion in the Authorisation List.

The RAC adopted opinions on seven proposals for harmonised classification and labelling across Europe in September 2011 (ECHA Newsletter, 2011), including one on DnHP. The regulatory status of DnHP is now classified as R1B (indicating that the chemical is a presumed human reproductive toxicant) under the Classification, Labelling and Packaging (CLP) regulation (ECHA RAC, 2011). Similarly, DnHP is classified as R60/R61 (Category 2) and labelled as 'T' (i.e. 'Toxic for Reproduction') under Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances (ECHA RAC, 2011).

Outside of Europe, DnHP is currently restricted in toys or childcare articles under California Proposition 65. The phthalate cannot be used at concentrations of greater than 0.1% by mass of the plasticised material (Bureau Veritas Consumer Products Services, 2008).

4.3.3 Production and uses of Dihexyl Phthalate (DnHP) in articles

DnHP is known as one of several "transitional phthalates", which are produced from alcohols with straight-chain carbon backbones of C4-6. Transitional phthalates are used in a variety of applications, from solvents to plasticizers for PVC. These phthalates have greater mammalian toxicity potential, particularly with regard to reproductive and developmental effects, compared to low or high molecular weight phthalate categories (EMBSI, 2001).

DnHP is primarily used as a plasticiser in PVC production. By suspending the PVC in the plasticiser, the plastisol imparts enhanced properties of flexibility and durability in the PVC. Phthalates are therefore a major functional additive in many PVC production processes. DnHP can be added on its own to PVC, or, more commonly, with another phthalate such as DiHP.

Products potentially containing DnHP identified in this study include:

- Automotive components (e.g. air filters, battery covers);
- Dip-moulded products (e.g. tool handles, dishwasher baskets)
- Printing inks and coatings (e.g. textile prints);
- Building/outdoor materials (e.g. traffic cones, weather stripping);
- Vinyl flooring;
- Conveyor belts (e.g. used in food packaging operations);
- Medical protective clothing (e.g. vinyl gloves);

[48] According to records in ECHA's database on registered chemicals (http://echa.europa.eu/search-chemicals) as of 13 November 2013.

- Footwear (e.g. plastic and rubber soled shoes); and
- Other household applications (e.g. toys, flea collars, notebook covers).

Based on consultation and literature search results and potential exposure to consumers of the uses listed above, this report considers that the applications of greatest exposure risk to consumers are dip-moulded products, printed textiles, outdoor products often used for recreation, household vinyl flooring, footwear and toys.

- Despite historic reference to the use of DnHP in Europe in the literature, no information was available on current production or use, despite the best efforts of trade associations and other stakeholders to provide this information. Through consultation it was confirmed that the substance is no longer commercialised in the EU or in the USA[49]. Indeed, EU producers have reported a phase-out since 2007. However, there is no certainty as to whether DnHP use is discontinued in other countries[50]. This implies that it may still enter Europe in imported articles. No evidence from testing bodies indicates that DnHP is present in articles in the quantities tested for, but its presence as an impurity or in low concentrations cannot be ruled out. A question of whether such quantities constitute a potential for exposure of consumers is however beyond the scope of this study.
- Equally, some residual quantities could remain in industrial chemical inventories from past production and usage. Given that EU producers have reported a phase-out since 2007, it is sensible to assume that any reserves have been consumed or otherwise destroyed by 2013.

4.3.3.1 *DnHP in articles*

Acknowledging that EU-manufactured PVC articles do not contain DnHP, the focus of the remaining analysis is on quantifying the volume of the substance in articles potentially imported into the EU per annum. Gathered information from the literature indicates that phthalate-based plasticisers are commonly used in a wide array of consumer products, and in particular in: construction/outdoor products, flooring and wall coverings, and household products (including childcare articles) (OEHHA, 2008 and EPPM, 2013). On the basis that DnHP is only present in imported articles, the following four consumer articles are selected based on knowledge of the volume of imports to the EU, and are representative of the four most common uses by group of consumer products identified in the literature. The four consumer articles are:

- plastic traffic cones;
- toys;
- footwear; and
- vinyl flooring.

The majority of EU's imports of these products originate in Asia (mainly China)[51]. Earlier assessment could not rule out the presence of DnHP across these product categories, as such, exposure to the substance can occur from two sources (US Department of Health and Human Services, 2003):

- By migration from consumer products where it has limited use; and
- Via its presence as a minor component of other commercial phthalates[52] used in consumer products.

[49] ICF/AMEC consultation with ECPI.

[50] Asian countries – such as China – remain dominant consumers of plasticisers. See: BASF, 2011.

[51] More information at: http://ec.europa.eu/trade/policy/countries-and-regions/countries/china/

[52] Primarily C6-C10 phthalates such as: DHP, DEHP, DINP, DIDP, DPHP. See: Cullen, 2012.

4.3.3.2 Plastic PVC traffic cones

Plastic cones of PVC are primarily used in traffic management applications. Other applications include use in sports equipment and in the home as a recreational toy. In each case exposure to the consumer and especially children cannot be ruled out.

There are an estimated 3,900 traffic cones in use in the UK (Highways Agency, 2011), which if scaled up to EU level on the basis of population would equate to around 32,500 existing across the EU[53]. If the average cone weight is around 4 kilograms[54], this equates to more than 125,000 tonnes of PVC cones currently in use in the EU. It is not known what total proportion enters the EU each year (i.e. due to replacement), although indicative figures from a county administration in the UK shows that they replace around 6% of their cones in a given year (Highways Agency, 2011).

Internet searches suggest that the majority of cone production occurs in China where DnHP may potentially be used as a plasticiser. Further, only a few per cent of production ends up in recreational applications and use by children within the home for which consumer exposure is likely.

4.3.3.3 Toys

Toys worth €5.5 billion were imported in the EU in 2011, with the majority of these coming from China (Toy Industries of Europe, 2012): in 2010, the imports from China accounted for 86.2% of total imports (EC, 2011a). Infant/preschool toys constituted the most popular toy category on the European market followed by dolls, outdoor and sports toys, and games and puzzles (Toy Industries of Europe, 2012). Each of these categories contains products of PVC, which could potentially contain DnHP.

DnHP concentrations in imported toy products are uncertain. In general, the total amount of phthalate contained in a toy product can vary – from about 10 to 50 per cent – depending on the degree of softness required (Australian Competition & Consumer Commission, 2013). Two phthalates, DEHP and DiNP are the most commonly-used plasticisers in 'mouthable' toys (such as teethers) for infants and other flexible vinyl toy products for children (Centre for Science and Environment, 2010). However, due to evidence of toxicity, six phthalates – DEHP, DPB, BBP, DiNP, DiDP and DnOP - have been banned in all toys and childcare articles in the EU (EC, 2005). A recent study published by the Washington Toxics Coalition reports that a number of European toy companies have already phased out the use of phthalates for all toy products (including imports) (Washington Toxics Coalition, 2008).[55]

Nonetheless, as phthalates are not regulated in China and other non-EU toy-exporting countries, their presence cannot be excluded in imported toy products. While Asian Inspection (a quality control service provider in Asia), has reported that 25 per cent of toys made in China contain dangerous levels of phthalates, destined for European and American markets, the type of phthalate found is not specified (Asian Inspection, 2013). Unable to verify this evidence and without knowing whether the phthalate found in articles is DnHP it is difficult to conclude whether DnHP is still used in articles.

In the absence of data on the number or weight of traditional toys imported in to the EU worth €5.5 billion in 2011, an alternative approach to scaling is applied. If the average online price for a toy is around €17 and offline prices are around €10 (NPD, 2012), taking €10-€12 as being representative price for a toy, that would equate to approximately 500 million toys being imported into the EU each year. Assuming that 70% of toys are composed of plastic based on a breakdown of traditional toy market share by type of toy (Toy Industries of Europe, 2012), and assuming the average soft toy, action figure, puzzle or construction toy

[53] Based on the UK share of total EU population of 12%.

[54] http://en.wikipedia.org/wiki/Traffic_cone , Accessed 4 November 2013.

[55] Importers and distributors are also refusing to sell imported toys and other childcare articles, where high levels of the banned phthalates have been detected, in order to comply with EU restrictions (RAPEX, 2011).

weighs between 200 and 300g based on casual observation from online toy specifications, between 70,000 and 105,000 tonnes of plastic in toys is likely to enter the EU each year.

The proportion of this total tonnage containing DnHP is likely to be very small, based on the evidence presented above for new toy imports. However, as toys are often re-used by future generations of children or recycled, the presence of DnHP in older toys is likely to be much higher, specifically if produced before 2007 (i.e. prior to phase-out in the EU).

In addition, DnHP has recently been classified as R1B and therefore should not be used in toys (accessible parts) placed on the EU market.

4.3.3.4 *Footwear*

Footwear articles include sandals, slippers, flip-flops and ladies' shoes made partly or completely of PVC. It also covers thermo boots for children and plastic boots (COWI, 2011).

The last ten years have witnessed a significant change in the composition of footwear consumed at global and EU levels. While the volume of leather footwear exported from non-EU countries remained fairly stable, exports of rubber and plastic footwear have more than doubled. As such, rubber and plastic footwear's share of world exports increased from 43% to 54%, in terms of volume from 2004 to 2008 (COWI, 2011). Imports to the EU from China have grown by 16.5% over the period 2004-9 (CBI (Centre for the Promotion of Imports from developing countries), Ministry of Foreign Affairs of the Netherlands, 2010) and are likely to continue as a potential source of phthalate substances in articles entering the EU. The World Footwear Yearbook 2011 reports that more than 3 billion pairs of shoes were imported into the EU in 2010, of which 2 billion were of plastic and rubber material. The UN Comtrade data suggest that in 2012, the EU-27 imported 34,560 tonnes of footwear and associated articles made of rubber, plastic or leather.

There is growing evidence that plastic footwear may not be phthalate-free. A recent study undertaken by the Danish Ministry of the Environment revealed that DIBP, DBP and DEHP have all been detected in plastic sandals and foam shoes imported and sold on the Danish market. Plastic sandals for children containing phthalates in the sole or strap of imports were found to be in the order of 10-46%. Nevertheless, there is no evidence to suggest DnHP is used as a phthalate in these articles (Danish Ministry of Environment, 2010).

In a similar vein, an inspection of plastic shoes imported from China (carried out by the Taiwan-based Consumers Foundation and the Bureau of Standards, Metrology and Inspection) found that 37% of these shoes contained excessive levels of phthalate esters. Of the 30 pairs inspected, eleven were found to contain between 7.9% and 34.9% of phthalate acid (ChinaTimes, 2011).

Of the 35,000 tonnes of shoes imported into the EU each year, and based on the evidence presented above, it is estimated that around 30% contain phthalates (given range of 10-46% above). Of the 10,500 tonnes of footwear articles, very few if any are expected to contain DnHP as the evidence points towards the use of other phthalates. Hence, it is not expected that large quantities of DnHP in footwear articles is entering the EU.

4.3.3.5 *Vinyl flooring*

The EU imported 111,709 tonnes of PVC flooring (with and without textile backing) in 2008 (Danish EPA, 2010). Whilst EU production of flooring and wall covering has ceased to use 'high phthalates,' the same does not apply to imports. It is reported that alternative plasticisers are now also used – in China, for instance – for various other product types. As such, a study by Høibye et al. (2011) reports those plasticiser concentrations to vary quite extensively depending on flooring type. 10-20% plasticiser content has been detected for products destined for the professional market, while higher concentrations, 25-30%, have been mentioned in relation to low-price cushioned vinyl for the consumer market (COWI, 2011).

Data for Denmark shows that the plasticiser consumption in imports of flooring was within the range of 11,000 - 34,000 tonnes in 2008. On the basis that 112,000 tonnes of vinyl flooring is imported into the EU each year and 20% by weight on average is a plasticizer, then around 22,400 tonnes of phthalates is imported each year. However, DEHP and other 'high phthalates' are most commonly used in flooring and as such, the proportion containing DnHP (a transitional phthalate) is likely to be very low and may only be present as a by-product of the use of other phthalates.

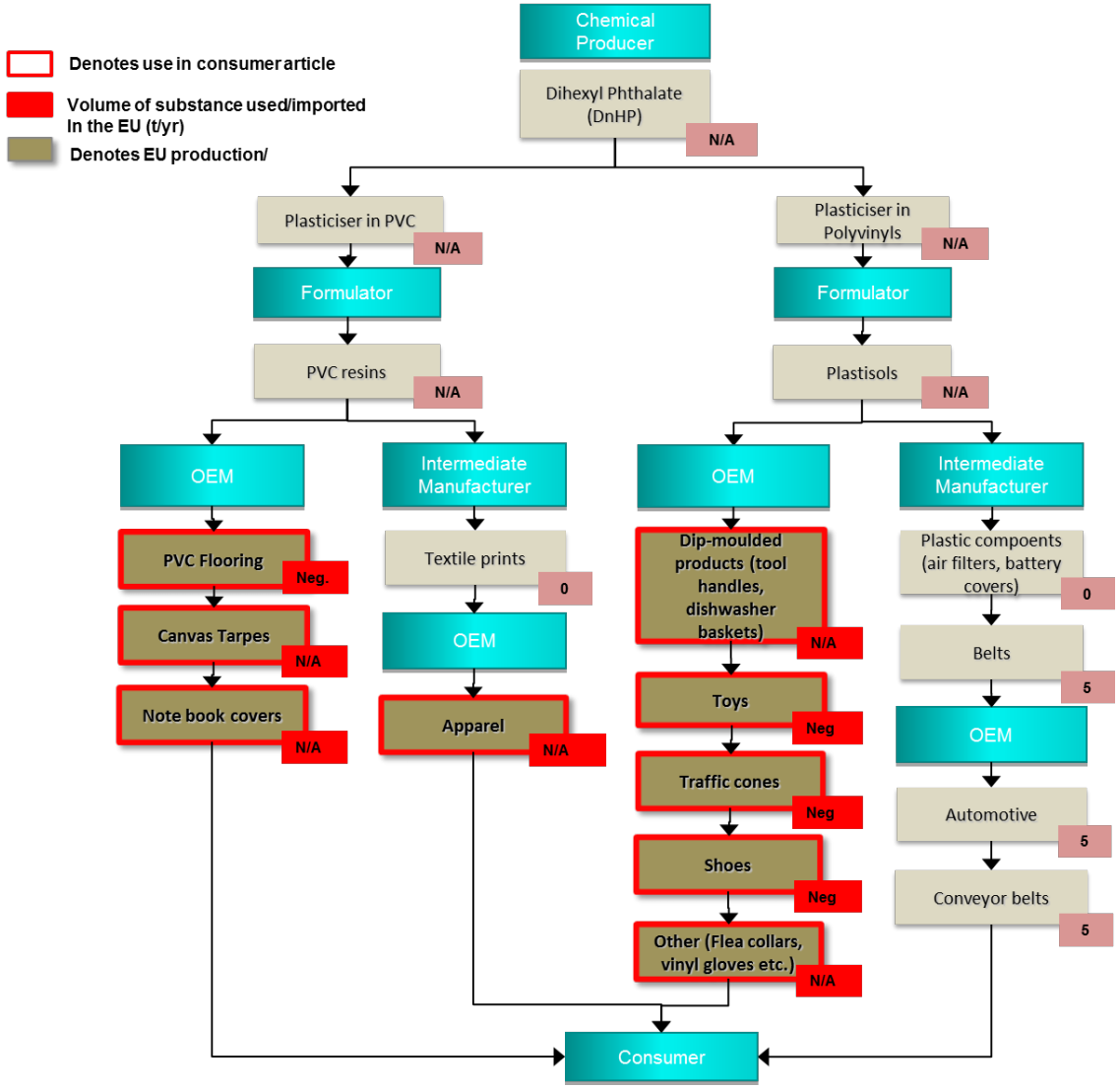
4.3.3.6 Trends in DnHP production and usage

Cessation of the production and marketing of DnHP in the EU and US suggests a shift in the world's largest consumer markets away from DnHP. Driven by human health concerns, this downward trend in production and use in consumer articles is anticipated to continue, as illustrated by the recent classification of DnHP as R1B. As the volume of imported articles is unlikely to change significantly in the near future and a switch to other phthalates is underway, it is plausible to suggest that most remaining uses in third countries are likely to diminish over time or remain at negligible levels (i.e. as by-products in other phthalate containing articles).

4.3.4 Supply chains affected

Figure 4.5 illustrates the supply chain for DnHP contained in consumer articles, identifying those stakeholders potentially affected by a restriction and summarising the volumes present in each use. The quantity of DnHP estimated to be present in the EU is provided in the flow diagram, with imported quantities in articles highlighted in red.

Figure 4.5 Summary of supply chains of DnHP



Source: ICF/AMEC

Upstream of those articles potentially containing DnHP, the supply chain starts with the production of DnHP which is known not to occur in the EU or USA (shown by the muted colours in the diagram). Equally the use of DnHP by formulators of PVC resins and plastisols, supplied to plastic manufacturers does not occur in the EU. Applications of DnHP containing plastics are then shown in the four branches of supply chain diagram. Use in the manufacturer of intermediate products such as components and parts for automotive manufacture usually indicate that the DnHP is embedded in the final product and exposure to consumers is consequently limited. For this reason, intermediate products are left outside the scope of the SEA (confirmed by earlier consumer exposure assessment). Final products (articles) where consumer exposure cannot be ruled out populate the remaining branches of the supply chain. With zero quantities of DnHP plastics produced in the EU, the diagram clearly highlights that any quantities of DnHP found in articles come from imported products. Based on the analysis conducted above, negligible quantities of DnHP are estimated to potentially enter the EU in imports per annum. With declining use, any estimate should be viewed as an overestimate rather than an underestimate of the quantities entering the EU.

With the USA also confirming that use of DnHP has ceased, it is assumed in the baseline that this decline in use inside and outside the EU will continue in the absence of any further

restrictions. This should be reflected in the imports of DnHP containing articles over time. Greater consumer awareness of the hazards from possible phthalate exposure together with an increase in the manufacture of many products to global standards are both considered drivers of this trend in the baseline scenario.

An additional consideration is the quantity of recycled PVC containing DnHP entering the supply chain in Europe. Despite efforts to gather information on the quantity of the DnHP in recycled PVC (historically consumed PVC articles) and its use in intermediate production of new consumer articles, no evidence was forthcoming in relation to DnHP presence or use.

4.3.5 Expected non-use scenario

During the preparation of the scoping SEA, a consultation exercise with industry (European manufacturers and importers of consumer articles, plus non-EU manufacturers) was undertaken to determine their anticipated response to a possible restriction on the use or presence of DnHP in consumer articles. The results of this consultation are included in the following table.

Table 4.9 Summary of consultation exercise

	Type of industry/article	Stakeholders contacted	Valuable responses received
Trade/industry associations	Dyes, paper, packaging, textiles, inks, plastics, toys.	9 European 3 International	5 European 1 International
Private companies	Manufacturers/importers.	5 all with EU representation	No responses

Source: ICF/AMEC Consultation

Taking into account that production and use of DnHP has already ceased in Europe, A focus was therefore placed on non-EU manufacturers to confirm whether or not DnHP is used in various production processes and what, if any, restrictions exist in third countries. The paucity of information generated by that research suggests that continued use in consumer articles imported to the EU could not be ruled out, however unlikely. Third country stakeholders were reluctant to engage on consultation efforts and therefore the remaining assessment has relied to a large extent on literature sources.

Driven partially by a tightening of regulation (a ban already exists on this and other phthalates in toys), and increasing consumer/regulatory concern more widely regarding the human health impact of phthalates, the rationale for a restriction of DnHP is clear. For each supply chain, the response of stakeholders to the restriction is summarised in Table 4.10.

Table 4.10 Expected response of article supply chain to proposed restriction

Article supply chain	Response of EU industry	Alternative (if applicable)
Traffic cones	Use already ceased, imports from outside EU to continue	Switch to other phthalates (i.e. DINP, DEHP) outside EU
Toys	Use already ceased, imports from outside EU to continue	Switch to citrates, sebacates, adipates, and phosphates as alternative to phthalates where toys and children's articles are concerned (Lowell Center for Sustainable Production, 2011)
Footwear	Use already ceased, imports from outside EU to continue	Switch to other phthalates (i.e. DINP, DEHP) outside EU
Vinyl flooring	Use already ceased, imports from outside EU to continue	Switch to other phthalates (i.e. DINP, DEHP) outside EU

Source: ICF/AMEC Consultation

4.3.6 Assessment of economic and social impacts

4.3.6.1 Identification of main impacts

The first step in the SEA is a screening of the impacts and stakeholders potentially affected by the proposed restriction. This ensures that the analysis is focussed on those stakeholders most affected by the proposed restriction and considers the nature and scale of the relevant impacts. The approach follows the SEA guidelines produced by ECHA in relation to the possible costs and benefits identified. Categories of impact are shown in Section 4.3.8, along with a qualitative assessment of impacts.

With no production or use of DnHP it is not surprising to find that no impact is expected directly on the EU industry. Nevertheless, a restriction which increases the costs for non-EU industry or imposes requirements on importers is likely to have a positive competitiveness impact on EU industry as manufacturers/producers already using alternatives and have incurred any substitution costs in the past. Consumers benefit from the mitigation of environmental and human health risks, but on the other hand may face higher prices for consumer articles imported into the EU, depending on the cost pass through in the supply chain.

4.3.6.2 Direct economic impacts

At present, DnHP is neither commercialised nor used in the production of consumer articles in the EU. Alternatives are widely available and have already substituted for the substance in production lines[56]. Consequently, an EU-wide ban on DnHP is unlikely to result in any significant direct impact for EU chemical producers or manufacturers of consumer articles.

In contrast, the stringency of ban is likely to have a significant cost impact on importers and non-EU suppliers. A formal ban would entail changes to import requirements which could be administratively onerous and/or changes to production, by using alternative substances or materials in the manufacture of articles. Requalification of materials can be a costly and time-consuming process whereby performance of replacement products will have to be thoroughly tested and verified. Replacing DnHP could also present other direct costs such as the purchase of different processing and handling equipment or increased amounts of raw materials in order to achieve similar functionality. Indirect costs – such as reduced efficiency from replacement products – could also potentially arise.

In a similar vein, it is highly probable that EU importers will be required to demonstrate that imported products do not have a detectable content of DnHP before they are marketed. This would necessitate adequate testing of replacement products and communicating safe-use information to relevant authorities and consumers, which could add to costs and potential pass through to consumers in higher prices. The competitiveness of importing businesses could consequently be adversely affected, relative to EU suppliers who have already switched.

4.3.6.3 Indirect economic impacts

Highlighted in previous sections, EU manufacturers have already switched to alternative substances in their production processes whilst phthalate-free production has also been widely promoted in some industries (e.g. in the manufacture of toys) (Washington Toxics Coalition, 2008). A formal ban on DnHP may induce non-EU producers to follow suit. This should provide greater certainty around imported products, especially at a time when consumers are increasingly worried about the long-term health consequences of chemical exposure.

[56] ICF/AMEC consultation.

As far as the use of substitute substances is concerned, European manufacturers are likely to have a comparative cost advantage over non-EU article manufacturers as switching and verification costs are not incurred. As imports are therefore likely to be more expensive, consumers may therefore substitute imports for EU manufactured products, allowing EU producers to capture a larger share of the market for some products, at least in the short term.

However, with limited DnHP use outside the EU anticipated, these impacts are expected to be minimal in scale and scope. In the long run, the impact on competitiveness should be insignificant as other factors such as labour costs become more important.

4.3.6.4 *Consumer impacts*

If a restriction is applied to imports of consumer articles, there is the potential for the price of these articles to increase due to a substitution of DnHP in production processes. However, other factors, such as labour costs and currency exchange rates may have a greater impact on the price of imports, given that the majority of production has already switched with minimal impact on industry competitiveness (EU and non-EU). Added to this, the cost pass through on what are likely to be highly elastic demand for final products is assumed minimal, indicated by high level of price competition casually observed in toy and footwear markets.

4.3.6.5 *Wider social impacts*

As no changes to production are foreseen for EU manufacturers, employment will not be affected by a formal restriction of DnHP or any of its uses. Similarly, provided importers and non-EU producers successfully phase out the use of DnHP through a shift to alternative methods and raw materials, no significant impact on employment can be envisaged. However, it is worth urging caution with regard to smaller companies. Complying with a potential ban on DnHP may require a significant commitment of skilled professionals which small companies may simply lack. If they cannot afford to channel resources, time and effort in to implementing alternative methods of production, they may be driven out of business in the longer term which would result in job losses.

It may not be straightforward to quantify the net environmental impact. In essence, an ecological benefits assessment will depend on two components: (1) the extent to which ecological benefits are or may be ameliorated as a result of the ban; and (2) the monetary value that could be ascribed to the ecosystems so protected. This could prove challenging given that ecological risk characterisations and assessments do not express effects in terms of 'impacts' that can be valued. Exploring an appropriate methodology is therefore advised.

4.3.6.6 *Administrative costs*

Administrative costs were not identified in consultation as a major impact, although some additional costs are likely for article importers into the EU to ensure compliance with any restriction (i.e. providing assurance and product testing information) and for national authorities responsible for enforcement. In the latter case, it is unclear what costs are associated with the addition of a single substance to current responsibilities, as one substance might be accommodated at little cost, while the addition of multiple substances could require much greater resources for effective monitoring and enforcement.

4.3.6.7 *Human health and environmental impacts (for consumers)*

Reported routes of exposure for consumers which may result in injury or illness include: ingestion of phthalate-containing articles orally (i.e. children putting toys in their mouth), or from breathing in phthalates contained in household dust as articles degrade in the home (i.e. toys and footwear). It is nonetheless worth mentioning that the former route may be less of a cause for concern given that the use of phthalates in mouthable toys for children has been banned. Exposure is more likely to occur in children than adults due to child behaviour (i.e. playing on the ground, crawling, etc.) There is also some evidence to suggest that phthalates are ingested through the skin in the case of vinyl flooring (Carlstedt, Jönsson and

Bornehag, 2013). Despite this, much of the literature and evidence focusses in inhalation of dust in the air as the main exposure route.

Phthalates, such as DnHP, are known to be a contributing factor to infertility in unborn children and even, in some cases, in adults (ECHA RAC, 2011) due to their endocrine disrupting properties. The beneficiaries of a restriction on the use of DnHP in articles could thus include couples no longer requiring fertility treatment due to the restriction on, and therefore a reduced exposure to, DnHP. The benefits should not only include the private costs to the couples concerned, but also the wider costs to their family and society (the social benefits). The benefits to include are:

- The medical cost of fertilisation treatment, which would have been incurred by the individual, couple and/or the state healthcare provider. This includes the costs of consultation, treatment and any medicines prescribed;
- The lost earnings incurred by the couple in undergoing consultation and treatment, plus the loss of productivity the employer may have incurred from the absence of the couple;
- The wider intangible effects on close friends and family, related to their stress and well-being, which they would have a willingness to pay to avoid or to experience (i.e. birth of grandchild).

4.3.7 Overall conclusions on potential costs and benefits

The review of socio-economic evidence in relation to DnHP indicates the absence of any substantial economic costs for EU industry due to the fact that DnHP is neither produced nor used in the EU. However, given the possibility of quantities of DnHP being imported in consumer articles, a restriction on imports containing DnHP could generate human health benefits.

4.3.8 Substance-specific considerations for development of draft criteria to implement art 68.2 to CMR 1A and 1B in consumer articles

There are a number of issues that arise in relation to DnHP that it will be important to take into account in the development of draft criteria to for implementing an Article 68.2 restriction. Preliminary identified factors include:

- Where the potential for exposure of consumers and presence in consumer articles is highly uncertain, it may be difficult to justify the need for a fast-track Article 68.2 restriction. The Article 69 process is likely need in order to gather evidence and build a suitable case for restriction.
- A restriction is potentially useful to EU manufacturers in terms of competitiveness where they have already switched to alternatives, but non-EU industry has not. This could help to level the playing field between producers.
- The international aspects of any restriction (i.e. on trade) should be considered.
- Recycled materials in the supply chain should be considered before opting for a restriction. Other risk management measures may therefore be more appropriate than an Article 68.2 procedure, in particular where this is the most significant source of the substance in consumer articles.

Table 4.11 Identification of relevant impacts by stakeholder group, impact category and supply chain

✓ - Benefit or positive outcome;
- No or insignificant anticipated impact;
× - Cost or negative outcome

SUPPLY CHAIN	IMPACT CATEGORY/STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	ISSUES SPECIFIC FOR SMEs	CONSUMERS
Traffic cones	Operating costs and conduct of business	No impact anticipated as production of DnHP has ceased in Europe -	No impact anticipated as EU manufacturers of articles are already using alternatives to DnHP (and phthalates in general) in production lines -	Significant impact on costs for non-EU manufacturers, possibly driving up prices of imports. A ban implies that article importers will have to demonstrate that the imported article is safe before it enters commerce in the internal market, requiring additional testing and assessment ×	No impact anticipated as production of DnHP has ceased in Europe - 	Increased prices of imports could be passed on to consumers. ×
	Competitiveness, Trade and Investment	No impact anticipated as production of DnHP has ceased in Europe -	No impact anticipated as EU manufacturers of articles are already using alternatives to DnHP (and phthalates in general) in production lines -	Non-EU manufacturers in compliance with any restriction on use of the substances in articles would likely experience higher costs in reformulation/requalification of (alternative) raw materials in production processes. Therefore, prices of imports may rise and EU importers of articles risk losing their competitive edge in a highly-competitive EU market ×	No impact anticipated as production of DnHP has ceased in Europe -	Greater certainty around imported products as well as potential health and environment benefits. Higher prices on imported products may induce substitution for what is locally-produced. Choice may thereby be restricted. ×/✓

SUPPLY CHAIN	IMPACT CATEGORY/STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	ISSUES SPECIFIC FOR SMEs	CONSUMERS
	Competition and the internal market	No impact anticipated as production of DnHP has ceased in Europe -	No impact anticipated as EU manufacturers of articles are already using alternatives to DnHP (and phthalates in general) in production lines -	Market potentially dominated (at least in the short-term) by EU manufacturers of articles who have already switched to alternatives and are thereby well-established in the internal market; higher prices on imported articles therefore likely to give competitive advantage to local article producers. ×	No impact anticipated as production of DnHP has ceased in Europe -	N/A -
	Innovation and research	No impact anticipated as production of DnHP has ceased in Europe -	No impact anticipated as EU manufacturers of articles are already using alternatives to DnHP (and phthalates in general) in production lines -	No significant impact on innovation and research -	No impact anticipated as production of DnHP has ceased in Europe -	N/A
	Distributive/Equity	No impact anticipated as production of DnHP has ceased in Europe -	No impact anticipated as EU manufacturers of articles are already using alternatives to DnHP (and phthalates in general) in production lines -	Foreign producers more likely to be disadvantaged by new EU regulation – additional costs likely to be borne by importers who have yet to switch to alternatives Larger impact on EU article importers than local manufacturers due to additional costs. ×	No impact anticipated as production of DnHP has ceased in Europe -	Higher prices on imported products will induce substitution for what is locally-produced. Choice thereby restricted. ×

Source: ICF/AMEC Consultation

4.4 Scoping SEA: Formaldehyde

4.4.1 Introduction

This section covers the scoping SEA for **Formaldehyde (CAS No. 50-00-0)** and follows the structure defined in the introduction, concluding with the identification of considerations and elements to help ECHA and the Commission in the development of criteria for application of article 68.2 for CMR substances in articles.

Formaldehyde is a naturally-occurring chemical compound. It is composed of hydrogen, carbon and oxygen and is present in all organic forms of life, namely – in plants, animals and humans (Box 1) (Formacare, 2010a). In the environment, formaldehyde is in a colourless gaseous form and is generally very quickly broken down by sunlight (when present in air), or by bacteria (when present in soil and/or water).

Box 1 Formaldehyde in the human body

The human body produces minimal amounts of formaldehyde, which are essential in the development of DNA proteins. Nevertheless, formaldehyde is very quickly broken down via a metabolic process, thereby restraining its ability to accumulate. Formaldehyde is said to have a half-life of about one minute, which means that over the course of one minute the amount of formaldehyde present in the human body decreases by half.

Whilst the human body is designed for dealing with formaldehyde, and also well-equipped to handle additional formaldehyde-intake from external sources, formaldehyde vapours can be harmful at high concentrations.

Source: Formacare, 2010a

Because formaldehyde has many useful chemical properties, it is also manufactured on an industrial scale and used as an important chemical building block in numerous applications. In general formaldehyde is commercialised, in its liquid form, as formalin (Formacare, 2010d). The latter is a saturated solution of formaldehyde dissolved in water, along with another agent – typically methanol – which is added to stabilise the solution. Formalin is therefore typically 37%formaldehyde by weight (or 40% by volume) and 6 -13% methanol by volume in water (US Department of Labor, OSHA, 2011).

4.4.2 Regulatory status

Formaldehyde has a harmonised classification in Annex VI to the CLP Regulation as: acutely toxic if swallowed, inhaled and in contact with the skin; as skin corrosive; as a skin sensitiser; and as suspected of causing cancer. The RAC has also agreed to the proposal from France to classify formaldehyde as also suspected of causing genetic effects (Muta. 2). In addition, there is an additional protective category under which the substance is currently classified, namely as a substance which is presumed to have carcinogenic potential for humans (Carc. 1B) (Cherrie, 2013).

Recently, due to its high tonnage and widespread use, formaldehyde was included in the February 2012 Community Rolling Action Plan (CoRAP). The evaluation of formaldehyde began in February 2013. The co-rapporteurs (France and the Netherlands) have been given one year to study the registration dossier. Once the evaluation is complete, likely by 2015, the co-rapporteurs may conclude that the risks are sufficiently under control and necessary measures are already in place. Otherwise, the co-rapporteurs can propose EU-wide risk management measures such as proposals for restriction, authorisation and occupational exposure limits (Formacare, 2010e).

Since the 1980s, many European countries started with formaldehyde regulations on particle boards. In 1985, emission class E1 (0.1 ppm boards) became obligatory for wood-based

panels in Austria, Denmark, Germany, Sweden. Emission classes, E1 and E2, were established by European Standard EN 13986 for use in construction in 2004 (limit values are outlined in the box below). In 2006, emission class E1 became obligatory for panel production. Similarly, in July 2010, the U.S. government imposed new formaldehyde emission legislative requirements - "Formaldehyde Standards for Composite Wood Products Act" - for various products such as plywood (PW), Medium Density Fibreboard (MDF), and others.

Box 2 Regulation and standards for formaldehyde for composite products

Acceptable levels of formaldehyde emission from composite wood products have been continuously reduced over the last years. Many countries have legislation in place to regulate formaldehyde emissions and developed an obligatory emission class E1 (0.1 ppm boards) for wood-based panels.

1. European guidelines

- Europe has established the emission classes E1 and E2 (European Standard EN 13986) regarding wood products used in construction. As such, in 2006, emission class E1 became obligatory for panel production. Europe's harmonised standard includes two emission classes - namely E1 and E2 (E1 ≤ 8mg/100g dry board; E2 >8 - ≤ 30 mg/100g dry board).
- Individual MS - namely Germany, Austria, Denmark and Sweden require compliance with emission limits of 6.5mg/100g dry board.
- The Blue Angel certification for environmental friendly products require a formaldehyde emission limit of 0.05 ppm.
- The European panel federation (EPF7) also has its own standard - the EPF-S [designed for PB 4mg/100g and for MDF (with > 8 mm thickness) 5 mg/100g]. In 2011, EPF agreed on a reduction in formaldehyde emissions for CE-labelled, uncoated wood panels for construction (EN 13986). The new limit value has been set at 0.065ppm.

2. Japanese guidelines

Japanese emission standards – the Japan Agricultural Standards (JAS) - are broken down into four levels labelled as F*, F**, F***, and F****. The limit values are currently set as follows

- F** emission class: ≤ 1.5 mg/L;
- F***: ≤ 0.5 mg/L; and
- F****: ≤ 0.3 mg/L.

3. North American guidelines

In California, USA, the *CARB Air Toxic Control Measure for Composite Wood Products* regulation imposes limits on formaldehyde emissions from products it considers to be "composite wood products". At the core of the regulation are three categories of composite wood products: 1) hardwood PW, 2) MDF, and 3) particleboard (PB). Phase 1" formaldehyde emission standards took effect for hardwood PW, PB, and MDF in 2009. More stringent "Phase 2" emission standards for hardwood PW, PB, and MDF were phased in between 2010 and 2012. Emission standards are currently set at:

- Hardwood/Plywood (HWPW): 0.08 ppm (phase 1); 0.05 ppm (phase 2);
- PB: 0.18 ppm (phase 1); 0.09 ppm (phase 2);
- MDF: 0.21 ppm (phase 1); 0.11 ppm (phase 2); and
- MDF (thin): 0.21 ppm (phase 1); 0.13 ppm (phase 2).

The U.S. Department of Housing and Urban Development (HUD) Manufactured Home Construction and Safety rule places limits on formaldehyde emissions from (nonstructural) PW and PB. PB is limited to 0.3 parts per million (ppm) emissions level and PW to 0.2 ppm. Products manufactured exclusively with phenol-formaldehyde (PF) resin systems are however exempt from the regulations.

Sources: Subsport, 2013.

4.4.3 Production and general uses of formaldehyde

Global formaldehyde production is expected to have reached 32.5 million metric tonnes in 2012 (Global Industry Analysts Inc., 2008). At an annual production level of over 7 million tonnes (Formacare, 2010c), the EU is currently the second largest formaldehyde-producer after China, which manufactures, on average, an estimated 12 million tonnes annually (Tang, et. al., 2009). Figure 4.6 shows global formaldehyde production and consumption by major regions.

Of the 22 EU MS producing formaldehyde, Germany is currently the largest producer, followed by Italy, Spain, the Netherlands and the UK (Formacare, 2010c).

Figure 4.6 Global formaldehyde production and consumption by major regions in 2008

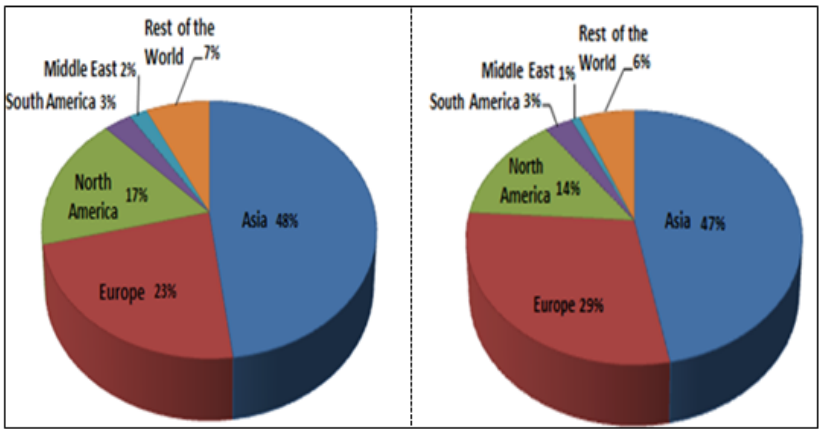


Fig. 4.6a: Formaldehyde global output *Fig. 4.6b: Formaldehyde global consumption*

Source: Methanol Market Services Asia (MMSA), 2013.

4.4.3.2 *Commercial market review*

Formaldehyde (or, in its commercialised state as, formalin) is primarily used in the production of thermosetting resins. These account for almost two thirds of the use of formalin)[57]. As depicted in figure 1.2 below, the three major commercially-used resins globally are:

- urea-formaldehyde (UF);
- melamine formaldehyde (MF); and
- PF resins.

According to recent data, UF, MF and PF resins account for approximately 63% of world consumption for formaldehyde (Figure 4.7) (Formacare, 2010d). UF resins are primarily used as binders in non-structural wood-based panels. Most UF resins that are manufactured in the EU are currently used to make building materials such as particle board, interior PW and MDF (Formacare, 2010d). In 2004, UF resins accounted for 55% (i.e. about 5.4 million metric tonnes) of EU 25 plus Norwegian formaldehyde consumption (Subsport, 2013).

MF resins are used predominantly as paper impregnating resins for surfacing of panels, for example in laminate flooring. They are also used as binders and adhesives where improved water resistance is required. The automobile industry, for instance, consumes MF resins in

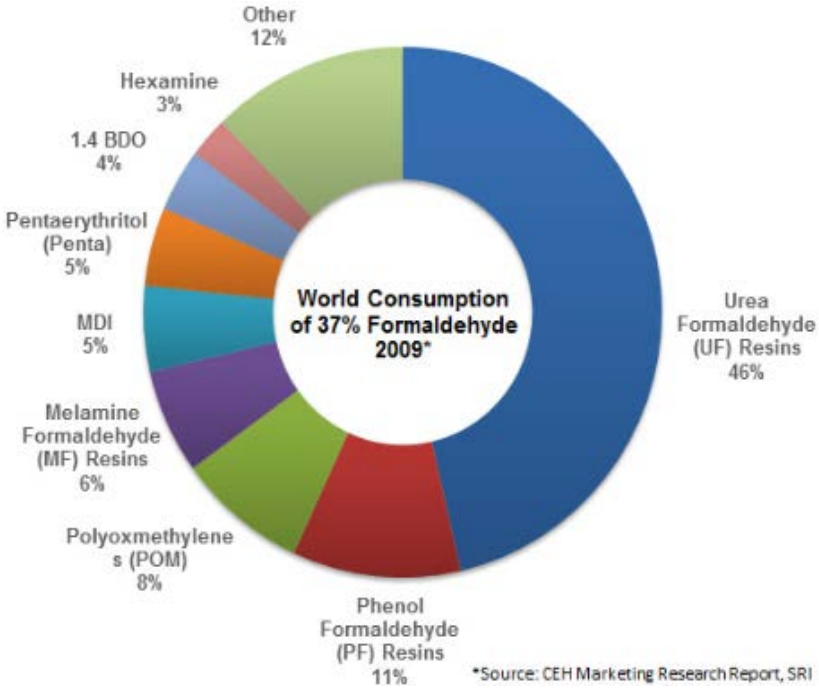
[57] Thermosetting resins are materials that when cured, form a highly cross-linked, glassy or crystalline structure that will not soften in the presence of heat. Cured, these resins become hard and stay hard until they are thermally, chemically or mechanically degraded and / or destroyed. These resins have excellent strength properties and tend to be resistant to solvents, heat and moisture. More info at: http://www.inda.org/events/training/reading/SuggestedReadings/Thermosetting%20Resins.pdf

the form of clear coats. MF consumption in the EU25 and Norway was estimated at about 1.3 million tonnes in 2004 (Subsport, 2013).

Equally water-resistant, PF resins are used as durable binders and adhesives in structural wood panels and as binders in mineral wool insulation. Their high thermal stability and fire-resistant properties are particularly well-suited to a wide spectrum of uses in the automotive and construction industries. In 2004, PF resin consumption in the EU25 and Norway has been estimated at about 75,000 metric tonnes (Subsport, 2013).

Formaldehyde is also used as an intermediary in the production of polyacetal resins [or polyoxymethylene (POM)]. Polyacetals are inherently self-lubricating and are particularly suited to a variety of applications such as replacing metal parts in electrical, electronic, automotive, and consumer applications. The demand for polyacetals in Europe is said to have grown by 10% from 2003 and 2008 and is estimated at about 220,000 tonnes a year (ICIS, 2009).

Figure 4.7 World consumption of formaldehyde for use in the production of formaldehyde resins and specialty chemicals



Source: *Formacare, 2010b.*

Another rapidly-growing formaldehyde derivative market is that of methylene diphenyl diisocyanate (MDI). MDI constitutes an important material for the manufacturing of polyurethane products, which are widely used in the footwear, household appliance, construction, automotive and furniture manufacturing industries. The global annual MDI production was estimated at about 5.9 million tonnes in 2010, of which Europe contributes an estimated 2.55 million tonnes every year (i.e. about 43% of total global MDI output)[58].

Similarly, butanediol (BDO) and pentarythritol are other industrial chemicals that are currently manufactured using formaldehyde. BDO is primarily used to produce intermediates for downstream production of polyester thermoplastics resins. These are in turn used in the textile fibres, electronics and automotive markets. On the other hand, pentarythritol – an alcohol produced from formaldehyde and acetaldehyde – is increasingly used in the EU for the

[58] More information at:
http://english.jl.gov.cn/Investment/Opportunities/Industry/syhg/201303/t20130319_1430974.html

production of alkyd resins and neopolyol esters. Alkyd resins are typically found in architectural coatings like paints and product finishes for automobiles whilst neopolyol esters constitute an important ingredient in engine lubricants for aeroplane turbines and automobile engines. Germany remains a major player of the EU's alkyd resins market, covering 37% of EU production and consumption. In 2010, it produced 190,000 tonnes of alkyd resins, and provided 45,000 tonnes for export. Other significant Western European manufacturing facilities are concentrated in Italy and France (Reuters, 2011).

Hexamine and paraformaldehyde are also derived from formaldehyde. Hexamine is primarily used in the production of vulcanized rubber for automobiles whilst paraformaldehyde is mainly used as a fungicide and/or disinfectant. As of 2012, nearly 145,000 tonnes of paraformaldehyde were produced in the EU.[59]

[59] Data from PRODCOM, Eurostats Database, http://epp.eurostat.ec.europa.eu/portal/page/portal/prodcom/introduction

Table 4.12 Summary of the key uses of formaldehyde in various applications

Application/sector	Upstream use(s) of formaldehyde	Intermediate use(s) of formaldehyde	Downstream users / End products	Suitability/chemical advantages of formaldehyde
Formaldehyde's use in the production of formaldehyde-based glues and resins				
Construction	■ Formaldehyde-based resins: ■ Urea formaldehyde (UF); ■ Melamine-urea formaldehyde (MUF); ■ Phenol formaldehyde (PF).	■ Manufacture of: ■ PB/wood-based panels; ■ Medium-Density Fibreboard (MDF); ■ Oriented Strand Board (OSB); ■ PW; ■ Laminates; ■ Fiberglass Insulation.	■ Furniture; ■ Home construction products.	■ Fast curing; ■ Hardness and abrasion resistance; ■ Dimensional stability (Ability of a material to maintain its essential or original dimensions while being used for its intended purpose); ■ Clear glue line (the point at which the wood product and adhesive meet in an adhesive binding); ■ Colour retention; ■ Water resistance; ■ Heat resistance; ■ Chemical resistance; ■ Arc resistance; ■ Flame resistance; ■ Water borne (can be applied in an aqueous suspension); ■ Allows for the recycling of older wood such as furniture, housing timber frames, windows and beams to create new wood-based products.
Automotive	■ Formaldehyde-based resins and chemicals: ■ MF resins; ■ Phenol formaldehyde (PF) resins;	■ Manufacture of: ■ Surface coatings; ■ Decorative laminates; ■ Moulded automobile	■ Many automobile components for example: ■ Tyres; ■ Brake pads;	■ Fast-curing; ■ Withstands high temperatures; ■ Excellent chemical resistance; ■ High moisture resistance;

Application/sector	Upstream use(s) of formaldehyde	Intermediate use(s) of formaldehyde	Downstream users / End products	Suitability/chemical advantages of formaldehyde
	■ Polyoxymethylenes (POM); ■ Methylene bis (dephenyl di-isocyanate) (MDI); ■ 1,4-Butanediol (BDO); ■ Pentaerythritol; ■ Hexamine.	components; ■ Formaldehyde-based thermoplastics; ■ Polyurethane foams (PUF); ■ Polyurethane coatings; ■ Polybutylene terephthalate resins (PBTs); ■ Alkyd resins; ■ Lubricants; ■ Vulcanized rubber.	■ Interiors; ■ Engine parts; ■ Fuel system components; ■ Foams in car seats ■ Body part adhesives; ■ Bumpers; ■ Engine lubricants.	■ High heat resistance; ■ High friction resistance; ■ Superior resistance to gasoline; ■ Excellent lubricant properties; ■ Durable.
Aircraft	■ Formaldehyde-based resins and chemicals: ■ Phenol formaldehyde (PF) resins; ■ Polyoxymethylenes (POM); ■ Methylene bis (dephenyl di-isocyanate) (MDI); ■ Pentaerythritol; ■ Hexamine.	■ Manufacture of: ■ High performance thermoplastics; ■ Neopolyol esters; ■ Phenol composites; ■ PUFs.	■ Many aircraft components, for example: ■ Tyres ■ Turbine lubricants; ■ Brake pads; ■ Interior panelling; ■ Seatbelts; ■ Seat foam.	■ High friction resistance; ■ High temperature resistance; ■ Extremely stable at high and low temperatures.
Clothing	■ Urea formaldehyde (UF) resins; ■ MF resins; ■ 1,4-BDO. ■ Tertahydrofuran (THF) resins.	■ Resins are used in the production of dyes and pigments; ■ Formaldehyde-derivatives (BDO, THF) are used in the production of spandex fibres and other similar types of	■ Various clothing items.	■ Prevents colour loss; ■ Wrinkle resistant; ■ Stain resistant.

Application/sector	Upstream use(s) of formaldehyde	Intermediate use(s) of formaldehyde	Downstream users / End products	Suitability/chemical advantages of formaldehyde
		sportswear materials.		
Formaldehyde is used as a disinfectant				
Healthcare	■ Vaccine additives and preservatives.	■ Production of bacterial and viral vaccines. Used to inactivate viruses so that they don't cause disease (e.g., influenza virus to make influenza vaccine) and to detoxify bacterial toxins (US FDA, 2011)	■ Vaccines.	■ Anti-bacterial properties; ■ Preservative properties.
Personal Grooming	■ Antimicrobial agent.	■ Antimicrobial agent.	■ Cosmetics (e.g. soaps, shampoos, hair preparations, deodorants, lotions, make-up, nail products); ■ Mouthwash, toothpaste.	■ Anti-bacterial properties.
Other industries	■ Used as: ■ Biocides; ■ Bacteriostatic agents.	■ Used as: ■ Biocides; ■ Bacteriostatic agents.	■ Bacteriostatic agent in some foods, such as cheese; ■ In food industry for preserving dried foods, disinfecting containers, preserving fish and certain oils and fats, and modifying starch for cold swelling; ■ In the rubber industry, as a biocide for latex; ■ In sugar industry formaldehyde is used as an infection inhibitor in producing juices.	■ Anti-bacterial properties; ■ Preservative properties.

Source: *Formacare, 2010b.*

4.4.3.3 Formaldehyde in consumer articles

This section presents an assessment of the likely presence of formaldehyde in consumer articles placed on the EU market. Due to the large number of formaldehyde uses and end user applications in what is a scoping study, this assessment is limited to estimating the presence of formaldehyde in a selected group of products. Given that formaldehyde is predominantly used in the furniture, automotive and household sectors in the EU, an in-depth analysis of the following consumer products has been carried out[60]:

- Formaldehyde resins in engineered wood-based furniture;
- Polyurethanes and formaldehyde-based coatings in automobiles; and
- Polyurethane memory foams and/or formaldehyde-based glues in mattresses.

4.4.3.3.1 Wood-based panel furniture

The use of engineered wood products in the furniture-making sector has grown substantially over the years. The main categories of engineered wood currently in use include: (1) PB; (2) medium-density fibreboard (MDF); (3) OSB; and (4) PW. In Europe, wood panels have become the material of choice for the furniture industry, displacing solid wood from many applications (ICF/AMEC Consultation). Currently, over 90 % of all furniture produced in the EU is made from wood-based panels (DIPP, undated), which in 2012 represented14 million tonnes of wood panel furniture[61].

Formaldehyde is primarily used as raw material for resins which are, in turn, used as binding material for wood-based panels. UF resins are widely used to make the adhesives for wood panels, such as PB and MDF, and are also used as components of melamine-phenolic resins for the production of laminated flooring board.

Estimating the amount of formaldehyde in finished (furniture) products is complex. Formaldehyde-based resins and glues, as supplied by the manufacturer, generally contain very small amounts of 'unreacted' or 'free' formaldehyde – typically about 0.1 % (by weight) (The Engineered Wood Association, 2002). This level of 'free' formaldehyde constitutes the main source of the trace amounts of formaldehyde which is contained in freshly-manufactured wood panels.

This (measured) amount of 'free' formaldehyde does not, however, provide a reliable basis for calculating the amount of the substance likely to be present in finished wood furniture. There is evidence that formaldehyde released from wood panels decreases by at least 50% within a few weeks of manufacture (Wood Panel Industries Federations, 2008). Moreover, obligatory emission classes for wood-based panels have been established in countries such as the US, Japan and several EU MS to limit exposure (see Table 4.13). Nevertheless, for the sake of simplicity, a 0.1% content level is retained for estimation purposes which could be treated as an upper limit.

[60] Formaldehyde is also widely used in the construction sector, whereby the substance may be contained in home (and office) construction products, notably in thermal insulation products (e.g. sheating and cladding, walls and wall panels. floors, and roof). However, consumers are less likely to be in direct contact with these products. Professional users may face greater exposure. Consequently, these products are not further analysed as part of this SEA. House interior products, on the other hand, are given greater consideration. Such products may include: furniture, countertops, cabinets, bedding, seating, etc. (for a full description see: Formacare, http://www.formacare.org/index.php?page=construction)

[61] Eurostat figures indicate that about 0.3 billion wood furniture items were produced in the EU in 2012. Wood furniture here refers to: wooden furniture used in offices, shops, domestic bedroom dining room and living room furniture (excluding floor standing mirrors, seats) and other wooden furniture. Assuming a wood panel furniture item weighs between 20 and 80 kg on average, this means that between 6m and 24m tonnes of wooden furniture items are produced in the EU. Given that the majority of this production is based on wood panels (90%), this generates volume of between 5.4 m and 22m tonnes. The average is around 14m tonnes.

Table 4.13 European formaldehyde emission limits for wood panels (e.g. PB)

Classification	Emission Limits (approx. parts per million (ppm) equivalent)	Applicable Products
EO	■ 0.5 mg/L (0.07 ppm) ■ 0.5 mg/L (0.07 ppm) ■ 0.5 mg/L (0.07 ppm)	■ PB ■ HWPW ■ MDF
E1	■ 0.12 mg/m³ (0.14 ppm) ■ 0.12 mg/m³ (0.14 ppm) ■ 8 mg/100 g (0.10 ppm)	■ PB), HWPW and MDF
E2	30 mg/100 g (0.38 ppm)	Industrial PW (PW), PB and MDF

Source: *CWC Modular Industries Corporation, Undated.*

To estimate the quantity of formaldehyde that is likely contained in finished wood furniture products, data on production, consumption and trade have been used for each category of wood panel material, where available.

Table 4.14 Estimated formaldehyde content in wood panel furniture

Product	Wood product volumes (million m^3)			Formaldehyde content in finished articles (tonnes)		
	Production	Export	Import	Articles produced in EU from EU materials	Articles produced in EU with imported materials	Articles imported into the EU
PB	37.2	11.0	8.8	2,800 to 3,200 [62]	900 to 1,000 [63]	320 [64]
MDF	14.1	Unknown	Unknown	1,500 to 1,700	Unknown	212 [65]
PW	4.2	3.3	Unknown	1,000 to	Unknown	70 [66]

[62] Stakeholder consultation revealed that 60-70% of particleboard produced in the EU goes into furniture production. Subtracting exports from total production this gives: 60-70% x (37.2-11.0) = 15.72m m^3 – 18.34m m^3 or 5.55m – 6.48m tonnes of particleboard used in furniture manufacturing in the EU. Given that formaldehyde content in particle board is estimated at 0.1 % this means that between 5,551 and 6,477 tonnes of formaldehyde are contained in particleboard. Based on the evidence that the level of formaldehyde decreases by 50% in the first few weeks of manufacture, we can further assume that the quantity of formaldehyde present in final products ranges between: 2,775 and 3,239 tonnes.

[63] Assuming 60-70% of imported particleboard is used in the manufacture of furniture, this would mean a formaldehyde content of: 0.1% x [60-70% x 8.8m m^3)] = 0.1% x [1.86m– 2.18m] tonnes = 1,865 – 2,175 tonnes in particle board imported. Assuming formaldehyde release decreases by 50% over time, we can assume that formaldehyde content in finished furniture is between 933 and 1,090 tonnes

[64] Data obtained from ICF consultation reveals that 2m m^3 of (finished) wooden furniture were imported into the EU in 2012. This is equivalent to around 700 ktonnes of imported wood panel furniture. Assuming that furniture made from particleboard accounted for 45% of these imports [based on evidence from: http://www.ettf.info/sites/default/files/ettf_2011-statistics_denmark.pdf], likely formaldehyde content is about: 0.1% x [45% x 700ktonnes] = 320 tonnes

[65] Assuming MDF- based furniture accounts for about 30% of imports, formaldehyde content can be estimated at: 0.1% x [30% x 706,293 tonnes] = 212 tonnes.

Product	Wood product volumes (million m^3)	Formaldehyde content in finished articles (tonnes)
		1,100

Source: ICF/AMEC

In all, the total amount of formaldehyde contained within wood based furniture is estimated to be in the range of 6,800 to 7,600 to tonnes in new consumer articles placed on the EU market per annum. This estimation does not take into account possible formaldehyde releases from old furniture, as these are likely to be negligible and undetectable over time.

4.4.3.3.2 Automobiles

Polyurethanes are amongst the most widely used formaldehyde-based raw materials in the automobile industry. Polyurethanes combine low weight and flexibility with great strength and durability. Their versatility helps in achieving the precise mechanical properties required for specific applications in the automotive industry, such as:

- Seat foam;
- Cushion overlay (fabric backing);
- Carpet backing;
- Door panels;
- Sound absorption and vibration dampening;
- Dashboards;
- Steering wheels;
- Bumpers;
- Energy absorbers;
- Headliners;
- Airbag covers; and
- Window encapsulation.

The production of PUF products, polyurethane paints and auto body products currently use formaldehyde-based specialty chemicals including MDI to impart fast curing, high moisture/heat/friction and chemical resistance properties and increase durability. It is reported that high-bake curing[67] ensures that isocyanate-based resins are no longer chemically active in intermediate products and therefore do not represent a major hazard to health in final products (ICF/AMEC Consultation and Dillon Consulting Limited, 2000). Given that a car of 1 tonne contains about 100kg of plastics (Plastics Portal, Undated.), of which about 15kg are polyurethanes (i.e. on average, a 1 tonne car contains about 1.5% of polyurethanes) (ISOPA and Euromoulders, 1999) and that car production in the EU was about 15 million units in 2010[68], it can be estimated that around 225,000 tonnes of polyurethanes were used in car manufacturing in 2010 in the production of 1-tonne cars[69]. Based on the evidence that producing one tonne of PUF requires about 0.616 tonnes of MDI

[66] Assuming plywood-based furniture accounts for about 10% of imports formaldehyde content can be estimated at: 0.1% x [10% x 706,293 tonnes] = 70 tonnes.

[67] High bake curing typically involves exposing moulded parts to additional heat in an oven.

[68] Statistics extracted from the European Automobile Manufacturers Association (ACEA) Statistics, 2013 available at: http://www.acea.be/collection/statistics

[69] There is a paucity of evidence regarding the likely content level of formaldehyde in MDI. Hence, a content level of 0.1% is assumed.

(Boustead, 2005), formaldehyde content in cars produced in the EU can be estimated to be around 163 tonnes[70] per annum (assuming other isocyanates are not used).

Melamine resins are also used in vehicle production, principally in resin coatings. Several coats are often applied to vehicle surfaces which may amplify formaldehyde release (See box below).

Box 3 Use of MF resins in automotive sector coatings

"Melamine resins are widely used in coatings and paints. Melamine resins as well as some other resins for coatings contain between 0.5 % and 2.5 % free formaldehyde […]. During the baking process, three to five times more formaldehyde may be released from melamine resins. In pure melamine resins, formaldehyde is reformed after extraction due to an 'equilibrium' reaction. In combination with alkyd or acrylic resins [...] melamine resins contribute to excellent technological and chemical properties of cured coatings. Fully-cured alkyd-melamine or acrylic-melamine coatings do not contribute to forming new free formaldehyde. However, free formaldehyde from the curing process may be adsorbed in the coating, and only partially-cured coatings may have some residual release of formaldehyde. The average concentration of formaldehyde in finished consumer articles would therefore be less than 0.1 % (case c). "

Source: ICF/AMEC Consultation

Based on the evidence that the amount of coating (involving volatile organic compounds), used per vehicle ranges between 2 and 20 kilograms (US EPA, 1982), it can be estimated that half will involve formaldehyde emissions (i.e. between 1-10 kg). Based on data for EU car production, an estimated 18,000-176,400 tonnes of coatings are used in the car industry and with a formaldehyde content of about 0.1 %, this suggests about 18-180 tonnes of formaldehyde content can be found in car coatings. A similar line of reasoning is applied as above in relation to vehicle production and trade in Europe to estimate the volume of formaldehyde in imported cars[71] (See **Table 4.15.**).

Table 4.15 Estimated formaldehyde content in cars (annual estimates)

	From EU sources	*From non-EU sources*
Source	**Formaldehyde content in cars produced in the EU**	**Formaldehyde content in cars imported into the EU**
Polyurethane/MDI	93 tonnes[72]	30 tonnes[73]
Surface coatings/paints	18-180 tonnes	3-33 tonnes

Source: ICF/AMEC Consultation

[71] Based on imports of 3million cars, volume of coatings ranges between: 3,300 – 33,000 tonnes. With a formaldehyde content of about 0.1%, this represents exposure to about: 3-33 tonnes.

[72] An estimated 7 million tonnes of cars were exported. That would mean about 115,800 tonnes of polyurethanes and 71,330 tonnes of MDI and 70 tonnes of formaldehyde content are exported. Therefore EU-based production exposes consumers to about 93 tonnes of formaldehyde in cars (as the 70 tonnes of formaldehyde content present in exported cars are subtracted from content level in local production).

[73] Around 3 million cars were imported in 2011-12 (Eurostat). Assuming the same weight of polyurethane in a 1 tonne car (i.e. 15kg) gives an estimated 50,000 tonnes of polyurethanes used in imported cars. This requires about 30,800 tonnes of MDI. Formaldehyde content can therefore be estimated at: 30 tonnes.

4.4.3.4 Foam mattresses

Polyurethane foam (PUF) (produced from TDI - toluene diisocyanate) is widely used in the production of polyurethane mattresses. Formaldehyde is also typically to be found in mattress foam [74] as the most common chemical flame retardant used in mattresses[75].

Recent data reveal that EU production of mattresses totalled EUR 5 billion or 67.6 million units, of which 23% were made from PUF (EC JRC, 2012). This would be equivalent to about 15.5 million polyurethane mattresses. Research suggests that a polyurethane mattress can weigh between 10 and 20 kg, implying that between 170,000 and 350, 000tonnes of polyurethane mattresses were produced in the EU. Based on industry information, the content of free formaldehyde in PUF is around 0.1% (Li W., et al., 2003.), consequently 170-340 tonnes of formaldehyde is likely to be contained in polyurethane mattresses produced in the EU.

Trade data for the same period indicates that EU exports of polyurethane mattresses were an estimated 81 kilotonnes whilst 110 kilotonnes were imported into the EU (EC JRC, 2012). Estimates of the formaldehyde content in polyurethane mattresses are provided in the Table 4.16 below. The estimated total is between 90 and 260 tonnes per annum accounting for imported and domestically consumed production.

Table 4.16 Estimated formaldehyde content in polyurethane mattresses

	From EU sources	*From non-EU sources*
Raw material	**Formaldehyde content in polyurethane mattresses produced in the EU**	**Formaldehyde content in polyurethane mattresses imported into the EU**
PUF	Between 90 and 260 tonnes[76]	110 tonnes[77]

Source: ICF/AMEC Consultation

4.4.3.5 Trends in formaldehyde production and usage

Formaldehyde demand in 2012 was worth €8.8 billion[78] and is expected to rise to € 14.2 billion by the end of 2018, based on CAAGR of 7.5% between 2012 and 2018 (Transparency Market Research, 2013). Whilst UF resins account for the largest share of the total formaldehyde consumption in 2012 (i.e. over 39%), PF resins are expected to exhibit the fastest growth over the next six years (Transparency Market Research, 2013). Accounting for 13% of consumption in 2011, PF resins constitute the second largest application market for the formaldehydes (Transparency Market Research, 2013).

In 2012, Europe was the second leading geographic market for formaldehyde followed by North America. Central and Eastern Europe, along with Central and South America and the Middle East, are forecast to experience significant growth in demand for formaldehyde, largely as a result of increased production of wood panels, laminates, MDI and pentaerythritol (IHS Chemical, 2012).

[74] Components researched include: isocynates; methylene chloride, 1,1,1-trichloroethane; acetone; benzene; ethylene oxide; and formaldehyde (Greendwellers, 2013).

[75] More information available at: http://www.tmasc.ca/memory-foam.html

[76] Between 170 and 340 tonnes of formaldehyde are estimated to be contained in polyurethane mattresses produced in the EU. Subtracting formaldehyde content present in exported polyurethane mattresses results in between 90 and 260 tonnes of formaldehyde are present in mattresses produced in the EU.

[77] Import volume x formaldehyde content level --> (109,879 tonnes x 0.1%) = 110 tonnes.

[78] Converted to Euros from US dollars using an exchange rate of $US 1=€0.755 from http://www.xe.com/ (10/09/13).

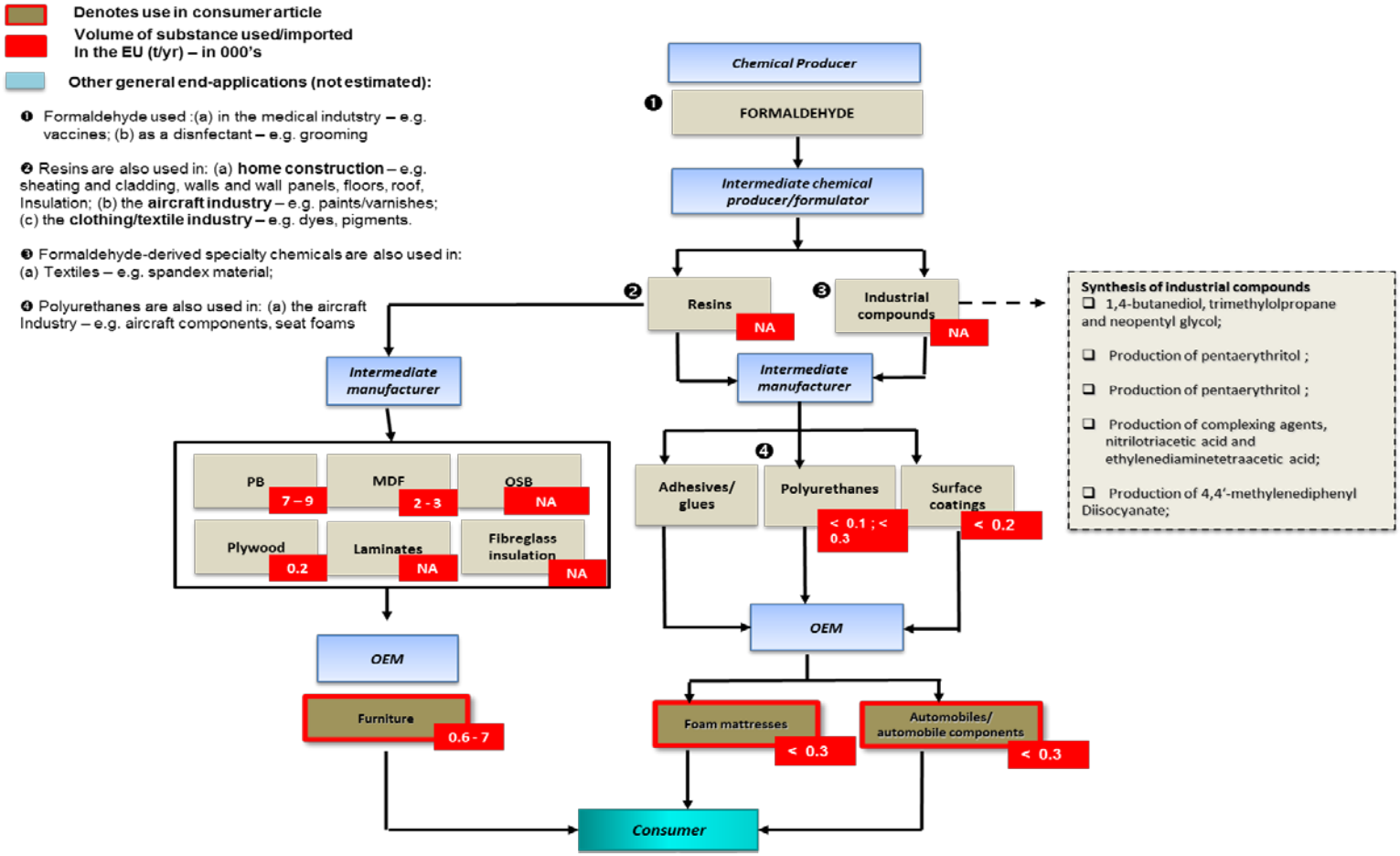
Rebound in the construction activity across the world is also expected to drive demand for formaldehyde-based resins in the coming years. As such, the construction industry has remained the predominant end-user of formaldehyde accounting for over 65 % of consumption by volume in 2012 (HIS Chemical, 2012).

Nevertheless, volatile raw material prices and environmental legislation are expected to be key concerns for formaldehyde manufacturers over the next five years. Growing health awareness and increasing environmental regulations are expected to restrict demand for formaldehyde derivatives and limit the growth of formaldehyde market (HIS Chemical, 2012).

4.4.4 Actors of the supply chain affected by a possible restriction

Upstream of those articles potentially containing formaldehyde, the supply chain starts with the annual production of formaldehyde which is an estimated 7 million tonnes in the EU. Formaldehyde is then primarily used by formulators and distributors in the production and distribution of resins and glues as well as specialty chemicals [such as: polyoxymethylenes (POM), methylene bis (dephenyl di-isocyanate) (MDI), 1,4-BDO, pentaerythritol, hexamine, and paraformaldehyde (PFA)]. The main intermediate applications of formaldehyde-based resins are in the construction, automotive, aircraft, clothing and healthcare industries. The use of formaldehyde-based resins in the manufacture of intermediate products such as components and parts for automotive manufacture indicates that formaldehyde is likely to be embedded in the final product, but primarily as an impurity and as a result, the substance can hardly be detected according to consultation responses. Exposure to consumers is consequently limited. Final products where consumer exposure cannot be ruled out in the three products elaborated on in this scoping SEA populate the remaining branches of the supply chain. Based on the analysis conducted above, in the region of the 7,500tonnes of formaldehyde (about 7000 tonnes in furniture, about 300 in automobiles/cars, and between 200 and 300 tonnes in mattresses) of formaldehyde per annum is estimated to be contained in consumer articles being commercialised in the EU.

Figure 4.8 An overview of the supply chain for formaldehyde contained in consumer articles, identifying those stakeholders potentially affected by a restriction and summarising the volumes present in each use, is illustrated below[79]



Source: ICF/AMEC Consultation

[79] The quantity of formaldehyde estimated to be present in the EU is provided in the flow diagram, with imported quantities in articles highlighted in red.

4.4.5 Expected non-use scenario

For the product categories considered for this scoping SEA, the general response of stakeholders to a possible restriction on the use of formaldehyde in consumer articles can be summarised in Table 4.17. As formaldehyde is naturally occurring in the environment it is anticipated that any restriction would establish a migration/emission limit in articles. A more in-depth discussion is provided in subsequent sections.

Table 4.17 Expected response of article supply chain to proposed restriction

Article supply chain	Response of EU industry	Alternative (if applicable)
Furniture	■ Switch to lower formaldehyde-emitting wood panels. Substitution has already started in the EU but only to a limited extent; ■ Because of the costly nature of low emission panels and other alternatives, any restriction must be extended to imported articles. Otherwise, adverse impact on the competitiveness of EU industry are likely;	■ Low emission wood panels; ■ PU-bound panels with a lower formaldehyde content; ■ Formaldehyde-free glues (currently in use by some operators in Canada).
Automobiles	■ The replacement of formaldehyde needs to be considered with caution according to consultation. . Alternatives (such as 2K coatings[80] contain other isocyanates that are acutely toxic (potentially more so than formaldehyde. ■ Other alternatives available but are less performing. 1K coatings already in use in the EU but tend to be less resistant /durable and may not offer UV protection.	■ 2K coatings with isocyanates as hardeners; ■ 1K coatings (do not contain hardeners); ■ Powder coatings ; ■ UV cure coatings.
Foam mattresses	■ Switch to alternatives to PUR mattresses such as natural, organic or organic latex foam mattresses that are made with non-toxic or 100 % natural materials (e.g. wool, organic cotton, horsehair, natural latex, unbleached cotton, and bamboo blend);	■ Organic/organic latex foam/natural mattresses

Source: ICF/AMEC Consultation

4.4.5.2 Evidence from the literature

An in-depth analysis of the economic contributions and benefits of the formaldehyde industry to the economies of the European Union (EU-25) and Norway and their consumers was carried out recently (Formacare, 2007). The analysis concluded that “a formaldehyde-free

[80] There are several automotive coatings available: (1) 1K coatings refer to coatings that do not require a hardener, catalyst or activator. They are often used to describe “single-component” or “one/single stage” paints, i.e., paints that do not require a clear top coat. On the other hand, (2) 2K coatings would typically need to be mixed with a hardener, catalyst or activator and would include “two-component” or “two-stage” paints (More information available at: Eastwood website: http://www.eastwood.com/1k-coating-vs-2k-coatings).

economy in the EU and Norway would be costly and disruptive" (Formacare, 2007), owing to economic and consumer benefits that would be lost if formaldehyde was discontinued. The main findings of the analysis are outlined in the table below.

Table 4.18 Lost consumer and economic benefits as a result of a ban on formaldehyde

Consumers	Industry/EU-wide economy
■ Consumers would have to spend an additional €29.4 billion per year if formaldehyde-based products were replaced by substitute materials	■ Almost €330 billion worth of sales that currently result from the formaldehyde industry's activities likely to be lost
■ Without formaldehyde-based resins (such as UF and PF resins), consumers would be forced to use more expensive, less versatile, and less durable materials or else switch to entirely different construction methods. In most cases, however, switching to different construction methods is likely to be a significantly more costly alternative. It has been reported that the substitution cost for replacing UF in its current applications is approximately €13.6 billion per year. This annual cost includes a capital recovery charge that reflects the investment to produce the incremental volumes of the substitute materials, as well as to retrofit plants at the point of application so that they can switch to substitute binders. In addition, the total capital investment required by industry to switch to substitutes of UF would be approximately €12 billion in order to have sufficient capacity to produce the required volumes of acrylic and vinyl acetate emulsions and emulsion polymer isocyanates (EPI).	■ Over 1.7 million workers – who are currently directly employed in chemical processing and downstream fabrication facilities in the European Union and Norway – likely to lose their jobs ; ■ Another 4 million workers – who are indirectly employed in the wide network of supplier industries that provide goods and services (e.g. raw materials, utilities, capital goods, services) to the formaldehyde industry – also likely to lose their jobs if formaldehyde was banned
■ In the absence of MDI (a formaldehyde-derived specialty chemical), consumers would be forced to use less effective materials and would experience a loss of utility due to decreased product quality .g. inferior insulation properties, increased breakage or spoilage)or shorter product life	■ Latest figures show that formaldehyde and derivatives production was carried out in facilities with an aggregate investment value of nearly €195 billion in the EU and Norway. This type of investment would not happen if formaldehyde is scrapped

Source: ICF/AMEC Consultation

4.4.5.3 *Evidence from stakeholder consultation*

In addition to a review of the literature evidence, the preparation of the scoping SEA, also involved a consultation exercise with industry (European manufacturers and importers of consumer articles or their representatives) that was undertaken to ascertain anticipated responses and impacts to a possible restriction on the use of formaldehyde in consumer articles. The results of this consultation are included in the Table 4.19 below.

Table 4.19 Consultation exercise on a potential EU-wide ban/restriction on formaldehyde

	Type of industry/consumer article	Stakeholders contacted	Valuable responses received
Trade/industry associations/environmental agency	Formaldehyde production, construction chemicals, rubber components (e.g. tyres), aerospace, textiles, lighting, wood-working, wood panels, furniture	■ 15 European ■ 1 International	■ 6 European
Private companies	Chemicals, inks/pigments, paint, surface coatings, lacquers, wood panels, furniture, automotive, aircraft/aerospace, energy-efficiency, insulation, medical devices, textiles	■ 18 European; ■ 4 International	■ 4 European

Source: ICF/AMEC Consultation

Formaldehyde is used in a wide range of applications and regarded as indispensable in many applications, for the following reasons[81]:

- The chemical properties of formaldehyde make it particularly suitable for imparting good designing possibilities to finished products (i.e., polymers) that contain it. For instance, formaldehyde has excellent binding properties, which is why it is used extensively in the manufacturing of glues and resins. Not only are these glues extremely effective, they are also economical due to the fact that formaldehyde is easily available, as opposed to alternatives;
- Alternatives are either too costly, have lower performance, are not readily available or are as hazardous (or more so) compared to formaldehyde;
- Alternative production processes and systems may have to be considered in some industries, requiring substantial effort and resources (e.g. additional training to staff, substantial equipment change, migration to non-EU locations). Industries could include vehicle manufacturing supply chains, and the production of mattresses, luggage and apparel which although already produced outside the EU and imported in to the EU in large volumes, may find it difficult to remain price competitive in the EU, due to compliance with any restriction.

4.4.6 Assessment of economic and social impacts

4.4.6.1 Screening of impacts

The first step in the SEA is a screening of the impacts and stakeholders potentially affected by the restriction. This ensures that the analysis is focussed on those stakeholders most affected by the proposed restriction and considers the nature and scale of the impacts, following the SEA guidelines produced by ECHA in relation to the possible costs and benefits.

Categories of impact are shown in section Table 4.20, along with a qualitative assessment of impacts (largely based on responses obtained from the stakeholder consultation).

4.4.6.2 Direct economic impacts

A potential withdrawal of formaldehyde raised several concerns amongst EU industry representatives. Whilst substitution for safer alternatives is already underway in many EU sectors, this is currently not undertaken on a wider scale, primarily for cost reasons and for

[81] ICF/AMEC Consultation with stakeholders from various industry sectors (e.g., publishing, furniture, aircraft, coating/paint, automotive, home insulation, construction, environmental protection).

the lack of initiative on the part of foreign producers (in particular in Asia) to follow suit which puts EU manufacturers at a cost disadvantage.

The loss in competitiveness will be disproportionately higher for some EU manufacturers if the restriction only applies to only EU-produced articles or there is a lack of enforcement in relation to imports of consumer articles.

Impacts on the furniture industry

Whist representatives of the EU furniture industry are willing to introduce lower formaldehyde-emitting panels or alternative intermediate products in their production lines following a restriction, they believe that this will not be economically viable if foreign producers do not follow suit. As such, alternatives are generally more expensive and would therefore put EU manufacturers at a disadvantage (due to higher production costs) if they are the only ones to revert to safer alternatives in the event of a ban.

An EU furniture trade association stated that a ban in the EU would increase the price of local furniture production but not that of imported furniture. They concluded that this would lead to lost market share for EU producers. The consultee noted that the industry would welcome using alternatives only if they are also encouraged or required in imported furniture products.

Box 4 A three per cent loss in annual turnover for the furniture industry

It has been estimated that businesses are likely to lose more than €20 million as a result of further legislative requirements that may forbid the use of formaldehyde in the EU.

In the event of a ban on formaldehyde, the production of formaldehyde-based resins will be discontinued by many, and alternatives to formaldehyde will be used in the production of intermediate products for the furniture industry. However, businesses responded that these alternatives are, on average, more expensive than formaldehyde. As raw materials become dearer, it is highly likely that many existing companies (typically micro enterprises) are driven out of business, leading to reduced levels of activity in the EU furniture sector.

Sources: ICF/AMEC Consultation

It is recommended by consultees, that any restriction would have to include the presence of formaldehyde in imported articles, in addition to use by the wood panel/ furniture industry in Europe, otherwise severe adverse impacts on competitiveness and jobs could occur.

Impacts on the textile/clothing industry

Similarly concerns were raised by the textile industry, stating that a potential restriction on the use of formaldehyde is seen as a “disaster for the EU textile-finishing industry[82].” Unless the restriction is extended to imported textiles, industry representatives have cautioned that tighter restrictions could eventually “increase the loss of producing-companies in the EU[83],” largely due to poor performance delivered by alternatives – such as methanol – in finished products. Lower quality would therefore induce consumers to switch to foreign products (assuming the ban does not apply to imports so that they would have retained desirable end-use properties), adversely impacting on EU manufacturers who are likely to lose an important share of the market.

The price of alternatives tends to be higher compared to that of formaldehyde which could undermine competitiveness of the EU industry if adopted in production lines

[84] ICF/AMEC consultation with private producer of surface coatings for car manufacturers.

[84] ICF/AMEC consultation with private producer of surface coatings for car manufacturers.

It is possible to replace formaldehyde in some applications. Nonetheless, in most cases, substitutes are more expensive making production economically unviable.

Impacts on the furniture industry

In the wood-working and furniture industries, a number of alternatives are known to be currently in use by producers of wood panels. Lower formaldehyde-emitting and PU-bound panels, for instance, are being used in furniture production. However, it has been estimated that such alternatives cost about 20% more than formaldehyde-based wood panels and constitute the main reason for which substitution is not being more widely promoted amongst EU manufacturers for fear of losing market to foreign producers. China, for instance, still produces and imports high emission panels and derived furniture products which are, on average, cheaper than low emission panels.

Impacts on the automotive industry

The use of 2K and 1K clear coats, powder and UV cure coatings have been recommended in place of formaldehyde-based coatings and lacquers in the automotive industry. Substitution for 2K and 1K coatings has already started in the EU. However, MF coatings remain more popular due to important cost differences. The price of 2K clear coats is significantly higher – by at least 50 % – compared to that of MF coatings. Similarly, powder or UV clear coats cost 100 % more than MF coatings[84].

Box 5 Evidence from the literature: alternatives to formaldehyde-based adhesives are available but may not be economically feasible or may entail adverse health impacts

A recent study commissioned by Formacare reveals that several alternatives to formaldehyde-based resins are available. Most of these alternatives do not generate formaldehyde emissions but are more expensive. These alternatives include:

- *Polymeric Diphenylmethane Diisocyanate (p-MDI)* –has excellent strength, heat, water and humidity resistance properties but are more expensive than UF and PF adhesives. On average, p-MDI costs around four times as much as UF. In addition, MDI and products containing unreacted MDI (such as p-MDI) are hazardous materials in that they may cause an allergic respiratory response causing asthma-like symptoms such as: coughing, difficult breathing and a feeling of tightness in the chest;
- *Emulsion Polymer Isocyanates (EPI)* – these have excellent high dry/wet strength, durable bonds properties and have fast setting speeds properties. However, they cost more than traditional formaldehyde-based adhesives and would require additional processing steps and equipment. In addition, depending on the hardener system used, isocyanates can be very hazardous causing potential irritability of the skin, eyes and respiratory system (Technical Committee on Wood Adhesives, 2007);
- *Polyurethanes* – these have high wet/dry strength properties and resist to water and damp atmospheres well. However, they bear a high cost and worker exposure is still likely to be high due to diisocyanates that are contained in polyurethanes. Diisocyanates can severely irritate the skin. ; and
- *Polyvinyl and Ethylene-Vinyl Acetate Adhesives (PVA; EVA)* – these have good dry strength properties and are easy to use but are limited by their poorer performance under moderately high temperatures (over 50°C), moist or humid conditions. In addition, they have higher viscosity than water-based adhesives, thus requiring manufacturers to make new capital investments before they could be used for panel production

Source: Formacare and RPA, 2013.

[84] ICF/AMEC consultation with private producer of surface coatings for car manufacturers.

4.4.6.2.1 Replacement products or alternative production processes are likely to be more costly

Impacts on the automotive and aircraft-making industries

As such, the production of surface coatings, paints and varnishes may not be satisfactorily met by alternatives to formaldehyde. In the automotive industry, it is reported that isocyanate-based coatings (such as 2K clear coats) would likely require the installation of new equipment and additional training to staff. In addition, additional short-term costs – in the form of testing and seeking new approvals – are likely to be incurred by substituting for this different coating technology. An estimated three years would be required for the transition to take place. In other industries, such as the aircraft industry, alternatives are yet to be tested, thereby requiring a longer transition period. Evidence provided in consultation suggests that the costs of transition are likely to be more than € 10 million for a producer of coatings and paint for aircraft/aerospace parts.[85]

Impacts on the mattress-making industry

Substitutes for PUF mattresses are regarded as expensive replacement products. As such, if a ban on formaldehyde was to be enforced, organic (or natural i.e. feather, plant material) mattresses would become a preferred option. However, these tend to cost more, mainly because of their overly complex production process. First, organic mattresses have to be made with either natural plant or animal products[86]. The price difference between a PUR mattress and a natural (or organic) foam mattress varies but this is estimated to be substantial[87].

In many applications, it is difficult to find a suitable alternative to formaldehyde mainly because substitutes do not possess the same attributes (i.e. foam memory mattresses). As a result, production processes have to be re-designed in order to allow for the use of an alternative (natural opposed to foam manufacture).

The literature identifies alternatives to formaldehyde-based resins that could be used in wood panel manufacturing. For instance, natural or bio-based adhesives are generally available at low cost. However, these tend to lack the required technical properties.

Box 6 Natural/bio-based adhesives

- *Protein glues* – these do not generate formaldehyde emissions and were therefore considered to be environmentally safe by the consultees. However, these have poor water/mould resistance and limited durability;
- *Lignin adhesives* – these are cheap and do not pose any serious environmental and health risks. However, lignin adhesives require long cure times and can be corrosive to machinery.

4.4.6.3 Indirect impacts

4.4.6.3.1 Impacts on the furniture industry

The risks associated with formaldehyde emissions have become a growing issue in many countries. As such, encouraging the use of alternatives (or lower emission panels) could therefore serve as an "export-promoting" argument, thereby boosting demand for EU-based products[88].

[85] ICF/AMEC Consultation with private producer of surface coatings for car manufacturers.

[86] More information available at: http://www.apsense.com/article/foam-vs-organic-crib-mattress-cribmattressreviewzcom-states-the-difference.html

[87] A quick search on the internet shows that PUR mattresses can cost as low as £60 in the UK (or €70) whilst the price of an organic mattress starts from £500 (or €590). Source: ICF/AMEC own research

[88] ICF/AMEC Consultation with furniture trade association.

4.4.6.3.2 Impacts on the mattress-making industry

Similarly, the replacement of synthetic foam mattresses with organic ones may not necessarily place EU manufacturers at a disadvantage. It is believed that 'natural' consumers are broadening their purchases across more categories of articles. In the US, for instance, natural mattresses are becoming increasingly popular (Marshall, 2013). Engaging in alternative production processes could provide EU manufacturers with new export avenues.

4.4.6.3.3 Other impacts

Wider promotion around safer alternatives to formaldehyde-based products could also induce non-EU producers to follow suit. It can be expected that foreign companies will become more engaged in the research and development of environmentally-preferred materials and processes in order to preserve competitiveness in the EU internal market. This should, in turn, provide greater certainty around imported products, especially at a time when consumers are increasingly worried about the long-term consequences of chemical exposure.

4.4.6.4 Wider social impacts

However, a potential restriction (particularly if only applied to EU production and article manufacturers) could have severe employment impacts, depending on the scale of competitiveness lost to non-EU industry and the degree of cost pass-through accepted by consumers who would continue to purchase EU manufactured articles at a premium. The location of supply chains may also be a factor in such circumstances, as any restriction could be a decisive (or final) factor in an automotive plant and supply chain relocating outside the EU, with consequent loss of employment.

The use of alternatives is already being considered and/or undertaken in these industries. However, if there is no collective effort (especially from exporting countries to the EU) to using safer alternatives, EU producers may lose their competitive edge as alternatives are generally more expensive or offer products of poorer quality, thereby reducing incoming demand and revenue.

4.4.7 Potential costs and benefits for consumers

4.4.7.1 Economic impacts

4.4.7.1.1 Impacts on the furniture industry

Consumers are likely to be hit with higher furniture prices following a restriction on the use of formaldehyde in wood-panels[89]. As outlined in earlier sections, costly alternatives – notably in the form of low-emission wood panels - are likely to trigger a rise in prices. However, furniture prices currently do vary owing to materials used, branding or other retailer-specific reasons. EU furniture typically costs about 15-20% more than furniture produced in China. European manufacturers thus foresee a similar price variation for furniture products they produce if alternatives are used (ICF/AMEC Consultation).

Price increases are also likely to affect imported furniture. However, if foreign producers also adopt alternatives in their production lines, prices of imported articles are expected to outpace those of furniture produced in the EU. According to a representative of the EU furniture industry, price increases are likely to be more important for imported furniture than for locally-produced furniture, mainly due to the cost of alternative (production) materials in non-EU countries being higher than in the EU. The consultee concluded that even with a generalised increase in production costs, EU producers will retain competitiveness compared to their non-EU counterparts.

[89] Stakeholders were unable to provide sufficient information which would have helped to infer the magnitude of such price increases across the different product categories.

4.4.7.1.2 Impacts on the automotive industry

In the automotive sector, substitution is already taking place. According to the consulted stakeholders, a restriction would therefore have limited impact on consumer prices in this sector.

4.4.7.2 Environmental impacts

The likely impacts on the environment of a restriction on formaldehyde are uncertain. On the one hand, lower formaldehyde emissions entail a cleaner and healthier environment. In the wood panel industry, several alternatives to formaldehyde-based adhesives are considered environmentally safer than formaldehyde. These include: polymeric diphenylmethane diisocyanate (p-MDI), EPI, polyvinyl and ethylene-vinyl acetate adhesives (PVA; EVA), protein glues, tannin and lignin adhesives (Formacare and RPA, 2013).

However, the use of certain alternatives – such as solid wood in the production of furniture – may amplify the problem of logging and deforestation. Nonetheless, it has been reported that wood harvested in a sustainable manner has a minimal impact on the environment. A study conducted by the Danish EPA on wooden furniture indicates that the consumption of wood generates no effect because it is a renewable resource. The study found wood to be CO_2 neutral (Taylor and Van Langenberg, 2003).

4.4.7.3 Human health impacts

There are undeniably numerous health benefits for consumers of switching to formaldehyde-free products, as risk assessments have identified formaldehyde residue in adhesives for household use as a leading exposure route in indoor air and dust (NITE, 2013).

Formaldehyde can pose acute as well as chronic health risks to those who are overly exposed to the substance (see box below). In the wood-working and furniture industries, urea formaldehyde (UF) resins are the most commonly used formaldehyde-based resins in the manufacture of wood-based panels. "*Because the formaldehyde component of UF adhesives is not completely chemically fixed by the urea, some formaldehyde is free to dissipate and, as such, UF resins are associated with the highest releases of formaldehyde when compared with other formaldehyde-based resins*" (Formacare and RPA, 2013).

MF resins are also believed to emit formaldehyde. Whilst formaldehyde release from end products is believed to be low, exposure to melamine still constitutes a health hazard – notably in cases of skin contact, eye contact, ingestion and/or inhalation (Formacare and RPA, 2013). The key fact that formaldehyde is found in consumer articles used in a confined space (i.e. the home or inside a vehicle) means that consumer exposure, particularly to minors is a concern, which as restriction could partially address.

Box 7 General health hazard information relating to formaldehyde

Acute health effects:

- Severe irritation of the skin and eyes, with possible eye damage;
- Exposure can irritate the nose, mouth and throat;
- Inhaling formaldehyde can irritate the lungs, causing coughing or shortness of breath.

Chronic health effects:

- Formaldehyde is a cancer hazard – it was proved to cause cancer of the nasopharynx and leukaemia;
- Formaldehyde is also a reproductive hazard – there is some evidence that it can damage female fertility.

Other health effects:

- Repeated exposure to formaldehyde can cause bronchitis to develop, with cough, phlegm and/or shortness of breath;
- Formaldehyde can cause skin allergy, leading to serious skin rash and itching;
- There is also evidence that formaldehyde can cause asthma attacks

Source: New Jersey Department of Health, 2010.

Nonetheless, evidence from the literature indicates that health gains may be moderate for consumers. A majority of formaldehyde-based wood adhesives already generate little or no release of formaldehyde from cured products. Any health risks would therefore fall primarily on workers (as opposed to consumers) as risk of exposure occurs during the manufacture and use of the resin itself (See Box above). Hence, a restriction on the presence in consumer articles may not be the most appropriate action for regulators.

Phenol formaldehyde (PF) resins emit very small amounts of formaldehyde (less than other formaldehyde-based resins) due to the fact that formaldehyde is efficiently consumed in the curing reaction and the cross-linking is more stable (Formacare and RPA, 2013). As a result, "completely cross-linked PF is inert and non-toxic" so that the health risks to end-users (consumers) are minimal.

Similarly, resorcinol formaldehyde (RF) and phenol resorcinol formaldehyde (PRF) adhesives do not emit substantial amounts of formaldehyde. In RF and PRF, the polymers do not chemically break down in service. This implies that no detectable formaldehyde is released and consumers are not at risk from formaldehyde emissions from the finished product. In a similar vein, polymeric diphenylmethane diisocyanate (p-MDI)[90] is not considered hazardous in bonded wood products. Final bonded products do not contain any risk of formaldehyde emissions because of the reaction of the isocyanate groups (Formacare and RPA, 2013).

Box 8 Some alternatives entail serious risks to workers' health

Alternative formaldehyde-based resins:

- *PF resins*: do generate low/no formaldehyde emissions from cured products and therefore, pose no risks to consumers. However, concerns for worker health may remain;
- *MF resins, RF and PRF resins*: these pose no risks to consumers. However, the extent of actual risk reduction for workers is uncertain as there is continued use of formaldehyde in production

[90] p-MDI is used in the wood-based panels industry for the manufacture of OSB and to a lesser extent for the manufacture of particleboard.

processes;

Synthetic substances:

- *Polymeric diphenylmethane diisocyanate (p-MDI)*: there are no formaldehyde emissions from the use of p-MDI and therefore, no risks to consumers of formaldehyde emissions. However, worker health risks due to contents of p-MDI, particularly MDI, cannot be ignored;
- *Emulsion polymer isocyanates (EPI) and polyurethanes*: when properly hardened, these do not release formaldehyde. However, there is a potential high degree of worker exposure to isocyanate – such as MDI - during manufacture;
- *Epoxy adhesives*: these present serious health risks to workers as many components are hazardous or irritants

Natural/bio-based adhesives:

- *Tannin and lignin adhesives*: there are no known health/environmental concerns for uncross-linked tannin and lignin adhesives. However, the extent of actual risk reduction when cross-linked using formaldehyde remains unclear.

Source: New Jersey Department of Health, 2010.

4.4.8 Overall conclusions on potential costs and benefits

The review of socio-economic evidence in relation to formaldehyde indicates that a restriction on formaldehyde may entail higher production costs owing to costly alternatives and new production processes that will have to be adopted in the event of a restriction. In many EU-based industries, alternatives are already being considered but are not currently in use. This is largely because foreign producers are not willing to make similar changes. This would therefore put EU producers at a disadvantage. It has been estimated that the EU furniture industry would lose about 3% of its annual turnover if a switch to alternatives was undertaken by EU producers only. However wider promotion of formaldehyde-free products could allow EU producers to capture new export markets where the demand for these alternatives is growing.

Consumers can be expected to face higher prices, owing to costly alternative materials. However, in other industries, where substitution has already started to take place and is well-engrained in production processes, price effects may be mitigated.

It has been difficult to quantify the benefits associated with a possible restriction on formaldehyde. Many alternatives would still pose serious health concerns. In many cases the exposure risk will be passed from consumers using the article to workers in the manufacturing process.

4.4.9 Substance-specific considerations for development of draft criteria to implement Article 68.2 to CMR 1A and 1B in consumer articles

The following criteria are identified for consideration:

- Current and future investment plans: these constitute an important indicator for prioritising a restriction on the use of formaldehyde. The ability of the EU industry to undertake current and future investments (and bear investment costs) in the production of alternative formaldehyde-based products ought to be given due consideration. The EU industry should be financially capable of implementing alternative production processes and to pursue further innovation in this field;
- Technical feasibility of alternative products and/or alternative production techniques: alternatives need to be technically feasible and share similar performance characteristics as formaldehyde-based products in order to ensure that businesses obtain sufficient demand for new products and can sustain production;

- Health hazards associated with alternatives: Potential hazards to human health associated with alternatives should be thoroughly assessed. It would not be technically feasible to replace formaldehyde-based products by alternatives if these pose equal or more serious concerns to human health;

- Avoidance of disproportionate costs: a restriction implies changes in production processes, investment in new capital, product redesign and changes in cost in relation to the use of alternatives. Where such costs are disproportionate and not borne by non-EU industry, disproportionality is likely, resulting in a loss of competitiveness, growth and jobs. Criteria should therefore account for the affordability of compliance for EU industry, partially dependant on the consumer's willingness to pay more for furniture, automotive vehicles and mattresses produced in the EU;
- Loss of competitiveness: can be mitigated provided a restriction does not apply to use, but rather to formaldehyde presence in consumer articles. Thus, EU producers will remain on a level playing field with non-EU producers;
- Complexity of issues: A restriction under the Article 68.2 fast track procedure may not be preferable to other RMOs, given that consumer exposure may be low in many articles making it difficult to enforce and detect. The complexity of the supply chain with so many end use applications may also make the fast track procedure difficult to implement and unsuitable in many cases; and
- Certainty of benefits: a restriction must ensure that environmental/health improvements are achieved by its introduction. It should therefore be clear that a consumer exposure potential exists, which cannot be mitigated through other means.

Table 4.20 Identification of relevant impacts by stakeholder group, impact category and supply chain

✓ - Benefit or positive outcome;
- No or insignificant anticipated impact;
× - Cost or negative outcome

SUPPLY CHAIN	IMPACT CATEGORY/STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
Furniture	Operating costs and conduct of business	A rise in costs is likely owing to manufacturers having to revert to the manufacture of alternative intermediate products. However alternatives are already being used so that this cost change is likely to be marginal ×	Production costs will increase due to alternative production materials being more expensive. However, due to current legislation on emission levels, furniture producers have already begun the switch to safer alternatives. Change may be marginal ×	Significant (cost) impact on EU importers of furniture in the event of a restriction. Costs will mainly arise from having to comply with legislative requirements by ensuring imported products are free from formaldehyde – e.g. demonstrating that the imported article is safe before it enters commerce in the internal market that would require additional testing and assessment. Even if importers are assured that foreign producers have switched to alternatives, significant costs may still arise due to much higher prices on imports ×	The formaldehyde industry has an important population of SMEs. Replacing formaldehyde is likely to lead to loss of business for many due to rising costs from having to switch to alternatives. The furniture industry is quite fragmented in that most of the companies are SMEs. Higher production costs will therefore disproportionately affect smaller businesses. If they cannot invest in alternative materials or alternative methods of production, many may be driven out of business. ×	Consumers likely to be hit by higher prices due to higher production costs being passed on to them, at least partially. The magnitude of this price change is expected to be much higher for imported furniture than for locally-produced furniture ×

SUPPLY CHAIN	IMPACT CATEGORY/STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
	Competitiveness, Trade and Investment	Switching to alternatives may open new export markets for EU producers. There is a growing demand for low formaldehyde-emitting panels from countries such as US and Japan. As alternatives are already being produced in the EU, EU chemical producers are also likely to have a comparative advantage in their production compared to non-EU manufacturers where switching has yet to start ✓	Significant loss of competitiveness for EU furniture manufacturers if non-EU manufactures are not using alternatives (local prices likely to be about 15-20% higher than import prices). On the other hand, if foreign producers also switch to alternatives, prices on imported products are likely to be much higher compared to those of locally-produced furniture × / ✓	Significant or highly significant loss in importers' competitiveness - this owing to higher costs incurred in ensuring imports comply with legislative requirements or higher prices on imported (formaldehyde-free) articles, ×	There is no certainty as to how competitiveness of EU businesses will be affected following a restriction. If non-EU businesses are also driven to follow suit, EU businesses (including smaller businesses) may have a comparative advantage in the production of substitutes if they can produce replacement products at a lower costs (which in turn will depend on availability of alternative raw materials). Similarly, depending on the lobbying around formaldehyde-free products, exports of EU replacement products may increase compared to non-EU products. Smaller businesses may be able to serve new markets. ✓ / ×	Greater certainty around imported products as well as potential health and environment benefits. Higher prices on imported products will induce substitution for what is locally-produced. Choice thereby restricted. ✓ / ×
	Competition and the internal market	No significant impact. At present, EU chemical producers are already substituting for formaldehyde in their production processes. -	No significant impact anticipated as EU manufacturers of furniture are already using alternatives to formaldehyde in production lines -	Market potentially dominated (at least in the short-term) by local manufacturers of articles who have already switched to alternatives and are thereby well-established in the internal market; higher prices on imported articles therefore likely to give competitive advantage to local article producers ×	There is likely to be a surge in the demand for formaldehyde substitutes. Increased demand may in turn lead to higher prices of raw materials, which may have a significant impact on cost of production. Given that the furniture industry has a significant population of SMEs, a major brunt of the	Greater choice of safer products for consumers. Greater certainty around imported articles will also allow consumers to make more informed purchasing decisions ✓

SUPPLY CHAIN	IMPACT CATEGORY/STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
					cost burden is likely to fall on these businesses. ×	
	Innovation and research	No significant impact as alternatives are already being developed and used -	No significant impact as alternatives are already being used in production lines -	N/A	A possible increase in research and development of environmentally-preferred materials and processes can be foreseen. However the extent to which smaller businesses are able to engage in such activities (which are likely to be resource-intensive) is uncertain - / ✓	Greater availability of safer products if local and foreign producers invest more in safer product materials - / ✓
	Distributive/Equity	No significant impact anticipated -	No significant impact anticipated -	Significantly larger impact on EU article importers than local manufacturers due to additional costs ×	Foreign producers, in particular small businesses, are more likely to be disadvantaged by new EU regulation – additional costs likely to be borne by these small non-EU producers who have yet to switch to alternatives ×	Higher prices on imported products will induce substitution for what is locally-produced. Choice thereby restricted. ×

SUPPLY CHAIN	IMPACT CATEGORY/STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
Automobiles	Operating costs and conduct of business	Some substitution has already started (e.g. 2-component coatings are currently being produced and used in the EU). Other alternatives – deemed more technically feasible - are still being considered but are significantly more expensive. A restriction would therefore have little to significant impact on costs. ×	Some substitution has already started. Higher costs likely due to more expensive production materials and due to new production systems required ×	Marginal or significant impact on EU importers of automobiles in the event of a restriction. Costs will mainly arise from having to comply with legislative requirements by ensuring imported products are free from formaldehyde – e.g. demonstrating that the imported article is safe before it enters commerce in the internal market that would require additional testing and assessment. Even if importers are assured that foreign producers have switched to alternatives, significant costs may still arise due to much higher prices on imported cars ×	The formaldehyde industry has an important population of SMEs. Replacing formaldehyde will lead to loss of business for many due to rising costs from having to switch to alternatives or alternative methods of production. On the other hand, the switch to safer alternatives has already started in the automotive sector. As a result, a restriction on formaldehyde may not have a significant impact on businesses, including smaller businesses who may have undertaken a change in production activities well before the restriction × / -	Substitution for 2K coatings has already started in the EU. A ban would therefore have little impact on consumer prices. If more expensive alternatives are considered, impact can then be higher, given that prices may rise further - / ×

SUPPLY CHAIN	IMPACT CATEGORY/STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
	Competitiveness, Trade and Investment	EU producers will only have a comparative advantage and will be more price-competitive if non-EU chemical producers are willing to use alternatives but do not have production systems/processes yet in place. -	If EU automobile manufacturers have already substituted for formaldehyde-based coatings in their production lines or have implemented new production processes, then they will have a comparative advantage if foreign producers have yet to change production processes to abide by new EU requirements ✓ / - / ×	Marginal or significant loss of competitiveness for EU importers of automobiles in the event of a restriction. Costs will mainly arise from having to comply with legislative requirements by ensuring imported products are free from formaldehyde – e.g. demonstrating that the imported article is safe before it enters commerce in the internal market that would require additional testing and assessment. Even if importers are assured that foreign producers have switched to alternatives, significant costs may still arise due to higher prices on imported cars ×	There is no certainty as to how competitiveness of EU businesses will be affected following a restriction. If non-EU businesses are also driven to follow suit, EU businesses (including smaller businesses) may have a comparative advantage in the production of substitutes if they can produce replacement products at a lower costs (which in turn will depend on availability of alternative raw materials). However, if replacement has already started in other countries, then competitiveness of EU businesses, including small businesses, may be adversely affected ✓ / - / ×	No significant impact -
	Competition and the internal market	As substitution has already started in the automotive sector, a restriction would have no or little impact on competition -	As substitution has already started in the automotive sector, a restriction would have no or little impact on competition -	Importers may find it harder to compete with local producers. Additional costs – arising from testing and other assessments – may force prices up ×	There is likely to be a surge in the demand for formaldehyde substitutes. Increased demand may in turn lead to higher prices of raw materials which may have a significant impact on cost of production. The extent to which this will impact on small businesses will depend on whether they have already begun to replace formaldehyde in their	Greater availability of safer products. Limited impact on final consumer prices possible -

SUPPLY CHAIN	IMPACT CATEGORY/STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
					production lines ✓ / ×	
	Innovation and research	Continued research and development likely ✓	Continued research and development likely ✓	N/A	Positive impact on research and development likely. However, this will depend on financial capability of smaller businesses ✓ / -	Greater availability of safer products. Better quality and prices ✓
	Distributive/ Equity	No significant impact anticipated -	No significant impact anticipated -	Larger cost impact on EU article importers than local manufacturers due to additional costs (testing, etc.) ×	Foreign producers more likely to be disadvantaged by new EU regulation – additional costs if they have not yet switched to alternatives - / ×	No significant impact anticipated -
Foam mattresses	Operating costs and conduct of business	Substitutes already being provided by many EU producers. - / ×	Substitutes already being provided by many EU producers. - / ×	Substitutes already being provided by many foreign producers. Because substitutes include organic materials, some costs may be involved in testing authenticity of certification marks ×	No major impact is likely. Substitutes for foam mattresses are already widely available. Many small businesses currently offer organic mattresses for instance -	Substitutes already cost significantly more. With a restriction this is not likely to change much -
	Competitiveness, Trade and Investment	Will depend on organic raw materials used and whether they are locally available ✓ / - / ×	Will depend on organic raw materials used and whether they are locally available ✓ / - / ×	Because substitutes include organic materials, some costs may be involved in testing authenticity of certification marks ×	Will depend on organic raw materials used and whether they are locally available ✓ / - / ×	Substitutes already cost significantly more. With a restriction this is not likely to change much -

SUPPLY CHAIN	IMPACT CATEGORY/STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
	Competition and the internal market	Limited impact -	Limited impact -	Because substitutes include organic materials, some costs may be involved in testing authenticity of certification marks Imported mattresses may be therefore less price competitive ×	Lack of certainty around imported products could reduce ability to compete with local producers ×	More competition – better information around organic products– likely to benefit consumers by helping them to exercise informed purchasing decisions - / ✓
	Innovation and research	Limited impact -	Limited impact -	N/A	Limited impact -	N/A
	Distributive/ Equity	No significant impact anticipated -	No significant impact anticipated -	N/A	No significant impact anticipated -	N/A

Source: ICF/AMEC Consultation

4.5 Scoping SEA: 1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione [TGIC]

4.5.1 Introduction

This section covers the scoping SEA for **1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione (TGIC; CAS No. 2451-62-9)**. This section follows the structure defined in the introduction, concluding with the identification of considerations and elements to help ECHA and the Commission in the development of criteria for application of Article 68.2 for CMR substances in articles.

4.5.2 Regulatory Status

TGIC was registered by two companies as a full substance in the tonnage band 100 - 1,000 tonnes per annum.[91]

TGIC has been identified by ECHA as a SVHC and is therefore, since June 2012, on ECHA's Candidate List. TGIC has been identified as a substance meeting the criteria of Article 57.b of REACH owing to its classification as mutagenic category 1B[92]. The substance is currently being evaluated by the Polish competent authority. The industry recognised the lack of available information and is collecting monitoring data to support the Substance Evaluation which was scheduled for 2013[93].

The toxicity of TGIC has been established for some time by different national authorities (NICNAS, 1994 and UK HSE, 2003). Since June 2012 TGIC has been included on ECHA's Candidate List of Substance of Very High Concern because of its mutagenic properties.[94] TGIC is still used for specific functions within the EU and can be present in the manufacturing process of articles imported in to the EU.

4.5.3 Production and uses of TGIC in articles

TGIC is an epoxy compound which is mainly used as a hardener for weather resistant resins and polyester powder coatings. It does not occur naturally. It is produced industrially by reacting cyanuric acid with excess epichlorohydrin. TGIC is a solid which may occur as a white opaque powder or granules or as clear crystals (Nordic Council of Ministers, 2001).

4.5.3.1 TGIC in articles

In the Annex XV Dossier for identification of the substance as SVHC, ECHA estimated that 80% of the TGIC currently used in Europe is allocated to powder coating applications; while the remaining 20% is allocated to the manufacturing of solder mask ink (Annex XV SVHC Dossier, TGIC, 2012).

As established by the industry and recognised by ECHA (Annex XV SVHC Dossier, TGIC, 2012), there exist no recent aggregated data on the quantities of TGIC traded in the EU. However, stakeholders estimated the quantity of TGIC sold in the EU in 2012 to be in the range of 90 to 100 tonnes. This corroborates with ECHA's statement that in 2012 the total current use of TGIC in Europe was estimated to be around the lower end of the 100-1,000 tonnes. According to the stakeholders that were consulted for this study, these quantities are

[91] According to records in ECHA's database on registered chemicals (http://echa.europa.eu/search-chemicals) as of 13 November 2013.

[92] Corresponding to classification as mutagen category 2.

[93] This substance evaluation is mentioned in the Comments on TGIC – Annex XV Dossier for identification of a substance as SVHC and responses to these comments (http://echa.europa.eu/documents/10162/9f61c3f4-8caa-4efc-a854-0b248815be1e). However, no additional information concerning this evaluation was identified.

[94] Candidate List of SVHC for Authorisation available at: http://echa.europa.eu/candidate-list-table/-/substance/954/search/+/del/20/col/CASNUMBER/type/asc/pre/4/view

strongly declining. One of the stakeholders forecasted in August 2013 that the total sales of TGIC on the EU market are likely to be below 50 tonnes in 2013. The same stakeholder estimated that approximately 4,000 tonnes of alternatives to TGIC are currently used in the EU.

The sections below will analyse in more detail the two main uses of TGIC. It is important to stress that other uses within articles produced outside the EU and potentially imported in to the EU may also exist.

4.5.3.1.1 TGIC in Powder Coatings

TGIC is used as a hardener and cross-linking agent during the manufacturing of powder coatings. During the manufacturing process, TGIC granules are mixed with resin, pigments (if the powder coatings are pigmented), fillers and additives. The mixture is heated until molten and the melt is mixed to ensure homogeneity. It is then extruded into a thin sheet, which cools and solidifies. The solid material is chipped, milled, sieved and packed as a fine powder. Generally, 90 to 95% of the powder particles are >10 µm. During that process, TGIC is partially cross-linked to the polyester resin. At this stage of the manufacturing process, the powder coatings typically contain around 4% of TGIC and in some specific cases up to 10%. The coatings are then sprayed onto metal or plastic objects by an electrostatic process. The coated objects are then placed in an oven. At a temperature of about 200°C the resin melts, flows, and chemically cross-links to form a paint film. The TGIC in powder coatings after application to metal particles is fully cross-linked and is bound in a solid matrix and therefore not present as a free substance (Annex XV SVHC Dossier, TGIC, 2012). There are therefore no risks of consumer exposure.

TGIC powders are used in the industry because of their very good adhesion properties, corrosion resistance and exterior durability. They also resist ultraviolet damage and are therefore used in many outdoor applications. One of the consulted stakeholders emphasised the unique technical profile of TGIC in terms of (un-)reactivity and stability of the cured coatings, as well as of efficiency and robustness of the manufacturing process. It is, moreover, the only hardener allowing extreme temperature (low and high) manufacturing. It is typically used where sharp edges and corners exist such as on air conditioners, lawn furniture and air conditioners cabinets. It is also used in different non-consumer articles (e.g., architectural elements such as façade cladding elements or window frames) (Powder Coating Centre, 2013). Assuming that 80% of the TGIC sold in the EU is used in the manufacturing process of powder coating, this represent a total of 80 tonnes for 2012 and 40 tonnes for 2013.

According to ECHA's consultation with the industry, more than 90% of the TGIC powder coatings formulations have successfully been replaced in Europe using beta-hydroxyl alkyl amide (HAAs) or glycidylester alternative cross-linkers. A few TGIC based powder coatings are however still being used in Europe. For some applications the current alternative cross-linkers do not completely satisfy the most demanding technical profiles. In other cases, the volume of powder coatings used is too small to economically justify the costs (e.g. parameter adjustment, requalification of part of the manufacturing process, etc.) associated with a switch of raw materials (Annex XV SVHC Dossier, TGIC, 2012).

Despite these exceptions, the phasing out of TGIC for the majority of its applications in the European powder coating industry has been confirmed during our stakeholders' consultation and by an industry survey undertaken in Italy in 2004 (Metal Finishing, 2004). In addition IFRAB Chemical Consultants analysed in an industry analysis published in 2006, that polyester-epoxy hybrids and polyester/TGIC-free powders dominated the European powder coating market, with epoxies, acrylics and polyurethanes only filling niche sectors (IRFAB, 2006). This phasing out process is estimated to have started in the late 1990s and is expected to be completed in the coming years.

4.5.3.1.2 TGIC in solder mask inks

The second main function of TGIC is its integration in the solder mask inks used in the printed circuit board industry. Based on its resistance to heat and to corrosion, TGIC is used as part of the hardener for solder mask inks. The two-part inks can contain up to 60% of TGIC in the hardener component, resulting in a very low level of TGIC in the final inks. The inks are applied primarily by screen printing, to a lesser extent by curtain coating and also as a niche application method via electrostatic spraying. The coated circuit board is finally passed through an oven at 150°C to complete the curing process (Annex XV SVHC Dossier, TGIC, 2012). During this process TGIC is immobilised through cross-linking in an insoluble matrix. There are therefore no risks of consumer exposure for TGIC in articles.

The total quantity of TGIC currently used in the manufacturing process of solder mask ink in Europe is not known. The World Health Organisation (WHO) estimated that during the 1990s four or five companies located in the UK were manufacturing around 30 tonnes of solder mask inks containing TGIC every year (WHO, 1998). As mentioned above, around 90-100 tonnes of TGIC was sold within the EU in 2012 and less than 50 tonnes in 2013. Assuming that 20% of the TGIC sold within the EU is used for solder mask ink purposes (Annex XV SVHC Dossier, TGIC, 2012), this represents a total of approximately 20 tonnes in 2012 and less than 10 tonnes for 2013.

Different stakeholders indicated that they no longer use TGIC in their European manufacturing processes. They also noted that it is still used in different parts of Asia. However, one facility located in Switzerland reported to ECHA the import of 84 kg of resin containing TGIC at 15% (12.6 kg of TGIC) in 2011 to use in the manufacturing of semiconductor devices. They also stated that the maximum nominal concentration in finished semiconductor devices being used in Europe or exported from Europe is about 6 % of TGIC. Alternatives are available to replace TGIC in solder mask inks for low performance electronics however it cannot currently be replaced for high performance electronics (Annex XV SVHC Dossier, TGIC, 2012).

4.5.3.1.3 Other uses

The literature identified the following additional uses of TGIC in articles. However we were unable to confirm whether production in the EU has ceased or whether articles produced outside Europe continue to contain TGIC which are then imported in to the EU.

- Electrical insulation materials;
- Resin-moulding systems;
- Laminated sheeting;
- Silk-screen printing coatings;
- Adhesives;
- Lining materials; and
- Stabilisers for plastics.

Given the findings of the Annex XV on identification as SVHC that TGIC production in the EU is limited to powder coatings and semiconductor applications it is suspected that the above additional uses have ceased. Imports in articles are therefore likely to be the main sources of TGIC in this context.

4.5.3.2 Trends in TGIC production and usage

TGIC is being phased out in Europe for the majority of its application in the powder coating industry. There are already several alternatives known and largely used, and R&D activities continue to search for additional alternatives. Considering the different regulatory initiatives to limit the use of TGIC and the availability of alternatives, this downward trend in use is expected to continue in Europe for the foreseeable future. In the rest of the world and in

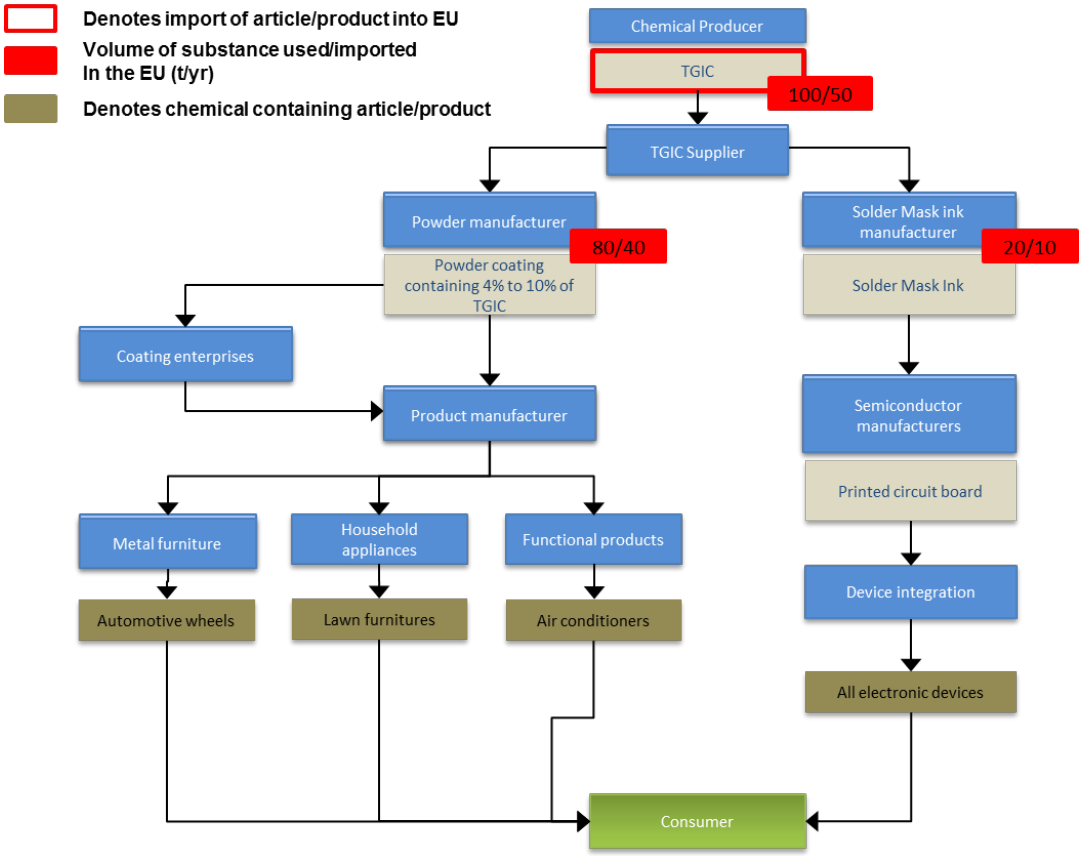
particular in Asian countries, TGIC is still largely used. However, some Asian companies are more and more considering the suitability of alternatives to replace TGIC.[95]

On the other hand, as stressed by one of the consulted stakeholders, most of the new, most promising coating developments in terms of efficiency, output, product quality, energy management and environment (e.g. coil coating, low temperature systems, high quality clearcoats, etc.) are based on TGIC. These new developments might drive the use of TGIC outside the EU. Moreover as final coated products do not contain TGIC, they would not be covered by a potential EU ban. This significantly reduces the incentive to switch to alternatives for non-EU manufacturers.

4.5.4 Supply chains affected

Figure 4.9 illustrates the supply chain for TGIC used in the manufacturing process of consumer articles, identifying the stakeholders potentially affected by a restriction. The data presented in the diagram are based on stakeholder consultation.[96] Moreover, as TGIC is reacting during the manufacturing process, TGIC is no longer present as free substance in the cured powder coatings. In addition, the durability of the coating is likely to minimise any consumer exposure of TGIC. Considering the high decline in the use of TGIC in Europe, the diagram presents estimations for 2012/2013.

Figure 4.9 Summary of supply chains of TGIC



Source: ICF/AMEC Consultation

[95] Example of a Vietnamese company comparing TGIC with Primid powder system and concluding that: "Primid powder system could completely replace TGIC in outdoor applications". Available at: http://www.mdi.vn/en/m/tin-tuc/351/

[96] The confidential Annex 2 of Annex VX Dossier on TGIC published by ECHA contains current data on production and use of TGIC.

TGIC is imported to Europe from different production sites located in Switzerland, Japan and China and distributed by a variety of suppliers located in Europe and abroad. The different suppliers located within Europe contacted during our consultation indicated a very low level of activity with regard to TGIC. Different suppliers indicated that they only sold very small quantities (few kg) of TGIC mainly to research institutes. Others stressed that they have not sold any TGIC in the last few years. ECHA estimated the total use of TGIC in Europe per year to be at the lower end of the 100-1,000 tonnes margin (Annex XV SVHC Dossier, TGIC, 2012). The companies purchasing TGIC are principally powder coating manufacturers and solder mask ink manufacturers.

4.5.5 Expected non-use scenario

During the preparation of the scoping SEA, a consultation exercise with industry (European manufacturers and importers of consumer articles, including non-EU manufacturers) was undertaken to ascertain anticipated responses to a potential restriction for the use of TGIC in consumer articles. The results of this consultation are included in the following table:

Table 4.21 Consultation exercise

Type of company	Stakeholders contacted	Valuable responses received
TGIC manufacturers	1 non-EU company	1 non-EU company
TGIC suppliers	6 EU companies	4 EU companies*
Article manufacturers	4 EU companies 4 trade associations	1 EU company* 0 Trade association

**The consulted companies did not provide fully completed questionnaire but only limited information.*

Source: ICF/AMEC Consultation

Considering the limited number of responses from the industry during our consultation, the non-use scenarios and economic and social impact estimates have been primarily based on the views of a small number of stakeholders. This was complemented by an analysis of data provided on the websites of key manufacturers and industry associations and in the literature on the use of TGIC. As stressed by the industry and recognised by ECHA, there is a strong need to collect more data on the applications of TGIC in Europe and the associated occupational exposure. Therefore the industry committed to collect monitoring data and report these to support the Substance Evaluation originally scheduled by the Polish Competent Authority for 2013 (Comments on Annex XV TGIC SVHC Dossier, May 2012).

4.5.6 Assessment of economic and social impacts

4.5.6.1 Identification of main impacts

The first step in the SEA is a screening of the impacts and stakeholders potentially affected by the restriction. This ensures that the analysis is focussed on those stakeholders most affected by the proposed restriction and considers the nature and scale of the impacts, following the SEA guidelines produced by ECHA in relation to the possible costs and benefits. Categories of impact are shown in section 0, along with a qualitative assessment of impacts.

4.5.6.2 Direct economic impacts

4.5.6.2.1 TGIC manufacturers

TGIC manufacturers have been identified in Switzerland, Japan and China. A ban on TGIC would therefore not represent any direct loss for the EU economy at that stage of the supply chain. Non-EU manufacturers will likely lose part of their market if they cannot export TGIC to Europe. However considering the phasing out process identified above, the EU market for TGIC is relatively small compared to the world market. The impact of the EU phasing out

process on TGIC manufacturers has been quite substantial in the past. Confidential data were provided by stakeholders to support this claim. For TGIC manufacturers the switch to alternatives has led to higher production cost and loss of competitiveness. Non-EU manufacturers will therefore have to invest more in the search for alternatives to TGIC. A full ban on TGIC will offer the opportunity to the manufacturers of alternatives (EU and non-EU) to increase their market share.

4.5.6.2.2 TGIC suppliers

EU-based TGIC suppliers typically offer a very large spectrum of chemical substances to their customers. Therefore, as indicated by one of the suppliers who participated in our consultation, a ban on TGIC would not have any consequences for chemical suppliers. The revenues from sales of TGIC are often very small compared to their total turnover. Suppliers will identify the best alternatives available and offer these to their customers. As they are intermediaries within the supply chain they will not have to bear the cost of investing in the research for alternatives.

4.5.6.2.3 Coating powder and solder mask ink manufacturers

There exist two types of powder coating manufacturers: (1) large multinational companies producing a large variety of powder and liquid coatings, with the top 25 major powder manufacturers accounting for 80% of the world powder coatings market; and (2) many medium and small powder coating producers operating in a limited market area. The manufacturers sell the powder coating either directly to product manufacturers which are active in different product segments as illustrated in Figure 4.9 or to coating enterprises. The latter are outsourcing partners of product manufacturers who don't have the technical expertise or equipment necessary to coat their products (Brun, Golini and Gereffi, 2010).

Large EU powder coating and solder mask ink manufacturers will probably not be heavily affected by a ban on TGIC. This is because, as described above, many have already stopped using TGIC and they all have alternative products within their portfolio. If some of these multinational manufacturers still have production entities in Europe using TGIC, they will probably relocate this production in manufacturing sites located outside Europe in order to avoid the costs associated with the formulation of alternatives. However based on consultation responses this is unlikely given the small proportion of production involving TGIC. For more innovative uses and as stressed by a producer of solder mask ink, there is reluctance within the industry to switch to more expansive alternatives for competitive reasons and companies are likely to prefer to relocate specific production outside Europe rather than to face extra costs within Europe. Considering the widespread use of alternatives to TGIC within the industry this should not lead to the definite closure of production sites but only to limited reorganisation.

The situation might be different for the small and medium powder coating manufacturers and the coating enterprises identified above. Some of these smaller companies might be more dependent on the use of TGIC and have more difficulties in facing the costs associated with the use of alternatives. Indeed, next to the cost of purchasing alternative products, replacing TGIC could present other direct costs such as the purchase of different processing and handling equipment or increased amounts of raw materials in order to achieve similar functions. Indirect costs – such as reduced efficiency from replacement products – could also potentially arise. Although this was not proven during our consultation, these additional costs associated with a potential ban on TGIC might disadvantage European SMEs. The impact of a ban of TGIC on these smaller players in the supply chain should therefore be taken into account in further studies.

4.5.6.2.4 Product manufacturers

Product manufacturers are consumers of powder coating. The product manufacturers that use powder coating containing TGIC at a level of 4% to 10% would not be allowed to import these to Europe anymore in the case of a total ban. They will have two options: either switch

to an alternative powder or liquid coating or relocate part or all of their production outside Europe.

In the first scenario they will have to face the additional cost of purchasing alternative substances and adapting their production process to these new substances. They might also have to purchase more of the alternatives to compensate with potential lower efficiency of the replacement products or adjust their products in other ways in order to utilise the different properties of the alternatives.

In the second scenario product manufacturers will face considerably higher costs as they will have to relocate part or all their production outside Europe. They might choose to only relocate their coating process outside Europe and import semi-finished products to Europe to assemble the final article within Europe. As already stressed at the end of the coating process, the TGIC is fully cross-linked into a solid matrix and the ratio of TGIC compared to the finished product is very low (<0.1%), therefore finished products would not be covered by a potential ban on TGIC. Other companies might choose to relocate all their production outside Europe and export finished products. In both cases these relocation will lead to net losses for the EU economy. It should nevertheless be emphasised that only companies strongly dependent on TGIC will consider these options in this scenario. In light of the above sections, only a few applications remain dependent on TGIC (e.g. specific coating applications and solder mask ink for high performance electronics).

4.5.6.2.5 Consumers

The different changes in the supply chain of TGIC described above are likely to drive up the prices of articles strongly dependent on the use of TGIC. The prices of articles for which an alternative could substitute TGIC in the production process should stay relatively stable as alternatives are available and already largely used by the European industry. Therefore consumers are not expected to be impacted by price rises.

4.5.6.3 Wider social impacts

4.5.6.3.1 Competitiveness and innovation

A final ban on TGIC in Europe would make all EU manufacturers that use TGIC definitely switch to alternatives. Therefore companies who have already borne the costs associated with this switch would have a competitive advantage against the ones that have not yet switched to alternatives.

A ban would also result in the ending of the technology developments based on this substance in Europe. Considering that TGIC is still widely used outside Europe and that a restriction would not affect TGIC-based (but not containing-) powder coated articles imported into the EU, a ban would hinder the competitiveness of the EU industry. EU companies would have to face extra costs and working with alternatives while this would not be the case for their non-EU competitors. Moreover, EU products based on alternatives might be difficult to export due to their potential lower quality and higher prices. On the short term an EU ban on TGIC might lead to loss of market shares on the worldwide markets for EU manufacturers.

On the other hand, as EU manufacturers are likely to invest more in the search for alternatives, this might give them a competitive advantage in the longer term especially if other regions impose restriction on the use of TGIC in the future.

4.5.6.3.2 Impacts on employment

The impact on employment of a ban on TGIC is difficult to assess given the lack of available information. It might be assumed that large companies in the supply chain will not be largely affected by a ban on TGIC as they are not very dependent on this substance. However, the situation might be very different for smaller companies which might be more dependent on TGIC. Moreover, complying with a potential ban on TGIC may require a commitment of

skilled professionals which small companies may simply lack. If they cannot afford to channel resources, time and effort in to implementing alternative methods of production, they may be driven out of business in the longer term which would result in job losses.

4.5.6.4 *Administrative costs*

Administrative costs are not relevant to the imposition of a restriction and therefore are not assessed.

4.5.6.5 *Human health and environmental impacts (for consumers)*

As already stated above and according to many sources, the TGIC used in the manufacturing of powder coated articles and printed circuit boards fully cross-links with the polyester resins during the manufacturing process. It is not present as a free substance in the final products and it poses therefore no health risk for the consumers. However, despite this statement, ECHA argues that: “without measurements (leaching data) it is not possible to say that consumer exposure is negligible, although this seems likely” (Annex XV SVHC Dossier, TGIC, 2012).

Occupational exposure to TGIC is more problematic and although this is out of the scope of this study, it is worth notifying that the Polish Competent Authority is working on an evaluation of the substance taking occupational exposure into account.

4.5.7 Overall conclusions on potential costs and benefits

The review of socio-economic evidences on the production and use of TGIC revealed that a ban on the substance in Europe would only have limited direct economic impact. The phasing out of TGIC in Europe has been ongoing since the late 1990s and most of the affected players have already borne the costs associated with a switch to alternatives. Considering the availability of alternatives most of the players in the supply chain that have not made this switch yet, should be able to adapt without undergoing significant costs. However, the impact of a ban on smaller players and on companies highly dependent on TGIC should be further investigated. The potential benefits are difficult to estimate considering the lack of available data.

4.5.8 Substance-specific considerations for development of draft criteria to implement Article 68.2 to CMR 1A and 1B in consumer articles

This section firstly includes consideration of issues that are important in determining whether an Article 68.2 restriction is potentially most appropriate, compared to other forms of restriction. The following considerations arise from this case study substance:

- TGIC appears to be already phasing out of use in Europe. In cases of phase-out, an Article 68.2 restriction may not be necessary, as the industry is already taking it out of use. It may therefore be difficult to justify the need for an Article 68.2 restriction in this case. Article 69 might be sufficient in this case to ensure consumer protection. However, if use of TGIC were to re-emerge in the future before an Article 69 restriction were in full effect, Article 68.2 might be considered to maintain consumer protection and provide certainty for producers of alternatives;
- Consideration should be given as to whether any restriction, whether fast-track or not, would be effective, given that TGIC may only be found in trace or undetectable quantities within articles. Equally, the potential for non-compliance, particularly with respect to imports of articles, should be considered (i.e. the practicality and feasibility of testing imports may be difficult). Restriction using Article 69 might lead to a situation where EU manufacturers are unfairly targeted with a burdensome restriction and imports continue to contain small amounts of TGIC that are undetectable by current testing methods;

- There should be consideration of the impact a potential restriction might have on SMEs, particularly those in the wider supply chain of article manufacturers.
- Given the uses of TGIC where consumer exposure is likely negligible, it may not be possible to justify a restriction under Article 68.2. Restriction under Article 69 may be justifiable, if the Commission feels that the steps to be undertaken for Article 69 restriction are worthwhile considering that the substance is being phased out by industry.

Identification of relevant impacts by stakeholder group, impact category and supply chain

✓ - Benefit or positive outcome;
- No or insignificant anticipated impact;
× - Cost or negative outcome

Impact Category/ Stakeholder	EU CHEMICAL PRODUCERS	POWDER COATINGS & SOLDER MASK MANUFACTURERS	PRODUCT MANUFACTURERS	DOWNSTREAM USERS (CONSUMER)	SPECIFIC ISSUES FOR SMEs
Operating costs and conduct of business	N/A	Large EU manufacturers will reorganise their manufacturing process in order to avoid additional costs. ×	Depending on their specificities, product manufacturers will either have to switch to alternatives or to relocate part of their production outside Europe. ×	N/A	SMEs might face high difficulties if they are highly dependent on TGIC. ×
Competitiveness, Trade and Investment	Manufacturers (EU and non-EU) of alternatives will have the opportunity to increase their market share. ✓	Large EU manufacturers will reorganise their manufacturing process in order to avoid additional costs. ×	Product manufacturers who have already switched to alternatives will have a competitive advantage and will most probably gain market shares. The other might lose market shares compared to EU and non-EU competitors ✓/×	Prices of articles strongly dependent on TGIC are likely to go up as results of the change in the supply chain. ×	SMEs might face high difficulties if they are highly dependent on TGIC. ×
Competition and the internal market	Manufacturers (EU and non-EU) of alternatives will have a competitive advantage. ✓	Product manufacturers who have already switched to alternatives will have a competitive advantage and will most probably gain market shares. ✓/×		Prices of articles strongly dependent on TGIC are likely to go up as results of the change in the supply chain. ×	SMEs strongly dependent on TGIC might be driven out of business leading to a reduction of competition on the EU market. ×
Innovation and research	A formal EU ban will support R&D efforts to identify environmentally friendly alternatives for TGIC. advantage.	A formal EU ban will support R&D efforts to identify environmentally friendly alternatives for TGIC advantage. ✓	A formal EU ban will support R&D efforts to identify environmentally friendly alternatives for TGIC advantage. ✓	N/A	N/A

Impact Category/ Stakeholder	EU CHEMICAL PRODUCERS	POWDER COATINGS & SOLDER MASK MANUFACTURERS	PRODUCT MANUFACTURERS	DOWNSTREAM USERS (CONSUMER)	SPECIFIC ISSUES FOR SMEs
	✓				
Macroeconomic and employment	If a ban in Europe leads to a worldwide ban, EU manufacturers of alternatives are likely to have a strong competitive advantage ✓	SMEs strongly dependent on TGIC might be driven out of business leading to employment losses ×	If manufacturers relocate outside Europe this will lead to employment losses ×	N/A	N/A
Distributive/Equity	N/A	N/A	Large manufacturers maybe not be as susceptible to a ban as they may be better able to substitute other substances or make up economic losses through other product lines. -	Additional costs likely to be borne by importers who have yet to switch to alternatives. Consumer prices may rise accordingly. ×	SMEs will be more vulnerable to a ban than large manufacturers ×

Source: ICF/AMEC Consultation

4.6 Scoping SEA: 2-Methoxyaniline [o-Anisidine]

4.6.1 Introduction

This section covers the scoping level SEA for **2-Methoxyaniline (o-Anisidine; CAS No. 90-04-0)** and follows the structure defined in the introduction, concluding with the identification of considerations and elements to help ECHA and the Commission in the development of criteria for application of Article 68.2 for CMR substances in articles.

4.6.2 Regulatory status

In terms of regulatory status, o-Anisidine is an aromatic amine classified as carcinogenic category 1B with Hazard statement H350 ("May cause cancer") under the CLP Regulation. Due to its carcinogenic properties it has been identified as a SVHC and was included in the Candidate List in December 2011.

The substance is restricted by REACH Annex XVII Entry 28. Therefore it is not allowed to be used in substances and preparations placed on the market for sale to the general public in individual concentrations equal to or greater than 0.1% w/w or other relevant concentration limit. This restriction does not apply to the use of the substance in articles, hence the potential need for restriction under Article 68.2.The use of o-anisidine is also prohibited in cosmetic products, as well as being restricted in leather and textile articles through REACH Annex XVII Entry 43 (detailed in section 4.6.2.3.2).

In addition, European Resolution AP 89(1) on the use of colorants in plastic materials coming into contact with food states that the content of aromatic amines singly or in total should not exceed 500mg/kg.

4.6.3 Uses of the substance

4.6.3.1 Overview

The aromatic amine o-Anisidine is an industrial intermediate used in the production of azo-colorants (EU RAR, 2002). Outside the EU, o-anisidine may also be used for the manufacture of vanillin, an aromatic ingredient (Annex XV SVHC Dossier, 2011).

Azo colorants are a family of chemical compounds characterised by the formation of an azo bond by the diazotization of aromatic amines, followed by coupling. This group includes both azo pigments and azo dyes. The Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD) indicates that generally o-anisidine is used in the manufacture of azo colorants either as starting material in the synthesis, for example, for Pigment Yellow 194, o-anisidine is directly linked to the azo bond, or as substructure unit of an intermediate (coupling compound) used for the synthesis, e.g. acetoacet-o-anisidide. In this case an o-anisidine type substructure is linked to an amide bond in the final pigment (i.e. Pigment Yellow 74).

Azo dyes based on o-anisidine are mainly used for the dyeing of textiles, leather and paper; although some derivatives may be used for other uses including hair dyes (i.e. Basic Red 76[97]). Azo pigments are mainly used for the production of printing inks for packing materials like paper, cardboard, polymer and aluminium foil (Annex XV SVHC Dossier, 2011). Other pigment uses include the production of paints, colouring of polymers and textile printing (i.e. napkins or for prints on t-shirts) (EU RAR, 2002). In recent years, azo pigments based on o-anisidine have also been used in tattooing and permanent make-up (Annex XV SVHC Dossier, 2011).

[97] Basic Red 76 is used as a hair dye and was assessed in 2011 for this application by the EC Scientific Committee on Consumer Safety (EC SCCS, 2011).

4.6.3.2 Overall quantities manufactured and imported

O-anisidine has been registered as a transported isolated intermediate for manufacture of fine chemicals such as dyes under strictly controlled conditions by four registrants (Annex XV SVHC Dossier, 2011)[98]. Consultation has revealed that all of this reported use is imported, which would indicate that o-anisidine is no longer manufactured in the EU (production was estimated to be >1,000 tonnes in 2002).There is one joint registration with one of the registrants being an intermediate trader that does not carry out on-site processing of the imported substance, which is entirely supplied to the other registrant of the joint dossier.

ECHA Registration data suggests that between 1,000 and 10,000 tonnes of the substance is imported into the EU per annum, with manufacture of the substance being reported in China by one of the registrants. However, the only registrant that has given information on quantities has indicated that they only import a small quantity of o-anisidine (below 10 tonnes per year) for dye production in the tonnage band of 1 to 10 tonnes per year. The dyes produced are Direct Yellow 44[99] and Direct Red 89 for textiles; Direct Yellow 132 for paper colouring. This registrant has also indicated that they import an intermediate, acetoacet-2 anisidide (produced from o- anisidine out of EU)[100] for the synthesis of Pigment Yellow 74 in quantities between 100-1,000 tonnes per year. Another registrant has indicated that o-anisidine is exclusively used as raw material for the synthesis of organic pigments.

4.6.3.3 Use in articles

o-Anisidine is used as an intermediate and therefore is not intentionally used in articles. However, consumers may come into contact with the substance during the use of articles coloured with pigments or dyes based on o-anisidine. These can include paper articles, polymers (e.g. packing foils), metal articles (mainly printed aluminium foils), textiles or leather (Annex XV SVHC Dossier, 2011).

In particular, the RAR (2002) indicates that contact with the substance through printed packings and foils and dyed textiles can be identified as the most important routes of consumer exposure. According to the RAR (2002), free o-anisidine may be present in these articles as a residue/impurity or from degradation during the printing/dyeing process or during their use. In particular it highlights that the substance can be released by reductive cleavage of the azo bond, by hydrolysis and/or metabolic degradation. This reaction is especially significant in the case of dyes due to their significantly higher water solubility as compared to pigments which are much less water soluble and thus less bioavailable. In this sense, a non-negligible risk was estimated to concern dermal contact with dyed textiles and oral uptake by young children sucking on dyed textiles (EU RAR, 2002). Risks could not be excluded for other exposure scenarios, as o-anisidine is identified as non-threshold carcinogen, although the risk assessment indicated that these risks were already low (EU RAR, 2002).

No data have been identified on volumes of o-anisidine incorporated in the different manufactured or imported in articles. Responses from consultation suggested that the concentration of the substance in consumer articles is below the legal limit value for carcinogens of 0.1%. In this sense, since its nomination as a SVHC and its inclusion in the REACH Candidate List in December 2011, there have been no notifications relating to the use of the substance in articles above the 0.1% limit, despite the relevant deadline having passed. An overview of potential concentrations of o-anisidine in end products is presented below for the main types of derivatives.

[98] According to records in ECHA's database on registered chemicals (http://echa.europa.eu/search-chemicals).

[99] Note that o-Anisidine hydrochloride is used as a chemical intermediate in the production of Direct Yellow 44. o-Anisidine hydrochloride is a salt of o-anisidine (US National Toxicology Program, 2011).

[100] Acetoacet-2 anisidide (CAS: 92-15-9), is an o-anisidine based product derived for the synthesis of yellow pigments (EU RAR, 2002).

4.6.3.3.1 Azo Pigments

Azo pigments are the primary products derived from o-anisidine in the EU and are mainly used for the printing of packaging (cardboards, polymer and aluminium foil) (o-Anisidine, Annex XV Dossier for Identification as SVHC, 2011, EC, 2011b). Specifically, most o-anisidine in the EU is processed to yellow azo pigments[101] (83% of the total 908 tonnes produced in 1995 according to the RAR (2002)) with much smaller quantities being used in the production of red azo pigments[102] (4%) (Annex XV SVHC Dossier, 2011, ECHA EU RAR, 2002). The literature review suggests that Pigment Yellow 74 is the main compound derived from o-anisidine in the EU (Annex XV 2011, EC, 2011b). This pigment is manufactured under a variety of trade names and formulations for use primarily in the printing ink and paint industry. This pigment is also commonly used for tattooing (Annex XV, 2011).

Pigments are practically insoluble in the application media and maintain their crystalline structure when applied to the substrate (Danish EPA, 1998). Therefore consultation has indicated that the presence of o-anisidine stemming from the synthesis of pigments in end articles is generally negligible. As explained by ETAD, o-anisidine may be present as an impurity in the pigment in small concentrations well below the 500 ppm specified in Council of Europe Resolution AP 89(1)[103]. The application of a dilution factor when the pigment is used in the formulation of printing inks or paints which are then applied to end articles leads to very low final concentrations in the end article. The German Printing Industry estimated that, for final paper articles, the concentration of o-anisidine could be between 0.02 and 0.2 mg per kg paper, whereas for printed packing and aluminium foil the final concentration is estimated to be between 1.5 and 15 µg per m² foil. These estimates were based on an o-anisidine content of 10 to 50 ppm in printing pigments (Annex XV 2011, ECHA EU RAR, 2002).

Similarly, consultation with two of the registrants reporting production of o-anisidine-based pigments has revealed that the content of o-anisidine as an impurity in the colorant Pigment Yellow 74 is estimated to be lower than 0.1 % (in fact below 150 ppm or 0.015%), whereas in printing inks, it could be around 70 ppm. This would lead to an even lower concentration in the final consumer article. The European Printing Ink Association (EUPIA) has pointed out that, assuming a pigment concentration of the ink of 20%, this then gives 100 ppm content of o-anisidine in the ink in a worst case scenario.

4.6.3.3.2 Azo Dyes

Azo dyes[104], unlike pigments, are soluble in the application medium and could cleave at the azo bond more easily to o-anisidine in the end products. Azo dyes can be used for both the printing and dyeing of articles such as textiles, leather and paper, but the RAR (2002) indicates that about 90 % of o-anisidine based dyes are used for textiles (ECHA EU RAR, 2002).

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[101] Including (by decreasing industrial importance): Pigment Yellow 74 (CAS No. 6358-31-2), Pigment Yellow 65 (CAS No. 6528-34-3), Pigment Yellow 17 (CAS No. 4531-49-1) and Pigment Yellow 73 (CAS No. 13515-40-7) (o-Anisidine, ECHA Annex XV).

[102] Including (by decreasing industrial importance): Pigment Red 15 (CAS No. 6410-39-5), Pigment Red 119 (CAS No. 61968-80-7 or 72066-77-4), Pigment Red 188 (CAS No. 61847-48-1), Pigment Red 261 (CAS No. 16195-23-6) and Pigment Red 9 (CAS No. 6410-38-4).

[103] Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food http://www.coe.int/t/e/social_cohesion/soc-sp/public_health/food_contact/RESOLUTION%20AP%20-%2089%201%20ON%20COLOURANTS.pdf

[104] The following dyes can to be considered as o-anisidine-based products: Acid Red 4 (CAS No. 5858-39-9), Acid Red 5 (CAS No. 5858-63-9), Acid Red 107 (CAS No. 6416-33-7), Acid Red 264 (CAS No. 6505-96-0),Basic Red 76 (CAS No. 68391-30-0), Acid Violet 12 (CAS No. 6625-46-3), Direct Yellow 118, Direct Yellow 120, Direct Yellow 132 (CAS No. 61968-26-1), Direct Red 24 (CAS No. 25188-08-3), Direct Red 26 (CAS No. 3687-80-7), Direct Red 72 (CAS No. 8005-64-9), Direct Red 123 (CAS No. 6470-23-1), and Food Red 16 (CAS No. 1229-55-6) (o-Anisidine, ECHA Annex XV).

The use of azo-dyes, based on primary aromatic amines in the textile and leather industry is already restricted in the EU through REACH Annex XVII Entry 43. According to this regulation, which repealed the Azo Colorants Directive 2002/61/EC, textile and leather articles produced or imported into the EU that may come into direct and prolonged contact with the skin or oral cavity are not allowed to contain azo dyes, which by reductive cleavage may release certain aromatic amines, including o-anisidine. The threshold limit for the detection of the prohibited amines, allowed to be found in the article or in the dyed parts thereof is 30 ppm for each amine (i.e. above 30 mg/kg (0.003 % by weight)).

The Regulation does not give a list with the names of dyestuffs that are prohibited. This means that all azo dyes which do not release one of the listed amines above the regulatory thresholds in final articles are in theory allowed to be used, unless other restrictions on the substances exist elsewhere. In addition, those textiles that do not come into direct and prolonged contact with the skin or oral cavity are not covered by the regulation. Consumer exposure to textiles and leather coloured with o-anisidine based dyes may therefore still occur.

In line with this regulation, ETAD has indicated that, when present in dyes, o-anisidine will be an impurity in a concentration of below the legal limit value for carcinogens of 0.1%. The concentration on the final article will depend upon the dye content in the dyeing product (usually a formulation) and the load used in the dying process. Using the general value of a 50% concentration in the formulation and the highest load for deep shades (5%) ETAD estimates that the final concentration on the articles would be around 25 ppm in the worst case (i.e. 25 mg/kg). One of the registrants reporting production of o-anisidine based dyes has confirmed that the concentration of o-anisidine in final goods should be below 30 ppm. However, it is possible that o-anisidine may be present in concentrations above regulatory thresholds in articles coming from other parts of the world in cases where they may not be covered by any restrictions.

4.6.3.4 Trends

Cessation of the production and marketing of o-anisidine in the EU seems to indicate a downward trend in the use of o-anisidine based colorants. In addition, the fact that no notifications with regards to the Candidate List have been received suggests that the amount of o-anisidine incorporated in articles entering the EU market may not be significant. It's CMR properties and its identification as SVHC in 2011 is likely to drive a further decline in the presence of the substance in articles over the coming years. Although no recent data on quantities of o-anisidine have been identified, information on potential usage scenarios regarding the different derivatives is presented below.

4.6.3.4.1 Dyes

Consultation has revealed that o-anisidine is still processed in the EU to produce azo dyes for the colouring of textiles and paper, although it appears that only small quantities are involved and that use is declining. This was already highlighted by the Risk Assessment Report (RAR) (2002) before the substance was subject to EU restrictions in textile and leather articles. This was illustrated by the fact that in 1995 the EU processing of o-anisidine to azo dyes was 118 tonnes whereas in 1998 it was estimated at 49 tonnes (almost a 60% decrease). Although these data are quite dated, and usage is likely to have changed in the intervening years, no more recent data are available.

Given that most dyes based on o-anisidine (about 90%) are marketed for textile applications their use is likely to have decreased substantially not only at EU level but also worldwide due to the introduction of regulations limiting the use of azo dyes that can cleave to aromatic amines in textiles in several jurisdictions (SGS Consumer Testing Services, 2012). These

include major exporters of textile products into the EU such as China[105] and India[106] with regulations dating back to 2005 and 1997 respectively. Imported textiles are controlled by retailers and authorities, with the results being communicated via the RAPEX system. According to the Ministry of Foreign Affairs of the Netherlands (Centre for the Promotion of Imports from developing countries (CBI), Ministry of Foreign Affairs of the Netherlands, 2012) most of the textile products placed on the EU market comply with the restriction on azo dyes with test institutes reporting that the vast majority of samples tested today are compliant. Azo dyes based on o-anisidine can also be used for paper applications but this is expected to be a less significant use (Annex XV SVHC Dossier, 2011 and COWI, 2003).

4.6.3.4.2 Pigments

With regards to the synthesis of pigments, no information on quantities used or consumed has been obtained, although this information has been requested from industry. The only data identified are presented in the RAR (2002), which estimated that 790 and 740 tonnes were processed in the EU to pigments in 1995 and in 1996 respectively. Current usage is likely to have changed in the intervening years but more recent data are not available.

The breakdown of quantities per type of article is highly uncertain. Literature review and consultation suggests that pigments are mainly used for the coloration of printed paper, polymers and aluminium foil (Annex XV SVHC Dossier, 2011 and Austrian Federal Environment Agency, 2002), although other uses such as wall painting or textile printing (e.g. t-shirts) are also mentioned. Furthermore, it has been reported (Annex XV SVHC, Dossier, 2011) that increasing quantities of pigments have been used for tattoo inks over recent years.

Consultation has revealed that o-anisidine and its derivatives (i.e. acetoacet-2 anisidide) continue to be processed in the EU to produce pigments such as Pigment Yellow 74, which is used primarily in the printing ink and paint industries (Herbst, et al., 2004) as well as for tattooing (Annex XV SVHC Dossier, 2011). Taking this pigment as an illustrative example (given that it is one of the major uses), literature review suggests that it has considerable commercial significance and an internet search shows that it is still marketed in the websites of several EU and foreign chemical suppliers. In particular, ECHA registration data show an aggregated volume between 1,000 and 10,000 tonnes per year. Other pigments mentioned in the literature, such as Pigment Yellow 65 (CAS No. 6528-34-3) and Pigment Yellow 17 (CAS No. 4531-49-1) have also been registered in the tonnage band of 100-1,000 tonnes per year.[107] This suggests that o-anisidine based pigments may still be of relevance for EU industry. However, due to the large number of pigments that can be derived from o-anisidine and the associated number of applications (which include non-article uses) there remains a high level of uncertainty on current usage trends of pigments containing or releasing o-anisidine in articles.

As indicated previously, no notifications have been received (and published) since its inclusion in 2011. This may suggest that significant amounts of o-anisidine are not being produced or introduced in the EU market in articles. However it is noted that due the fact that o-anisidine is used as an intermediate; article producers/importers may not have the expertise, knowledge, or resources to identify whether their articles actually contain the substance (i.e. they are not aware that a certain pigment has been derived from o-anisidine).

[105] Azo dyes releasing carcinogenic amines are currently banned in China through the GB 18401-2010 “National general safety technical code for textile products“. However, consultation has revealed that the substance continues to be used and supplied in China (at least 36 suppliers).

[106] Environment Canada (2009); Screening Assessment for the Challenge: 2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt (Direct Black 38)

[107] According to records in ECHA’s database on registered chemicals (http://echa.europa.eu/search-chemicals) as of 13 November 2013.

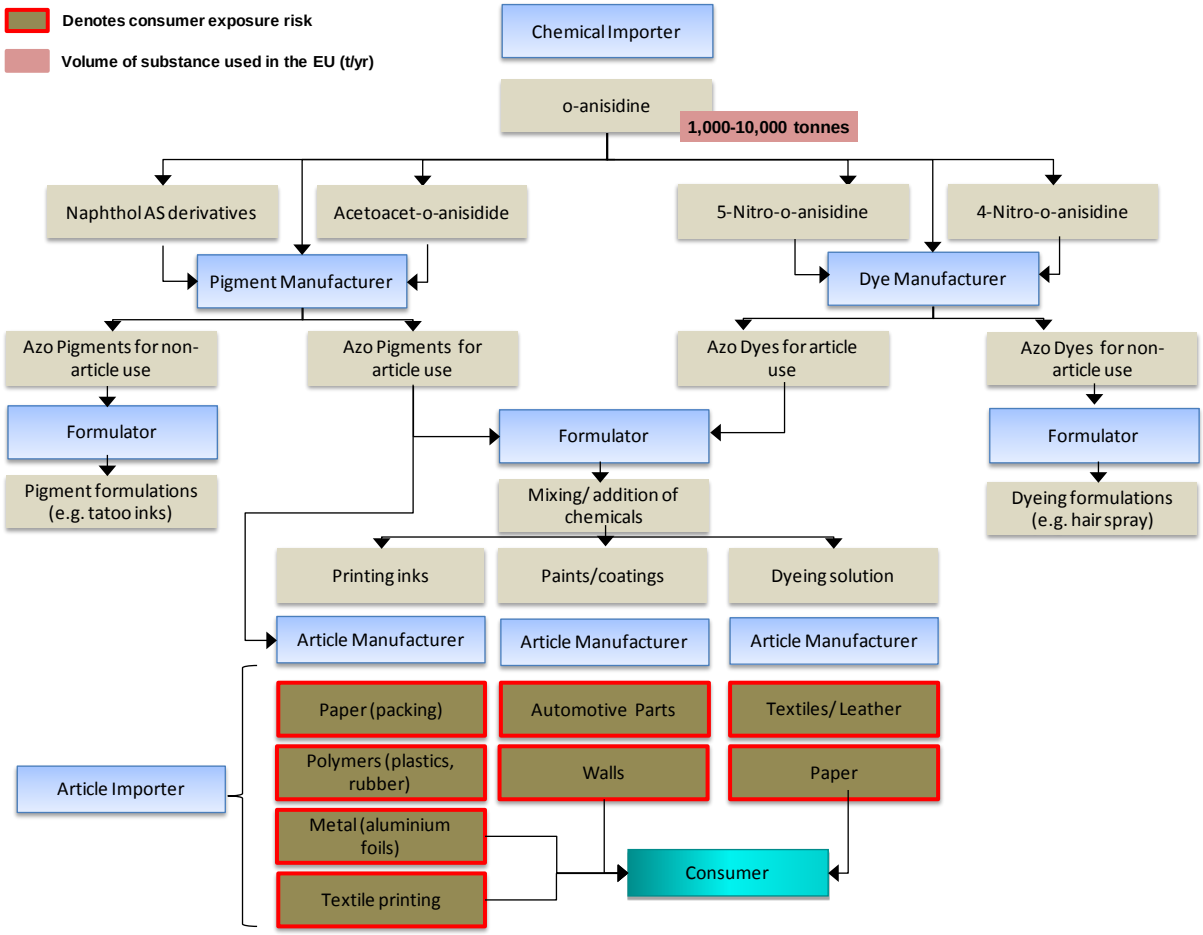
In addition, micro and small enterprises may not be aware of REACH legislation regarding notifications.

4.6.4 Supply chains affected

Figure 4.10 provides an overview of the key stages in the supply chain related to the use of o-anisidine in consumer articles. This is clearly a simplification but does serve to highlight the key players in the supply chain. Those of particular importance for the scoping SEA are the o-anisidine importers; colorant manufacturers; intermediate formulators (e.g. printing inks producers); manufacturers/producers or importers of articles coloured with o-anisidine based substances; and consumers.

The production of o-anisidine and its subsequent processing to form dyes and pigments occurs within closed systems. ECHA Registration data indicate that o-anisidine has been registered as a transported isolated intermediate under strictly controlled conditions with no subsequent service life relevant for that use in the three registration dossiers. As indicated previously o-anisidine appears not to be manufactured in the EU and is only imported for the manufacture of colorants by three registrants, although total imported quantities remain uncertain. Colorant manufacturers process o-anisidine to form dyes and pigments within closed systems, which can then be mixed with other components to form formulations (i.e. printing inks, paints) to be applied to articles. There are expected to be a larger number of o-anisidine based colorants producers (i.e. using imported primary derivatives of o-anisidine such as acetoacet-2 anisidide as starting material) and intermediate users (i.e. printing ink and paint formulators). Some companies act as intermediaries, acquiring and mixing the ingredients and selling the printing ink to final article manufacturers. However, no robust data on quantities can be identified.

Figure 4.10 Summary of supply chains of o-anisidine [1,000-10,000 tonnes]



Source: ICF/AMEC Consultation

4.6.5 Expected non-use scenario

During the preparation of the scoping SEA, a consultation exercise with industry was undertaken to ascertain anticipated responses to a restriction on the use/presence of o-anisidine in the production of consumer articles. A number of key stakeholders were selected from the 171 organisations contacted during the first round of consultation. This was done according to the answers provided and their expertise. Relevant organisations that were not previously considered were also included in phase 2 of the study in order to close identified knowledge gaps. In total 25 organizations were contacted for detailed consultation on o-anisidine, as detailed below. The number of respondents and the amount of information gathered through consultation was limited, despite making numerous requests for information.

Table 4.22 Consultation exercise

	Type of industry/article	Stakeholders contacted	Valuable responses received
Trade/industry associations	Colorants, paper, packaging, textiles, inks, paints, plastics, toys.	12 European 4 International	6 European 1 International
Private companies	Colorant manufacturers/importers.	9 all with EU representation	3 REACH registrants

Source: ICF/AMEC Consultation

The non-use scenarios have been developed primarily based on the views of o-anisidine based colorant manufacturers and relevant industry associations, supplemented by expert judgement taking into account the literature on the use of o-anisidine based compounds. The literature review has indicated that the applications with greatest potential for exposure of consumers relate to dyed textiles as well as to printed packaging and foils (EU RAR, 2002; Austrian Federal Environment Agency, 2002). Taking this into account and acknowledging existing restrictions covering dyed leather and textile articles, the analysis has been mainly focused on potential scenarios restricting its presence in such articles.

The anticipated non-use scenarios at each key stage of the supply chain are described below, covering importers of o-anisidine and manufacturers of colorants, downstream users and consumers of the final coloured articles.

4.6.5.2 *Importers of o-anisidine and manufacturers of based colorants*

In the case of a total restriction on o-anisidine in consumer articles in the EU, the importers of o-anisidine and manufacturers of derived colorants are expected to cease imports and production of colourants for this purpose. Use of alternative substances is expected to continue in synthesizing colorants for the printing, dyeing and painting of articles. Evidence reviewed has indicated that o-Anisidine based colorants have been widely replaced in the EU by alternatives in textile and leather articles and in the cosmetic sector (Annex XV SVHC Dossier, 2011;). There also seem to be suitable alternatives to the substance in printing and painting applications, although this will depend upon the specific derivative (e.g. Pigment Yellow 17) considered and the desired properties of the final product.

In order to be effective, the restriction would need to specify whether this applies only to o-anisidine or if it includes also its primary derivatives (i.e. acetoacet-2 anisidide) as these can also incorporate or release o-anisidine as an impurity[108].

A different scenario would result if the phrasing of the restriction only limits the maximum concentration of o-anisidine in the final articles or if it only applies to one of its derived forms (pigments or dyes). In this case, o-anisidine based colorants could still be manufactured providing that the regulatory thresholds are met. Producers of final goods would be the ones responsible for ensuring compliance.

4.6.5.3 *Formulators*

Similarly to the o-anisidine based colorants manufacturers, it is assumed that, in the case of a total restriction on o-anisidine, downstream formulators of colorants (e.g. printing ink producers) would substitute away from colorants releasing o-anisidine in their products. If restrictions only limited its concentration in the final article or cover only specific derivatives,

[108] As noted earlier, o-anisidine can be directly linked to the azo bond, or be used as substructure unit of an intermediate (coupling compound) used for the synthesis of colorants, e.g. acetoacet-o-anisidide. In this case an o-anisidine type substructure is linked to an amide bond in the final pigment (i.e. Pigment Yellow 74). Importers or article manufacturers may not be aware that some of these substances are derived from o-anisidine.

formulations may need to be changed (i.e. amount and nature of additives used) in order to reduce trace residues of o-anisidine in end products.

4.6.5.4 *Producers of articles coloured with o-anisidine based compounds*

In the case of a total restriction on o-anisidine in the production of consumer articles, producers of these articles are expected to avoid the use of o-anisidine based colorants and formulations (e.g. printing inks) and use alternatives. In the event of stringent concentration limits in final articles they would have to ensure and demonstrate compliance with those regulatory thresholds.

4.6.5.5 *Importers of articles coloured with o-anisidine based compounds*

In the case of a total restriction on o-anisidine in consumer articles, importers of these articles are expected to import articles made without o-anisidine based colorants..

European firms importing coloured articles might face additional costs associated with the need to demonstrate that their imported products are compliant with the restriction. Generally, this can be done by requiring their non-EU suppliers to provide evidence of non-use (e.g. certificate, declaration or documented test results); but in certain cases importers may decide to test themselves for the presence of the substance (e.g. if suppliers do not collaborate or for certain products directly sold to consumers such as textiles).

A key issue would be the wording of any restriction. If the restriction only limits use of o-anisidine in manufacture of consumer articles, and not also the concentration of o-anisidine in the articles, imports of articles containing o-anisidine could potentially increase (i.e. if non-EU companies are not affected by the restriction). In contrast, if the restriction introduces concentration thresholds it would cover both domestic and overseas manufacture.

4.6.5.6 *Consumers*

Assuming that the articles can be coloured with alternative substance(s) that can provide comparable technical performance to o-anisidine based colorants, consumers will continue to purchase these articles without any change in their satisfaction levels. They will potentially face additional costs if e.g. testing costs or the costs of alternative substances are passed on to consumers.

4.6.6 Assessment of economic and social impacts

This section provides a discussion of the likely economic impacts of the response (non-use) scenarios to a restriction. In the case of o-anisidine, due to the fact that this substance is the precursor of a wide variety of chemical compounds which can then be differently formulated it has not been possible to quantify the impacts. In this sense, it was beyond the scope of the SEA to gather information across the different o-anisidine based colorants on current usage volumes as well as on their potential to release o-anisidine in the final products (as impurity or as a degradation product). Therefore, qualitative analysis of potential impacts supplemented with quantified estimates whenever possible is presented in this section.

The impacts are based on a review of information provided through industry consultation, as well as expert judgement informed by a review of literature sources.

4.6.6.1 *Identification of main impacts*

The first step in the SEA is a screening of the impacts and stakeholders potentially affected by a possible restriction on o-anisidine based products in consumer articles. This is so that the analysis is focussed on those stakeholders most affected by the possible restriction and considers the nature and scale of the impacts, following the SEA principles in relation to the possible costs and benefits. Categories of impact are shown in Table 4.23. The following sections provide an appraisal of potential impacts for the identified stakeholders in the previous section.

4.6.6.2 Economic impacts

4.6.6.2.1 Importers of o-anisidine and manufacturers of based colorants

One of the registrants reporting production of o-anisidine based colorants in the EU has indicated that a legal ban on the use/presence of the substance and its derivatives in articles could have a significant impact. In case they had to stop the synthesis of the three dyes derived from o-anisidine (Direct Yellow 44 and Direct Red 89 for textile and Direct Yellow 132 for paper colouring) as well as the synthesis of Pigment Yellow 74 derived from acetoacet-2 anisidide for printing inks they estimate that they could lose about 3 million EUR of turnover (representing about 5% of their colorants sales) and the work opportunity of six employees.

This registrant notes that there are not aware of any alternatives to the produced substances with the same properties and similar price. In particular, Pigment Yellow 74 provides good physical properties (i.e. good stability) for printing inks with a relatively low price. As o-anisidine/acetoacet-2 anisidide forms part of their structure, a colorant with the same shade and application properties cannot be produced without it. The registrant highlights that their products fulfil current EU concentration limits (i.e. for textiles or food contact materials) but if these become more stringent, application of these colorants could be problematic and their customers would have to substitute them by compounds than can be 3-5 times more expensive.

Another registrant producing o-anisidine based pigments has highlighted that, depending on the intended field of application, several of the alternative products are also based on aromatic amines with a toxicological profile similar to that of o-anisidine (e.g. dichlorobenzidine).

Although detailed information has been only provided by one of the three EU o-anisidine registrants, it seems that a total restriction covering all forms of o-anisidine derivatives would have a noticeable negative impact on the EU industry in economic and employment terms. Requalification/reformulation of materials and processes with substitutes is likely to be a costly and time-consuming process for the companies concerned and it seems that there are no suitable safer alternatives for some applications The extent of this impact is likely to be smaller if the restriction only covers azo dyes due to the lower quantities involved as opposed to pigments and the fact that suitable alternatives for the dyeing of articles seem to be more available (Annex XV SVHC Dossier, 2011 and consultation for the current study).

4.6.6.2.2 Intermediate formulators (inks and paints manufacturers)

Generally, o-anisidine based colorants are mixed with other chemical compounds to create a formulation (ink or paint) that will be then applied to the final article. Printing inks and coatings are intended to be applied to a variety of substrates using different techniques.

In order to gather information on the likely impact of implementing a restriction on o-anisidine, relevant industry associations of ink and paint manufacturers were contacted. The responses suggest that azo colorants (especially azo dyes) or raw materials containing such azo colorants are not significantly used as intentionally-added ingredients.

In particular, the EUPIA has published an exclusion list for printing inks and related products, which includes azo dyes which can decompose in the body to bio-available carcinogenic aromatic amines of category 1A and 1B according to the CLP Regulation (EC) No. 1272/2008, including o-anisidine. Regarding the use of pigments, and according to the information of the pigment suppliers, o-anisidine may be used as the precursor of some azo pigments, but non-intentional residues would not be present at levels triggering any classification of raw materials such that they would fall under the criteria of the EuPIA Exclusion List, which would ban them from use by the members of EuPIA. In this sense, the

association has also published a statement with restrictions on the use of azo pigments[109] that may release through reductive cleavage the carcinogenic primary aromatic amines listed in Reach Annex XVII (entry 43). In line with this statement it has been identified that an ink manufacturer has published a declaration of non-use of both azo pigments and dyes based on o-anisidine (Siegwerk, undated). They however point out that the presence of traces of aromatic amines in the product coming from impurities in raw materials, namely azo pigments, cannot be excluded, although if present this will be below 0.05% w/w.

The Association of Paints, Printing Inks and Artists' Colours in Europe (CEPE) notes that there is no similar exclusion list for paints as for printing inks but it may be reasonable to assume that paint manufacturers are moving away from these o-anisidine based substances. In this sense, ETAD has indicated that there are suitable alternatives to the substance in painting applications.

If a total restriction was to be implemented, the impact of the measure will depend on the specific colorants and application concerned. In general it seems that the restriction of azo-dyes would have a lower impact as compared to pigments. Literature reviewed and consultation for the current study suggests that alternatives are currently available to replace the use of o-anisidine in synthesis of dyes used for dyeing textiles and printing/painting applications (Annex XV SVHC Dossier, 2011). The fact that there is a voluntary industry ban in the ink industry may be an indicator that the cost difference is not significant and therefore formulators still using the restricted azo dyes would experience little difficulty or expense in switching to alternatives. However, one consultee has indicated that if concentration limits become more stringent substitute compounds can be 3-5 times more expensive.

4.6.6.2.3 *Manufacturers of articles coloured with o-anisidine compounds*

Information from industry associations contacted suggests that most companies are not manufacturing goods that have been coloured with o-anisidine based colorants. This seems to be supported by the fact that no notifications related to Candidate List substances in articles have been received. However, it should be noted that is likely that some companies may not be aware of the use of o-anisidine as an intermediate in the production of the colorants they use or may not have the resources to identify or asses its presence, especially in the case of small and medium sized enterprises In view of data uncertainty, it is not possible to determine the extent of the impact that a total restriction on the use of o-anisidine based colorants would have for the EU industry. As with preceding sections this will depend upon the derivatives and types of articles concerned and on the availability of suitable alternatives.

If companies find that the articles they produce do not comply with a restriction covering o-anisidine under article 68.2, it is likely that they would face extra costs resulting from the change/adaptation of production processes to substitutes of o-anisidine based colorants, which could be also more expensive (depending on the concentration limit specified in the restriction). As indicated previously, one consultee has indicated that substitute compounds can be 3-5 times more expensive. In addition, firms may need to find alternative suppliers if their current supplies of colorants are found to contain o-anisidine and would also be required to demonstrate compliance with the restriction

4.6.6.2.4 *Importers of articles coloured with o-anisidine based compounds*

As indicated previously the current volume of o-anisidine incorporated into imported articles is unknown, although the fact that no notifications have been received with regards to the Candidate List suggests that this amount may not be significant. As it has been highlighted in previous sections, the situation is expected to be different for dyes and pigments.

[109] Statements: EuPIA Customer Information "Azo Pigments in Printing Inks", March 2001 (updated in 2005 and 2009).

With regards to dyes, existing restrictions across several jurisdictions on the use of azo dyes that can release harmful aromatic amines suggest that there are suitable alternatives worldwide to o-anisidine derived colorants, at least in textile and leather articles. These being the main reported uses of this substance, it is likely that it has also been substituted with regards to other applications such as dyed paper. Although there remains a possibility that o-anisidine based dyes may still be present in imported goods, it is reasonable to assume that the volume of the substance entering the EU is low and therefore it is considered likely that the implications of a restriction would be limited for importers.. In contrast, it is expected that further regulation on the use of pigments derived from o-anisidine could have a more significant effect. Similarly to the processing pattern of o-anisidine in the EU, articles coloured with o-anisidine-based pigments are expected to be more widely used (and thus exported) in third countries than those dyed with o-anisidine based colorants.

In general, companies may need to find alternative suppliers if their current imports of coloured goods are found to contain o-anisidine. In addition, compliance costs to demonstrate that imported products are free from o-anisidine could also increase, especially if it is necessary to carry out tests. However, depending on the colorant concerned it may be possible to pass these extra costs on to consumers.

With regards to testing, a consultation document on the implementation of the European Azo colorants directive 2002/61/EC (currently REACH Annex XVII Entry 43) developed by the UK Department for Trade and Industry (DTI) and Department for Environment, Food and Rural Affairs (DEFRA) (2003) indicates that if EU importers cannot secure reliable evidence from their overseas suppliers that their products do not contain azo dyes affected by the prohibition (such as those based on o-anisidine) then they will need to conduct tests themselves in line with methods developed by the Commission. According to this study the costs of these tests were estimated to be in the order of £105 and £126 per test and involved the destruction of the sample of material tested (at current 2013 prices this would be around €180 and 220€[110]).

4.6.6.2.5 Consumers

Consumers may face additional costs if companies raise the prices of the final articles in order to compensate for more expensive alternative colorants, changes in processes/ formulations or increased compliance costs (i.e. running tests). However, with regards to its main applications on textiles and leather, a consultation carried out by the UK DTI and DEFRA in 2003 concluded that any price increase resulting from the substitution of azo dyes that could release harmful aromatic amines would be negligible in relation to the total cost of the finished product (UK DTI and DEFRA, 2003). This statement could be valid also for pigments and other applications.

4.6.6.3 Social impacts

It is unclear to what extent the current level of employment by European manufacturers of o-anisidine based colorants and articles containing these would be affected by additional restrictions on the use/presence of o-anisidine in consumer articles. As indicated previously, one company that process o-anisidine for the synthesis of dyes and pigments could lose up to 6 jobs in the event of stricter regulations. The total impact on employment could be greater, as this company only represents a fraction of the market.

However, it is worth noting that SMEs may be more significantly affected as they would require skilled professionals and resources to ensure compliance with the restriction. These companies are likely to face more difficulties in bearing the costs resulting from a change in suppliers and from ensuring compliance, although they may be able to pass them on to consumers (UK DTI and DEFRA, 2003). If they cannot afford channelling resources, time

[110] These have been calculated using an exchange rate (2003) of 0.701 and harmonised indices of consumer prices (HICP) statistics for 2003 and 2013.

and effort to implementing alternative methods of production, they may be driven out of business in the longer term, which would result in job losses.

It is of note that Entry 28 of REACH Annex XVII, which prohibits its direct use in consumer products (preventing supply of the substance itself and mixtures), does not apply to the use of the substance in imported articles. A restriction could therefore serve to improve the competitive position of EU firms as compared to non-EU firms, as they would both then only supply o-anisidine-free articles onto the EU market, which could have associated benefits in terms of jobs.

4.6.6.4 Administrative costs

Due to the complexity of the supply chain, the huge variety of articles involved and the number of importers, distributors, etc., it is very difficult to estimate administrative costs. The main administrative costs would be associated with demonstrating compliance e.g. monitoring reports to authorities if requested. Procedures and test methods currently listed by the Commission to show compliance with existing requirements covering azo dyes in leather and textiles may need to be modified or extended to cover other applications and pigments (Centre for the Promotion of Imports from developing countries (CBI), Ministry of Foreign Affairs of the Netherlands, 2012).

4.6.6.5 Human health and environmental impacts

Restriction of o-anisidine in consumer articles is likely to result in human health and environmental benefits through reduced exposure levels. The EU risk assessment (2002) assessed the environmental and consumer risks resulting from the use of o-anisidine.

4.6.6.5.1 Environmental impacts

According to the ESR Risk Assessment, o-anisidine may be released into the environment mainly during its production and processing. The aquatic compartment is expected to be the main target. The report concluded that there was no need for risk reduction measures beyond those which were being applied already at that time.

In view of the current cessation of production in the EU, similar conclusions are assumed to apply in the current case. The baseline environmental impacts are therefore likely to be minimal and so the potential reduction in risks (i.e. environmental benefits) through a restriction is likely to be also minimal.

4.6.6.5.2 Human health impacts

In terms of human health hazards, relevant conclusions of the Risk Assessment are:

- o-Anisidine is identified as a genotoxic carcinogen for which a threshold cannot be reliably identified.
- Exposure is possible at the workplace during production and processing, and during formulation and use of o-anisidine based pigments. The main possible exposure routes are inhalational and dermal.
- The general population may come into contact with the substance during the use of consumer products coloured with pigments or dyes based on o-anisidine. From the use pattern of the substance, contact with printed packaging and foils and with dyed textiles can be identified as most important. The main exposure routes appear to be dermal (skin contact with printed packaging and foils and dyed textiles) and oral (young children sucking at dyed textiles). These materials may contain free o-anisidine as residues or resulting from the cleavage of the azo bonds. This reaction will be much more significant in dyes due to their higher water solubility as compared to pigments.
- A non-negligible risk was derived from exposure estimations concerning the dermal and oral contact with dyed textiles and so a risk limitation was recommended.

- Notes that risks cannot be excluded for all other exposure scenarios (especially for dermal contact with packaging materials printed with o-anisidine based pigments), since the substance is identified as a non-threshold carcinogen. However it indicates that risks are already low.

Based on this information, it is reasonable to assume that there would be reduced cancer incidence for consumers if the use/presence of o-anisidine in articles was further restricted. Even though concentrations of the substance in final articles seem to be low (especially regarding the use of pigments as indicated in section 4.6.2.3), it is a non-threshold genotoxic carcinogen so there is no safe level. Concentrations should therefore be as minimal as reasonably achievable. However, it has not been feasible to quantify the (avoided) health effects due mainly to lack of data on the quantities of o-anisidine based colorants on the market.

4.6.7 Overall conclusions on potential costs and benefits

As is clear from previous sections, there is a high level of uncertainty regarding the quantities of o-anisidine used by the industry and present in manufactured or imported articles. The fact that o-anisidine is an intermediate involved in the production of a wide variety of colorants that can be used in a range of applications has hindered the evaluation of potential costs and benefits across the EU. In this sense, whereas only three EU companies appear to process o-anisidine to colorants, it is expected that a larger number of companies use some of its primary derivatives for secondary processing (mainly pigments), for the production of formulations and in the manufacture of articles. In line with the views expressed by one consultee, it is likely that the prohibition of o-anisidine would cause a significant economic impact and extra costs to these EU companies, unless they could pass these additional costs on to consumers.

A restriction would however reduce the negative health and environmental impact due to reduced exposure to these products and would also result in a more level playing field between EU and non-EU companies, who would both only sell articles free of the substance on the EU market

4.6.8 Substance specific considerations for development of draft criteria to implement article 68.2 to CMR 1A and 1B substances in consumer articles

This section firstly includes consideration of issues that are important in determining whether Article 68.2 restriction is potentially most appropriate, compared to other forms of restriction. Following this, the identified socio-economic issues that it would be important to take into account in assessing the merits of a restriction are discussed.

With regard to the potential choice of Article 68.2 as a RMO (compared to other forms of restriction), the following considerations arise from this case study:

- o-Anisidine is an intermediate used for the production of a wide variety of azo colorants with diverse applications. Some of these colorants are intended to be used in consumer articles (i.e. textiles) whereas others will be used for other purposes such as tattooing. There are complex supply chains involved, many primary/secondary derivatives and hundreds of uses which hinder the gathering of information on consumer exposure scenarios. *Criteria may therefore need to take into account whether the nature of the substance (in this case an intermediate) and the complexity of supply chains lead to a lack of knowledge related to the level of use, exposure and risks to the consumers with a substance.*
- Azocolorants that can be derived from o-Anisidine can be classified as dyes or pigments. The fact that dyes have the potential to cleave more easily to o-anisidine in the final article due to their high water solubility as compared to the pigments, which are practically insoluble in application media, has led to the adoption of a restriction under REACH Annex XVII, specifically limiting the use of azodyes that could cleave to o-

anisidine in textile and leather articles that may come into prolonged contact with human skin. Exposure resulting from o-anisidine in other imported articles is still possible but, at present, data showing evidence of o-anisidine content in consumer articles and on associated exposure levels are limited. Specifically, the information about azo pigments releasing o-anisidine in consumer articles may not be sufficient to warrant a restriction under article 68.2. *Criteria could therefore consider the existence of different chemical forms that could lead to differences in exposure/risks. In addition, criteria could also take into account whether a restriction needs to be justified in risk terms.*

Having determined whether an Article 68.2 restriction might be potentially suitable (in this case it would probably not), there are a number of socio-economic issues arising from this case study that are relevant to deciding whether this simplified route is likely to be suitable:

- The fact that o-anisidine is an intermediate makes it difficult to trace o-anisidine across the supply chain as article manufacturers or importers may have difficulties in identifying if a specific colorant used in an article has been derived from o-anisidine. In the context of a potential restriction on the presence of o-anisidine in all types of articles it is problematic to gather knowledge on exposure scenarios derived from the different articles and to target consultation to identify relevant stakeholders' views on likely implications of a restriction. *Criteria may therefore need to take into account whether the nature of the substance (in this case an intermediate) and the complexity of supply chains could be a barrier to understanding the socio-economic impacts of a 'fast track' restriction under Article 68.2.*
- Most o-anisidine based colorants processed and used by the EU industry or present in imported articles are pigments, with much smaller quantities of dyes being processed or used. Evidence reviewed suggests that o-anisidine based colorants, mainly pigments, are still marketed by a considerable number of EU chemical suppliers although no information on quantities or use trends of such substances has been identified due to the wide variety of derivatives involved. The views expressed in the consultation by one REACH registrant suggest that a total ban on o-anisidine in articles could have a significant impact on their industry. *Criteria could therefore take into account the existing uncertainties on current usage of the substance by the EU industry.*
- o-Anisidine based colorants have been widely replaced in the EU by alternatives in textile and leather articles and in the cosmetic sector due to existing restrictions. There also seem to be suitable alternatives to the substance in other applications, although this will depend upon the specific derivative (e.g. Pigment Yellow 17) considered and the desired properties of the final product. In this sense, one of the responses received during the consultation has highlighted the non-availability of feasible alternatives for some of these o-anisidine-derived pigments. *Criteria should therefore take into account the evidence on availability of suitable alternatives.*

Table 4.23 Identification of relevant impacts by stakeholder group, impact category and supply chain

✓ - Benefit or positive outcome;
- No or insignificant anticipated impact;
× - Cost or negative outcome;

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL/ COLORANT PRODUCERS OR IMPORTERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
Dyes	Operating costs and conduct of business	Production of o-anisidine has ceased in Europe and only small quantities of the substance appear to be processed to produce dyes by a number of companies. Colorant manufacturers would have to search for safer alternatives. Requalification/changing of production processes can be a costly and time-consuming process. ×	Potential impact on costs as EU article manufacturers would need to ensure and demonstrate compliance. Requalification/reformulation of raw materials can be a costly and time-consuming process. Nevertheless, due to existing restrictions covering o-anisidine based dyes in its main application (textiles) it is not expected that the impact on EU industry would be significant (i.e. companies are already used to ensuring compliance with existing restrictions). ×	Potential impact on costs. A ban would exert pressure to check whether products they supply comply, either through obtaining information from suppliers (certification/declaration or test results) or by undertaking their own testing. They would also need to bear (and pass on to consumers) any potential increase in costs of articles using alternatives. However, due to the fact that o-anisidine based dyes are already subject to strict controls in textiles and leather (main application) it is not expected that a total ban will result in significant additional costs (i.e. companies are already used to testing methods in its main applications of textiles and leather) ×	SMEs may face additional difficulties in channelling resources, time and effort to requalification/ changing of production processes. Also, SMEs may find it more hard to exert pressure on suppliers to demonstrate compliance and/or to bear the costs of doing so themselves, although they may be able to pass them on to consumers.	Compliance and substitution costs may be passed on to consumers but It is expected that price increase resulting from the replacement of o-anisidine based dyes would be negligible in relation to the total cost of the finished product. -
	Competitiveness, Trade and Investment	No significant impacts expected. EU and non-EU companies would be affected equally. -	There could be a negative impact on competitiveness for EU companies exporting to global markets and using dyes derived from o-anisidine if they can no longer supply articles to global markets while non-	Importers of articles potentially containing o-anisidine based dyes risk losing competitive edge due to potential increased prices of final products and extra costs (testing, change of suppliers). However, the volume of the substance entering the EU is considered to be low due to existing restrictions in third	No specific issues for SMEs identified. -	Not applicable.

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL/ COLORANT PRODUCERS OR IMPORTERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
			EU companies can. The scale of this impact would depend on whether EU companies' production remains viable with only an export market. ×	countries and its total prohibition is unlikely to cause significant impact (i.e. companies are already used to tests). In addition article price increases as a result of dye substitution are not expected to be significant. ×		
	Competition and the internal market	Manufacturers of o-anisidine based dyes would need to channel resources, time and effort to produce and market alternative dyes for use in articles. EU manufacturers processing alternative products have a competitive advantage in the EU market. Given existing restrictions in its main applications (textile and leather) it is likely that most manufacturers have moved away from these dyes and therefore the impact on internal competition is not expected to be significant. ×	Manufacturers of articles using o-anisidine based dyes would need to channel resources, time and effort to apply alternative dyes. EU manufacturers that have already switched to alternative products have a competitive advantage in the EU market. Given existing restriction in its main applications (textile and leather) it is likely that most manufacturers have moved away from these dyes and therefore the impact on internal competition is not expected to be significant. -	EU importers of articles would face a competitive disadvantage if their current imports of dyed goods are found to contain o-anisidine based dyes. Additional costs would be related to increased prices related to substitution and potential tests and changes in suppliers. Even so, the volume of the substance entering the EU is considered to be low due to existing restrictions in third countries and its total prohibition is unlikely to cause significant impact on internal competition ×	No specific issues for SMEs identified. -	No significant impacts for consumers identified.
	Innovation and research	Colorant manufacturers may explore and research alternative substances for the production of dyes with lower environmental and health risks. ✓	Increased research and development into lower environmental and health-risk materials and processes. Impact of redirection of research activities	Although alternatives seem to be readily available, importers may engage with suppliers to promote substitution with safer alternatives. Impact of redirection of research activities towards regulatory compliance (as opposed to genuine	No specific issues for SMEs identified.	No impacts anticipated. As the use of o-anisidine based dyes in its main applications (textiles and leather) is already restricted

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL/ COLORANT PRODUCERS OR IMPORTERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
			towards regulatory compliance (as opposed to genuine search for market driven innovations) is not expected to be significant due to existing restrictions (i.e. already subject to regulatory controls). ✓	search for market driven innovations) is not expected to be significant due to existing restrictions (i.e. already subject to regulatory controls). ✓		the benefit of innovation compared to the baseline is expected to be noticeable or marginal
	Distributive/Equity	Larger impacts on EU dye manufacturers directing most of their production for article applications. Companies with production oriented towards non-article uses or with the potential to do so will be less affected by a restriction on consumer articles. ×	EU article manufacturers using o-anisidine based colorants are expected to be the most impacted stakeholder. A restriction for articles is likely to involve significant extra costs such as research activities, change in production processes or administrative costs. ×	A restriction would also affect EU article importers. They will also need to face additional costs (demonstrating compliance, passing on price of alternatives, supplier change) but these are expected to be passed on to consumers. ×	SMEs are likely to face more difficulties to afford the costs resulting from a change in suppliers and from ensuring compliance, although they may be able to pass them on to consumers. ×	No impacts are anticipated
Pigments	Operating costs and conduct of business	Production of o-anisidine has ceased in Europe but quantities of the substance appear to be processed to produce pigments by a number of companies. Requalification/reformulation of materials can be a costly and time-consuming process for the companies concerned and may result in job losses if suitable alternatives for specific	Potential impact on costs as EU article manufacturers would need to ensure and demonstrate compliance. Requalification/reformulation of raw materials can be a costly and time-consuming process. ×	Potential impact on costs. A ban would exert pressure to check whether products they supply comply, either through obtaining information from suppliers (certification/declaration or test results) or by undertaking their own testing. They would also need to bear (and pass on to consumers) any increase in costs of articles using alternatives. ×	SMEs may face additional difficulties in channelling resources, time and effort to requalification/ changing of production processes. Also, SMEs may find it more hard to exert pressure on suppliers to demonstrate compliance and/or to bear the costs of doing so themselves, although they may be able to pass them on to consumers.	Compliance and substitution costs may be passed on to consumers but It is expected that price increase resulting from the replacement of o-anisidine based dyes would be negligible in relation to the total cost of the finished product.

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL/ COLORANT PRODUCERS OR IMPORTERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
		applications are not identified. ×			×	
	Competitiveness, Trade and Investment	No significant impacts expected. EU and non-EU companies would be affected equally. -	There could be a negative impact on competitiveness for EU companies exporting to global markets and using pigments derived from o-anisidine if they can no longer supply articles to global markets while non-EU companies can. The scale of this impact would depend on whether EU companies' production remains viable with only an export market. ×	Importers of articles potentially containing o-anisidine based pigments risk losing competitive edge due to potential increased prices of final products and extra costs (testing, change of suppliers). ×	No specific issues for SMEs identified. -	Not applicable.
	Competition and the internal market	Manufacturers of o-anisidine based pigments would need to channel resources, time and effort to produce and market alternative dyes for article purposes. EU manufacturers that have already switched to alternative products have a competitive advantage in the EU market. ×	Manufacturers of articles using o-anisidine based pigments would need to channel resources, time and effort to apply alternative pigments. EU manufacturers that have already switched to alternative products have a competitive advantage in the EU market. ×	EU importers of articles would face a competitive disadvantage if their current imports of dyed goods are found to contain o-anisidine based pigments. Additional costs would be related to increased prices associated with substitution and potential tests and changes in suppliers. ×	No specific issues for SMEs identified. -	No significant impacts for consumers identified.

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL/ COLORANT PRODUCERS OR IMPORTERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
	Innovation and research	Colorant manufacturers may explore and research alternative substances for the production of pigments with lower environmental and health risks. ✓	Increased research and development into lower environmental and health-risk materials and processes. Potential impact of redirection of research activities towards regulatory compliance (as opposed to genuine search for market driven innovations) regulatory controls). ✓ and ✗	Importers may engage with suppliers to promote substitution of o-anisidine based pigments with safer alternatives.. There might be a potential impact of redirection of research activities towards regulatory compliance (as opposed to genuine search for market driven innovations) ✓ and ✗	No specific issues for SMEs identified. -	No impacts anticipated.
	Distributive/Equity	Larger impacts on EU pigment manufacturers directing most of their production for article applications. Companies with production oriented towards non-article uses or with the potential to do so would be less affected by the restriction. ✗	EU article manufacturers using o-anisidine based colorants are expected to be the most impacted stakeholder. A restriction for articles is likely to involve significant extra costs such as research activities, change in production processes or administrative costs. . ✗	A restriction would also affect EU article importers They will also need to face additional costs (demonstrating compliance, passing on price of alternatives, supplier change). ✗	SMEs are likely to face more difficulties to afford the costs resulting from a change in suppliers and from ensuring compliance, although they may be able to pass them on to consumers. ✗	No impacts are anticipated

Source: ICF/AMEC Consultation

4.7 Scoping SEA: Boric Acid [BA] and Disodium tetraborate decahydrate [Borax Decahydrate]

4.7.1 Introduction

This section covers the scoping SEA for the following two substances:

- **Boric acid (BA; CAS No. 10043-35-3)**; and
- **Disodium tetraborate decahydrate (borax decahydrate, also referred to as 'borax'; CAS No. 1330-43-4).**

Boric acid and borax are both compounds of the same element, boron; both have similar properties (classified R1B) and applications in articles, confirmed in consultation undertaken for this study. For these reasons boric acid and borax are analysed together in this SEA.

This section follows the structure defined in the introduction, concluding with the identification of considerations and elements to help ECHA and the Commission in the development of criteria for application of Article 68.2 for CMR substances in articles.

4.7.2 Regulatory status

Boric Acid and Borax are classified as substances toxic to reproduction in category CMR 1B. As of June 2010, boric acid has been included in the Candidate List of SVHCs for authorisation. A proposal to downgrade the classification for boric acid to category 2 was advanced by Poland in April 2013.

Both Boric Acid and Borax were registered by several registrants/suppliers by the REACH deadline of 30 November 2010 as a full substance in the tonnage band of 100,000 - 1,000,000 tonnes per annum.[111]

The uses of boric acid and borax are also regulated under the following pieces of sectorial legislation:

- The Cosmetics Directive (76/768/EEC) prohibits the use of boric acid, borates and tetraborates in products for children under 3 years of age and imposes specific limits of concentration for boric acid in talc (5 per cent), oral products (0.1 per cent) and other products (3 per cent);
- Under Regulation (EU) No 10/2011 on food contact materials, borates are authorised as monomers and additives for plastic materials and articles in contact with foods with a combined SML with other substances containing boron of 6mg/kg;
- The Biocidal Products Directive (98/8/EC) and the Biocidal Products Regulation (528/2012/EU) authorise the use of boric acid and borax as active ingredients in the formulation of biocidal products for wood preservation. The articles incorporating the biocidal products must indicate the presence of the substance on their label.
- The use of boric acid and borax in pharmaceuticals is regulated by the Medicinal Products Directive (Directive 2001/83/EC).

4.7.3 Production and uses of boric acid and borax in articles

The EU market for the boric acid and borax relies almost exclusively on imports: in 2012, about 91 thousand tonnes of boric acid and 203 thousand tonnes of borax have been imported to the EU[112]. Two major producers/importers, operating respectively in the US and

[111] According to records in ECHA's database on registered chemicals (http://echa.europa.eu/search-chemicals) as of 13 November 2013.

[112] ICF/AMEC consultation.

in Turkey (RPA, 2008), cover approximately 90 per cent of the EU imports of boric acid and borax. The remaining 10 per cent is supplied by smaller exporters and producers mainly operating in Russia, Chile, Peru and Argentina.

Most of the uses of boric acid and borax consist in intermediate uses[113] where the two substances are entirely consumed in the production process and transformed into a new substance. In 2012, 45,445 tonnes of boric acid (or 50 per cent of the total quantities of boric acid imported in the EU) and 175,215 tonnes of borax (86 per cent of the total) were used in for intermediate uses by the EU industry. As regards non-intermediate uses, boric acid and borax are mainly used in mixtures with other substances. The supply chains for these types of uses are generally characterised by the presence of a chemical formulator responsible for the production and supply of boric acid and borax mixtures, such as fertilisers or biocides. One example of use in mixtures is that of fertilisers: in 2012, respectively 25 per cent and 9 per cent of the total EU quantities of boric acid and borax were used for the production of fertilisers (see Figure 4.11 and Figure 4.12)

Boric acid and borax are two largely used and versatile boron compounds. They are used for a wide range of purposes, including: as preservatives and flame retardants for insulation and wood materials; as nutrients for the production of fertilisers, and as additives to materials increasing the strength of glass and ceramic products.

According to ECHA, boric acid and other borates have more than 140 different end-use applications, including use in 'articles and products such as adhesives, brake fluids, cosmetics, hygienic powders, fabrics, matches, ink, motor oil, waxes, starch, paper, plaster, fire retardants, wood preservatives, and photographic solutions' (ECHA, 2007). The EU association of producers of boric acid and borax estimate that there are thousands of applications of borates (IMA Europe, 2011).

Based on the information gathered from producers of boric acid and borax, the main uses in Europe can be grouped in to the following six categories:

- 'Intermediate' uses, where boric acid and borax are entirely consumed in the production process. This includes uses in the metallurgy sector and in the production of glass and ceramics.
- Uses in articles falling under 'ad-hoc' legislation which covers the use of borates:
- Biocides: boric acid and borax are authorised as active ingredients in the formulation of biocidal products for wood preservation under the Biocidal Products Directive (98/8/EC).
- Cosmetics: the Cosmetics Directive (76/768/EEC) allows the use of boric acid and borax in specific cosmetic applications under certain restrictions; and
- Pharmaceuticals, which are regulated under the Medicinal Products Directive (Directive 2001/83/EC).
- Uses where boron is essential, namely the use as micronutrient for the production of fertilisers. This use has been defined by consultees as essential due to the fact that boron represents an essential element for plant nutrition: there are no alternatives to borates for the treatment of boron-deficient crops;
- Uses in mixtures below the concentration limits specified by the REACH Regulation, including uses in adhesives, detergents, industrial fluids and in the nuclear sector, where crucial properties and uses include neutron absorbing capabilities and equipment rinsing;
- Uses of the substances in articles: these uses include the production of cellulose insulation materials, of plaster board for the construction industry and of refractories.

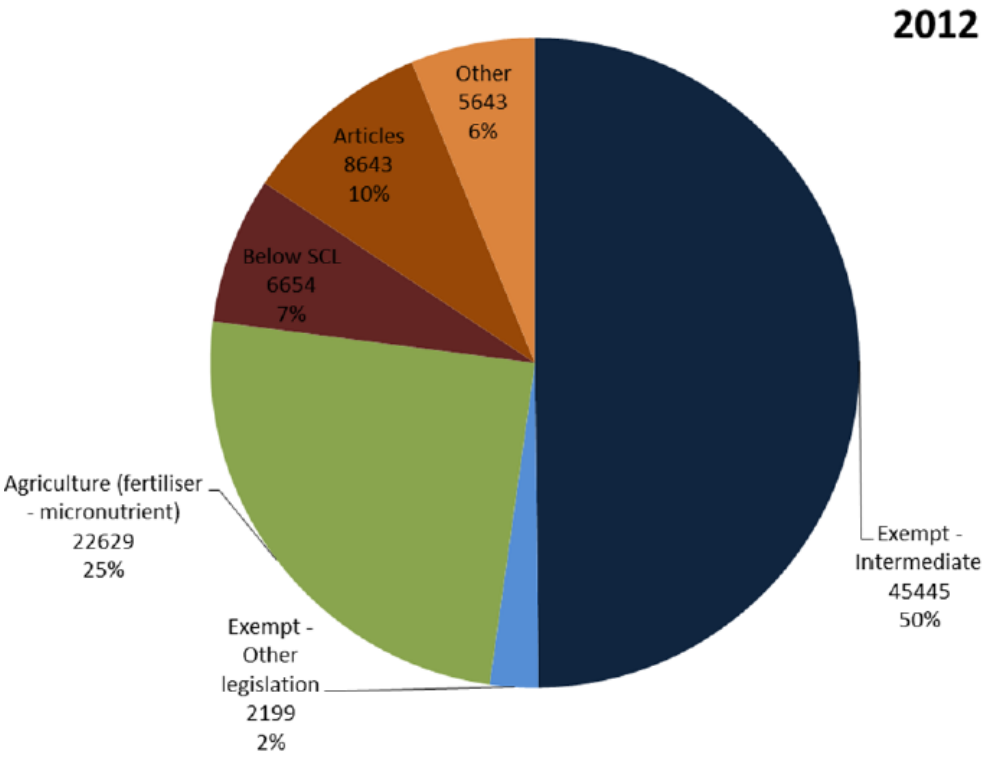
[113] According to the REACH Regulation, an 'intermediate' is defined as 'a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance'.

However, these articles are mainly handled and installed by professional users, with minimal risk of consumer exposure; and

- Other uses: these uses may include products produced with boric acid and borax that are eventually incorporated into/onto an article. However, according to an EU industry association consulted for this study, there is very limited or no data on these uses. Examples of 'other uses' include the use of boric acid and/or borax: as ingredients in mixtures used as flame retardants for articles; as ingredients in paints used to coat articles; as ingredients in brazing flux pastes that are incorporated in welding rods for metal welding; in the bond of abrasive wheels used for grinding metal and cutting stone; and as pure substances used to clean metal impurities (for example, in the jewellery sector when recycling metals). In terms of quantities used, the main 'other use' of boric acid and borax is represented by applications in the metals industry as non-intermediate substances. Examples of these applications include the uses for the manufacture of precious metals and the production of aluminium packaging, which will be discussed in Section 4.7.3.6.

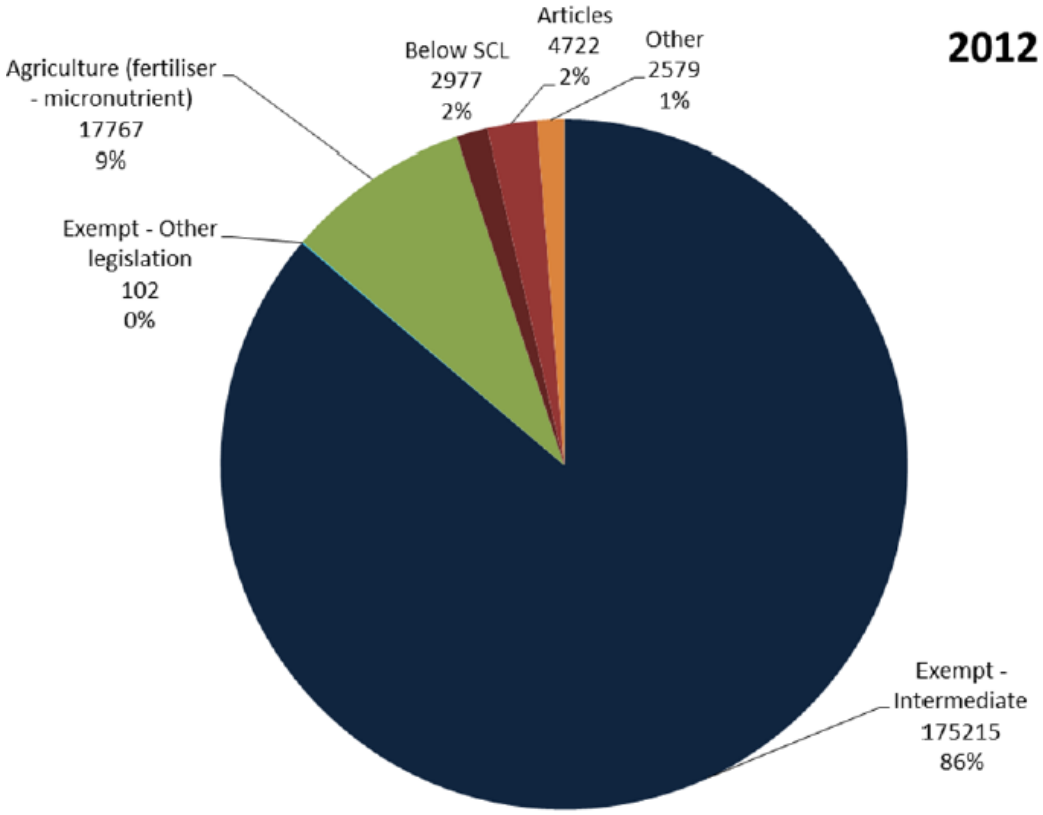
Figure 4.11 and Figure 4.12 summarise the main EU27 markets respectively for boric acid and borax.

Figure 4.11 Uses of boric acid in EU27 countries (tonnage and percentages of the total market)



Source: ICF/AMEC Consultation

Figure 4.12 Uses of borax in EU27 countries (tonnage and percentages of the total market)



Source: ICF/AMEC Consultation

For each of the six general categories of uses of boric acid and borax listed above, this scoping SEA will analyse in more detail at least one example of a specific supply chain for the two substances, based on information made available through industry consultation on the availability of alternatives and impacts of any potential restriction. The following supply chains and end user applications where consumer exposure to boron compounds may potentially occur; are as follows:

- Ceramics and glass;
- Biocides for wood preservation;
- Fertilisers;
- Precious metals;
- Aluminium packaging materials;
- Cellulose insulation materials;
- Flame retardants for textiles;
- Pharmaceuticals; and
- Corrugated paperboard.

4.7.3.2 *Ceramics and glass*

The largest proportion of the boric acid and borax imported in the EU is consumed by ceramics, glass and glass fibres producers. Borates are essential to increase the strength and chemical resistance of glass. The use of boron in glass and ceramics production represents an intermediate use, and any risk of consumer exposure to boric acid and borax

is extremely unlikely (RPA, 2008). Human exposure may result from the production and application of fibre glass insulation (Jensen, 2008). However, glass fibre insulation material is generally installed by professional users, and not by consumers.

Boric acid and borax are entirely consumed during the production process according to stakeholders, and the substances are not detectable in the final product. More specifically, the element boron is combined with other raw materials and transformed in to a new material: borosilicate glass. In this process, the element boron 'disintegrates' and gets bound into the chemical structure of the glass in which the boron is inseparable. A similar process is adopted for the production of ceramics.

Consumer articles resulting from this process include glass containers, lamps, liquid-crystal displays (LCDs), glass for windows, optical glasses for microscopes and glass for coffee machines.

Boric acid is also essential for the production of glass wool, which is one of the most commonly used insulation material in the EU. As explained by an industry representative consulted for this study, the percentage of borates used for the production of glass wool has decreased from 8 per cent to approximately 3.5 per cent in recent years. The consultee confirmed that similar reductions in the use of boron compounds have been achieved in the rest of the EU glass industry, including most of the uses of boric acid and borax in the production of glass and ceramics.

4.7.3.3 *Biocides for wood preservation*

The use of the two substances as biocides is covered by the Biocidal Products Directive (98/8/EC). There may be a potential for consumer exposure from wood articles, although exposure is likely to be minimal (RPA, 2008).

Boric acid and borax are used in mixtures as wood preservatives. One consultee reported that boric acid (purity 99.9 per cent w/w) is mixed in water with other components. In the final product the concentration of boric acid in wood preservative is less than 0.5 per cent w/w.

Examples of consumer articles produced with wood treated with boric acid and borax mixtures include wood panels and wood furniture.

4.7.3.4 *Fertilisers*

Boric acid and borax are used in mixtures as raw material in the manufacturing and formulation of fertilizers which are used in most cases by professional users, i.e. farmers. The two substances contain boron, which is a micronutrient considered essential to plant growth (RPA, 2008). Presence in these mixtures is however outside the scope of the study which concerns only substances in consumer articles.

4.7.3.5 *Precious metals*

Consultees for this study explained that boric acid represents a key substance for the melting process of precious metals such as gold and silver in the manufacture of finished products.

Boric acid creates a protective film within new crucibles used to melt metals. The film prevents the release of impurities into the precious metal, preventing contamination. Once the new crucible has been used, the protective film remains, so that boric acid is used only once in the production process. The boric acid used is a pure substance (about 99.5 per cent concentration). The largest proportion of the articles produced with this process consists of precious metal bars for investment purposes. Other articles produced include coins and medals. According to consultees for this study, boron is not detectable in the final product and therefore poses little risk to consumers from use of these articles.

Borax is also used in the metallurgy industry to coagulate impurities when precious metals are melted. Again, consultation confirmed that boron is not detectable in finished metal articles.

4.7.3.6 Aluminium packaging

Another example of the possible uses of the substances in analysis is the production of lacquered aluminium, which is used for food packaging, but also in medical applications and in construction. One industry representative explained that boric acid is used to degrease aluminium from the rolling oil used in the production process. After degreasing, boric acid is removed by careful washing so that no residue of the substance remains on the surface of the aluminium foil which is then lacquered.

4.7.3.7 Cellulose insulation

Boric acid and borax are used as flame retardants for insulation materials made from cellulose fibres produced from recycled newspapers.

Explained by EU industry representatives, potential exposure may only occur during the installation of the material since the insulation product tends to be located in cavity walls and floors. Installation is generally made by professionals provided with appropriate protective equipment and the resulting exposure is expected to be low. Installation is likely to occur only once in household's lifetime due to the service life of the product (sixty years). Hence, consumer exposure is not foreseen.

4.7.3.8 Flame retardants for textiles

Boric acid and borax decahydrate are used in auxiliary substances for dying and coating of textiles. Mixtures containing boric acid and/or borax are provided by the chemicals industry to textiles producers. The two substances act as flame retardants and, according to the industry, the concentration of the substances in articles is generally 1 to 10 per cent. However, in some fabrics the substances cannot be detected.

Boric acid and borax are mainly used in the production of technical textiles; which are textiles with specific technical properties including fire resistance and elasticity. End products include apparel and home furnishings. Stakeholders stated that boron compounds are used in intermediate mixtures; however presence in the final article could not be quantified or confirmed due to a paucity of data.

4.7.3.9 Pharmaceuticals

The use of boric acid and borax in pharmaceuticals is covered by the Medicinal Products Directive (Directive 2001/83/EC). Consumer exposure is very limited as the concentration of the substances in pharmaceutical products is very low: as emerged from the consultation undertaken for this study, in vaccines, for example, the concentration of boric acid is less than 0.1 per cent

Boric acid and borax decahydrate have several uses in the pharmaceutical industry. According to the consultation undertaken for this study, boric acid and borax are essential for the culture of cells used in the production of vaccines and antibiotics, falling under the Pharmaceuticals Regulation. As use relates to mixtures, not present in consumer articles, this end-user application of boron compounds is beyond the scope of this study.

4.7.3.10 Adhesives for corrugated board

As explained by EU industry representatives consulted for this study, corrugated board manufacturers are downstream users of boric acid and borax. Borax represents a key substance for the corrugated board industry, but also boric acid and another borate (sodium tetraborate; CAS number 1330-43-4) are used. These substances are used as a minor but essential component of the glue used to manufacture corrugated board. Borax is applied to guarantee the viscosity of glue used during the corrugating process; it gives stability to the glue and also improves the tack. The concentration of borax in the glue is less than 0.5 per cent but the total amount of borax in corrugated board is less than 0.1 per cent w/w. The concentration in a corrugated box of 240g/m2 is about 0.02 per cent.

One of the main end use of corrugated board is food packaging: approximately 43 per cent of the total EU turnover from corrugated paperboard derives from the production of food and beverage packaging [114].

4.7.4 Supply chains affected

Illustrated in the stakeholder consultation undertaken for this study, boric acid and borax are mainly intended for intermediate uses where the substances are completely consumed in the production process and are not present in articles (hence zero quantities are reported in articles within the supply chain diagram). Intermediate uses, as explained by representatives of the production and import of boric acid and borax, include mainly the production of glass and ceramics, the production of chemicals and industrial fluids and application in metallurgy. These uses can be excluded from further examination as a restriction on the presence of Boron in consumer articles would not affect EU production uses of these boron compounds. Overall, intermediate uses cover approximately 50 per cent of the EU consumption of boric acid and 86 per cent of the consumption of borax. An assessment of the impacts should boron be restricted in production is however provided in what follows as an illustration of the impact which should be considered in developing prioritisation criteria.

As reported in Section 4.7.2, almost 100 per cent of boric acid and borax used by the EU industry is imported from countries outside the EU, i.e. mainly the US and Turkey. Imported boric acid and borax are mostly supplied by producers directly to industrial users. This is typically the case when boric acid and borax are supplied to the largest EU users, including the glass and ceramic industries. A relatively small proportion of imports are supplied to intermediary distributors operating in the EU and serving industrial users of relatively smaller quantities of boric acid and borax, such as the metallurgy sector.

4.7.5 Expected non-use scenario

During the preparation of the scoping SEA, a consultation exercise with industry was undertaken to ascertain consumer exposure due to the presence of the Boric Acid and Borax in articles. Efforts were made to engage with the European manufacturers and importers of consumer articles, including non-EU manufacturers.

In total, 18 stakeholders have been consulted as part of the second phase of this study. Information has been provided by consultees through interviews, by the submission of written responses, or by both means. The scoping analysis has aimed at covering the different actors operating in the EU and international supply chain of boric acid and borax, from the production of the two substances to the manufacture of articles. The results of this consultation are summarised in the following table:

Table 4.24 Consultation exercise

	Sectors	Main articles covered	Stakeholders contacted
Trade/industry associations/national competent authorities	Importer/producer of substance, producer of chemicals, manufacturers of intermediate products, manufacturers of articles	Paper food packaging, wood furniture, textiles, glass containers, light bulbs, fertilisers	9 European
Private companies	Importer/producer of substance, producer of chemicals, manufacturers of intermediate products, manufacturers of articles	Chemicals, pharmaceuticals, medals and coins, industrial oils, chemicals, LCD	7 international 2 European

[114] The following countries are considered: Austria, Belgium, Croatia, Czech Republic, Finland, France, Germany, Hungary, Italy, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Spain, Sweden, Switzerland, Turkey and UK (FEFCO, 2011).

	screens, insulation material, aluminium packaging

Source: ICF/AMEC Consultation

Boric acid and borax are largely used by EU and international article manufacturers. Potential non-use scenarios vary depending on the use of the substance and are determined by factors such as the presence of alternative substances or processes and the importance of the substance for the industry. Assessment of economic and social impacts

4.7.5.1 *Identification of main impacts*

The first step in the SEA is a screening of the impacts and stakeholders potentially affected by the restriction. This ensures that the analysis is focussed on those stakeholders most affected by the proposed restriction and considers the nature and scale of the impacts, following the SEA guidelines produced by ECHA in relation to the possible costs and benefits. Categories of impact are shown in Section Table 4.26, along with a qualitative assessment of impacts.

As emerged in the course of the stakeholder consultation, impacts identified vary widely depending on the use of the substance. Stakeholders consulted have been interviewed over the possible consequences of the loss of boric acid and/or borax in terms economic and social impacts, including:

- loss of production due to the absence of viable alternatives to boric acid and borax;
- increasing costs of production due to the need to use more expensive alternatives to boric acid and borax;
- impacts in terms of research and innovation;
- social costs in terms of loss of employment; and
- impacts on the final consumer, such as reduced product choice, increased prices and need to switch to alternative products.

The identified impacts, where relevant, are discussed in this section as related to the uses of boric acid and borax examined in Section 4.7.2.

4.7.5.1.1 *Ceramics and glass*

Informed by consultees, there are currently no alternatives to borates for the production of strengthened glass; the consequence of a ban on boric acid and borax would imply the loss of production and trade of all glass and ceramic articles produced with these substances.

Examples of critical uses of boric acid and borax include the following:

- Borax and boric acid are used for the production of special glasses for high intensity discharge lamps, which are predominantly used in outdoor lighting (road / parking lots) or by industrial users (shop floor / warehouses).
- Borax is applied on the surface of the so called ‘dumet wire’, which is the electrical conductor used in the production of fluorescent lamps, compact fluorescent lamps, high-intensity discharge lamps and incandescent lamps. The dumet wire makes possible a vacuum tight glass-to-metal sealing. Without borax coating, the sealing reliability through the glass is significantly lower.
- Boric acid is used as an important additive in the production of highly efficient phosphors for low-pressure discharge lamps (luminescent lamps).

A ban on boric acid and borax would imply ceasing trading and a loss of business as related to the mentioned product lines. Potential impacts on EU consumers include:

- the loss of some articles where boric acid or borax are essential, including new technologies such as all articles containing LCD screens, or
- the need to switch to products that do not present the same qualities in terms of strength and resistance to heat.

The box below provides an example of the socio-economic costs linked to the loss of fluorescent lamps.

Box 9 Case study: light-emitting diode (LED) and fluorescent lamps

Boric acid is a fundamental substance for the production of LED and fluorescent lamps. The impossibility to produce these types of lamps could lead consumers to switch to less efficient lighting:

- LEDs: the Commission reports as follows (EC JRC, 2011): 'LED lamps efficacy and luminous characteristics are improving very rapidly. In the future, LED lamps are expected to deliver substantial energy savings. LED lamps last 5-25 times as long as the traditional lamps.'
- Fluorescent lamps: as reported by the Commission Joint Research Centre (EC JRC, 2013): 'compact fluorescent light bulbs (CFLs) use at least 60% less electricity than the traditional incandescent lamps while lasting ten to twelve times as long and can therefore deliver substantial savings in terms of both electricity and money.

In terms of wider implications, the production of the lighting articles such as those listed above would move outside of Europe, with consequent loss of jobs. As reported by industry representatives interviewed for this study, in 2012 about 100,000 persons were employed in the EU lighting industry, and the sector's total turnover was 20 billion €. The loss of production would also result in cease of R&D activities with loss of know-how and knowledge in innovative technologies in which Europe is being in the lead presently. As exemplified by industry representatives, currently the EU is global leader in the production of LED, a sector that in the EU has grown sevenfold over the period 2009-2012. At the current state of technology, LED cannot be produced without boric acid and/or borax. Therefore, in the event of a ban of the two substances, the EU would lose its leading position in LED-based technologies.

Borates are also essential for the production of stone wool for insulation products. One of the leading companies in the EU market for glass wool has commented that research on alternatives to borax has been ongoing for many years, but the tests conducted have failed to find substitutes. The consultee also estimated that glass wool currently represents up to 80 per cent of the insulation material used in the EU. Another type of insulation material is stone wool, which can be produced without the use of borates. However, as explained by the interviewee, stone wool has different uses from glass wool, and cannot be considered as a viable alternative material: stone wool presents a lower mechanical and insulation performance and has half of the density as compared to glass wool, meaning that exemplified by an industry representative, even by using the double of the stone wool material, the performance in terms of insulation would be 10 per cent lower than glass wool. Additionally, stone wool is not compressible and therefore cannot be as easily stored as glass wool. The consulted company reported that without the use of boron, the EU market for glass wool is expected to disappear. For one of the EU market leaders consulted for this study, a ban would mean the loss of about 150.000 tonnes of glass wool produced yearly; about 800 employees involved in the production of glass wool in the consulted company would lose their job. At EU level, this could mean the loss of about 3.6 million tonnes of end-product (RPA, 2008).

4.7.5.1.2 Biocides for wood preservation

One national authority consulted for this study[115] reported that, in the event of a ban on boric acid, wood producers would seek for alternative substances/mixtures for the preparation of wood preservatives. Representatives of small and micro companies operating in the furniture industry stated that alternative substances are more expensive than boric acid, and estimated that increased costs would likely imply ceasing trading and losses of business as related to the product lines involving the use of boric acid. According to industry representatives, such losses could range between 3 and 40 per cent of the annual turnover of the wood and furniture sector, which was valued at €36 billion in 2011. At EU level, in 2009 small and medium-sized enterprises (SME) operating in the wood manufacturing sector were more than 130.000, and accounted for more than 99 per cent of total number of enterprises operating in the sector[116]. Additionally, the use of more costly wood preservatives could imply the availability of more expensive furniture for the final consumer. The ability of SMEs to afford changes to production processes and absorb or pass on cost increases from the use of alternatives is therefore questionable, leading to severe adverse impacts on jobs and sector growth prospects.

As reported by consultees, the potential alternatives to boric acid for the production of wood preservatives are didecyldimethylammonium chloride (DDAC), iodopropynyl butylcarbamate (IPBC) and tebuconazole. One representative of a micro enterprise explained that these alternatives are compounds usually delivered as aqueous mixtures with organic solvent, and that they have an unacceptable odour, sophisticated conditions of use for the manufacture of articles (such as the need to apply the biocide in a closed system and specific conditions in terms of ventilation), more requirements for handling and storage and limited expiry date. One company who was consulted reported that:

- The price per tonne of DDAC is 275% more than that of boric acid. In addition, 25 per cent more DDAC is needed than boric acid.
- The price per tonne of IPBC and tebuconazole mixture is 1800% more than that of boric acid, and 0.29% more mixture of the two substances is needed as compared to boric acid.

In terms of wider implications, the representatives of macro enterprises producing wood panels reckon that a ban on boric acid would mean the loss of cost advantages and reduced competitiveness as compared to non-EU producers. Consultees explained that increased production costs due to more expensive alternatives to boric acid are likely to be passed on to consumers. As a consequence, overall consumer demand for wood furniture manufactured in the EU is likely to fall.

Finally, organic chemical mixtures used as alternatives to boric acid are considered by consultees as more hazardous for human health: the industry mentioned risks related to vapour intoxication, risk of serious damage to eyes and suspected damages to the unborn child.

4.7.5.1.3 Precious metals

Regarding direct impacts, a consultee explained that relocation of the manufacture of precious metals would be unlikely. The most likely potential response is the research of alternative substances or alternative production processes, including different types of crucibles used for metals production. This would probably imply higher costs due to the need to invest in innovation. However, a consultee explained that their company has been investing in the research of alternatives for the last 50 years without success. In absence of alternatives, the most relevant direct impact would be the loss of a relevant part of the production: the silver manufactured in crucibles that are used for the first time would be

[115] ICF/AMEC Consultation

[116] Source: Eurostat, Structural Business Statistics (SBS) database, data extracted on 19 July 2013

impure, and therefore would need to be refined in order to obtain a pure metal. This would imply a longer and more expensive production process, with yearly losses that could reach millions of euros per company, as estimated by one producer.

Indirect impacts would also be relevant: as explained by consultees, the loss of boric acid and borax would mean longer and more expensive production processes, and customers are expected to switch to suppliers that are able to supply the quantities required in a shorter amount of time. The loss of the substances in exam may affect a significant part of the production: one of the consultees estimated that borax is used for 50 per cent of their gold refining activities, and the loss of the substance could potentially affect 10 per cent of the workers employed in precious metals processing.

Due to the absence of the substances in the final consumer article, a ban on boric acid and borax is unlikely to provide significant human health or environmental benefits.

4.7.5.1.4 Aluminium packaging

The consulted industry representatives stated that currently there are no viable alternatives to boric acid for the production of lacquered aluminium. Possible alternatives have been tested, but they didn't show the same performance as boric acid. The main impact, as reported by the consultee, would likely be an increase of the costs of production due to the need to test potential alternatives, with possible increases in consumer prices. However, the consultee added that it would be unlikely that a ban would result in a significant damage to growth and innovation for the aluminium packaging industry. On the contrary, according to the consulted company the need to find new solutions could be an incentive for innovation.

4.7.5.1.5 Cellulose insulation

Borates are used as flame retardants, and substitutes with similar properties are potentially available without significant price differences. However, there are concerns in terms of the safety of such alternatives (RPA, 2008). As the risk of exposure mainly relates to professional installers of insulation material, it is unlikely that a restriction would be effective in terms of consumer protection. The same argument is applicable to glass wool insulations assessed earlier.

4.7.5.1.6 Flame retardants for textiles

Industry representatives consulted for this study indicated that the chemical industry has recently prepared new formulations that can be used in alternative to boric acid and borax. In most of the applications, these alternatives have shown the same performance of the mixtures including boric acid and borax, without any significant cost difference.

The consultee also reported that there are specific uses of boric acid and borax in coatings for technical textiles where currently there are no alternative substances. This type of production can be defined a 'niche market' as compared to the EU textiles industry. However, without boric acid and borax, this innovative market segment would disappear. The consultee also explained that this niche market is highly competitive; it can be therefore concluded that the likely impact of a ban would be relocation of production outside the EU. Additionally, the risk of non-compliance of imported goods would be high: in 2012, one third of all the products notified to the European rapid alert system for dangerous products (RAPEX) were clothes, textiles and fashion items, and about 50 per cent of these notifications related to clothing imported from China (RAPEX, 2013).

The likelihood of imports being the principle source of boron compounds in textiles and the frequency of non-compliance suggests that EU importers would incur significant administrative and testing costs to assure downstream retailers and competent authorities that what is placed on the market complies with any restriction. The complexity of supply chains and the ability to detect small quantities of boron compounds would make this difficult.

4.7.5.1.7 Adhesives for corrugated board

In 2011, more than 22 million tonnes of corrugated paperboard were produced in Europe[117]. The number of companies operating in the EU were 426, employing close to 83,000 persons. The main end-use of corrugated board is packaging for food and beverage (43 per cent of the total EU turnover). Other uses include packaging of non-food products, such as tobacco, textiles and electric appliances, and the production of other paper goods and printed matter (FEFCO, 2011). As explained by the industry representative consulted for this analysis, most of the corrugated board is intended for 'primary packaging', which is packaging of products that are sold by the retail market to the final consumer.

The corrugated paperboard industry mainly uses borax; however, also boric acid and another boron compound (sodium tetraborate: CAS No. 1330-43-4) are used, although in smaller quantities.

As explained by EU industry representatives, a potential ban of boric acid and borax is likely to affect the whole EU production of corrugated board, as currently there are no alternatives to borax, boric acid and related compounds.

A total loss of production is considered by consultees as unlikely. The main impact of a ban would probably be the production of alternative materials of lower quality, the need to invest in the research of alternatives, increased costs of production and consequent loss of international competitiveness.

In the absence of viable alternatives, the main impact on consumers could be the lower quality of packaging, including food packaging, and the switch to other types of packaging different from corrugated board.

4.7.6 Overall conclusions on potential costs and benefits

Costs and benefits of restrictions on boric acid and borax vary widely depending on the sector examined. Even within the same sector, there may be different impacts depending on the specific end-use application of the substance. One example is the use of boric acid and borax as ingredients for coatings in textiles production: most of the companies operating in the textiles sector are not expected to be affected by a ban, with the exception of small market segments involved in the production of innovative technical textiles. The availability of viable alternatives to boric acid and borax is a key determinant: in several sectors, such as the glass and ceramic sector, the absence of alternatives would imply loss of production and/or relocation of production activities outside the EU. Where alternative with similar costs and performance to boric acid and borax are readily available, such as in the production of some flame retardants, impacts are expected to be absent or not significant.

With boron compounds predominantly used in intermediate production, the human health and environmental benefits are likely to be more pronounced for workers and professional users (i.e. installers of glass wool insulation), than for its presence in consumer articles. The potential for exposure of consumers would therefore need to be established at the outset, before any restriction procedure is considered.

Consideration of the human health and environmental benefits of a restriction should also consider the comparable impacts of alternatives, as many flame retardants, isocyanides in alternative insulation products and substances in adhesives may be of comparable or greater toxicity to boron compounds.

[117] The following countries are considered: Austria, Belgium, Croatia, Czech Republic, Finland, France, Germany, Hungary, Italy, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Spain, Sweden, Switzerland, Turkey and UK (FEFCO, 2011).

Substance-specific considerations for development of draft criteria to implement Article 68.2 to CMR 1A and 1B in consumer articles

With regard to the potential choice of Article 68.2 as a RMO (compared to other forms of restriction), the following considerations arise from this case study:

- Considering the state of play/advancement in research undertaken by EU industry on potential alternative substances to boric acid and borax, a fast track Article 68.2 restriction might be justified, as industry could more readily adapt to a quicker restriction in this case rather than one where no research into alternatives has been undertaken;
- Availability of substance outside the EU in order not to affect EU competitiveness;
- Quick evolution of the markets and use in innovative products that become part of consumers' everyday life (for example, LCD screens and innovative technical textiles) can make an Article 68.2 restriction less justified, as the socioeconomic impacts could be more costly;
- Complex supply chains in which many uses may not be relevant for consumer exposure, and may be unsuitable for restrictions under Article 68.2;
- Use of the substances in the supply chains is focussed on intermediate production, which can hinder traceability in final consumer articles and may affect compliance in imported articles, where assurance can be more complex.

Table 4.25 Identification of relevant impacts by stakeholder group, impact category and supply chain

✓ - Benefit or positive outcome;
- No or insignificant anticipated impact;
× - Cost or negative outcome

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
Glass	Operating costs and conduct of business	Little or no EU impact: chemicals are produced outside the EU -	Loss of product lines, including glass and ceramic articles that have properties linked with the use of borates, such as high mechanical strength and products such as microscopes using optical glasses produced with borates, products containing LCD screens. ×	Impact on costs, possibly driving up prices of imports. A ban implies that article importers will have to demonstrate that the imported article is safe before it enters commerce in the internal market, requiring additional testing and assessment ×	Requirements for additional testing and assessment could negatively impact SMEs, which have fewer resources to accomplish these tasks ×	Higher operating costs would be borne by consumers. Consumers may switch to less efficient products (for example, traditional lamps with lower efficiency as compared to fluorescent lamps) ×
	Competitiveness, Trade and Investment	Little or no EU impact: chemicals are produced outside the EU -	Relocation of production to non-EU countries ×	Ceasing trade with articles produced with the use of boron ×	Potential relocation of production to non-EU countries could negatively impact competitiveness of SMEs ×	Higher operating costs would be borne by consumers. Switch to less advanced technologies could result in lower efficiency and decreased functionality of the products. ×
	Competition and the internal market	Little or no EU impact: chemicals are produced outside the EU -	EU and non-EU operators are expected to be impacted: no alternative substance is available -	All EU operators are expected to be impacted: no alternative substance is available -	Potential relocation of production to non-EU countries could negatively impact competitiveness of SMEs ×	N/A

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
	Innovation and research	Little or no EU impact: chemicals are produced outside the EU -	Cease of R&D activities with loss of know-how and knowledge in innovative technologies in which Europe is being in the lead presently ×	Cease of R&D activities with loss of know-how and knowledge in innovative technologies in which Europe is being in the lead presently ×	N/A	Newest technologies (for example, products with LED screens) could become unavailable and consumer choice would be limited. ×
	Distributive/Equity	Little or no EU impact: chemicals are produced outside the EU -	EU manufacturers are expected to lose their leading position at global level as compared to non-EU manufacturers ×	In many cases, manufacturers are also importers/distributors: as such, they are likely to be equally affected -	As EU manufacturers lose their leading global position, SMEs would likely be negatively impacted ×	N/A
Wood articles treated with boric acid/borax preservatives	Operating costs and conduct of business	Little or no EU impact: chemicals are produced outside the EU -	Alternatives generally require sophisticated conditions of use for the manufacture of articles more requirements for handling and storage and limited expiry date. Increased inputs costs due to these factors. This could mean losses ranging from 3 to 40 per cent of the annual turnover ×	Significant impact on costs, possibly driving up prices of imports. A ban implies that article importers will have to demonstrate that the imported article is safe before it enters commerce in the internal market, requiring additional testing and assessment ×	Partial loss of production for small and micro enterprises due to the difficulty to afford and handle more expensive alternatives. ×	Increased operating costs will be passed on to consumers. On the other hand, alternatives are considered as more hazardous. ×/✓
	Competitiveness, Trade and Investment	Little or no EU impact: chemicals are produced outside the EU -	Loss of cost advantages and reduced competitiveness as compared to non-EU producers ×	Loss of competitiveness due to increased costs of imports ×	Expected to be disadvantaged in terms of increased cost competitiveness (on non-EU markets) ×	Switch to more expensive articles; when not affordable, decreased demand for wood furniture or substitution with lower quality articles (for example, furniture) ×

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
	Competition and the internal market	Little or no EU impact: chemicals are produced outside the EU -	Small producers are expected to be impacted more than large manufacturers: some small operators expected to disappear from the market ×	N/A	The ability of SMEs to afford changes to production processes and absorb or pass on cost increases from the use of alternatives is questionable, to severe adverse impacts on jobs and sector growth prospects. ×	Switch to more expensive articles; when not affordable, decreased demand for wood furniture or substitution with lower quality furniture ×
	Innovation and research	Little or no EU impact: chemicals are produced outside the EU -	Boric acid and borax are used because research shows that alternatives are more hazardous for consumers. Research funds may be directed towards regulatory compliance instead. ×	N/A	Boric acid and borax are used because research shows that alternatives are more hazardous for consumers so SMEs may spend more on regulatory compliance. ×	Boric acid and borax are used because research shows that alternatives are more hazardous for consumers ×
	Distributive/Equity	Little or no EU impact: chemicals are produced outside the EU -	Small producers are expected to be impacted more than large manufacturers: some small operators expected to disappear from the market. ×	N/A	Small producers are expected to be impacted more than large manufacturers: some small operators expected to disappear from the market ×	

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
Lacquered aluminium	Operating costs and conduct of business	Little or no EU impact: chemicals are produced outside the EU -	Potential increase in costs to be borne in the short term due to the need to research new alternatives ×	No significant impact expected -	Potential increase in costs to be borne in the short term due to the need to research new alternatives. SMEs may not have the resources to perform this research like larger firms. ×	Potential price increase due to increase in production costs ×
	Competitiveness, Trade and Investment	Little or no EU impact: chemicals are produced outside the EU -	No significant impact expected -	No significant impact expected -	No significant impact expected -	No significant impact expected -
	Competition and the internal market	Little or no EU impact: chemicals are produced outside the EU -	No significant impact expected -	No significant impact expected -	SMEs without research and development capabilities could have business negatively impacted when no substitute is yet available.	No significant impact expected -
	Innovation and research	Little or no EU impact: chemicals are produced outside the EU -	Need to find alternative solutions could be an incentive for innovation ✓	No significant impact expected -	Need to find alternative solutions could be an incentive for innovation ✓	Could benefit from innovative products ✓
	Distributive/Equity	Little or no EU impact: chemicals are produced outside the EU -	No significant impact expected -	No significant impact expected -	No significant impact expected -	No significant impact expected -

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
Textiles	Operating costs and conduct of business	Little or no EU impact: chemicals are produced outside the EU -	The largest proportion of the industry would not be affected as alternative formulations are available without large cost impacts. Substances considered irreplaceable in some smaller market segments (i.e. niche markets for technical applications). Loss of the substances would mean ceasing production in the EU. -/×	No significant impact expected -	No significant impact expected -	No significant impact expected -
	Competitiveness, Trade and Investment	Little or no EU impact: chemicals are produced outside the EU -	No significant impact expected -	No significant impact expected -	No significant impact expected -	No significant impact expected -
	Competition and the internal market	Little or no EU impact: chemicals are produced outside the EU -	No significant impact expected -	No significant impact expected -	No significant impact expected -	No significant impact expected -
	Innovation and research	Little or no EU impact: chemicals are produced outside the EU -	Impossibility to produce some innovative technical textiles (niche market). Relocation of production of these articles outside the EU ×	No significant impact expected -	No significant impact expected -	Loss of innovative technical textiles (niche market) ×
	Distributive/Equity	Little or no EU impact: chemicals are produced outside the EU -	No significant impact expected -	No significant impact expected -	No significant impact expected -	No significant impact expected -

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
Adhesives in paperboard	Operating costs and conduct of business	Little or no EU impact: chemicals are produced outside the EU -	Increased cost of production linked to the need to invest in alternative solutions ×	Significant impact on costs, possibly driving up prices of imports. A ban implies that article importers will have to demonstrate that the imported article is safe before it enters commerce in the internal market, requiring additional testing and assessment ×	Increased cost of compliance and increased costs due to the need to invest in alternative solutions for products sold on the EU market ×	N/A
	Competitiveness, Trade and Investment	Little or no EU impact: chemicals are produced outside the EU -	If boric acid, borax and sodium tetraborate were restricted, loss of competitiveness vis-à-vis extra-EU producers is likely. If alternatives are available to extra-EU producers, EU producers could lose market shares. ×	Could be disadvantaged in terms of increased cost competitiveness (in non-EU markets) ✓	Loss of competitiveness to extra-EU producers would negatively impacts SMEs. ×	In the absence of viable alternatives, the main impact could be the lower quality of packaging and the switch other types of packaging different from corrugated board ×
	Competition and the internal market	Little or no EU impact: chemicals are produced outside the EU -	No significant impact expected -	No significant impact expected -	No significant impact expected -	No significant impact expected -
	Innovation and research	Little or no EU impact: chemicals are produced outside the EU -	Manufacturers are likely to invest in alternative materials ✓	No significant impact on innovation and research -	Manufacturers are likely to invest in alternative materials ✓	Potential availability of innovative solutions ✓
	Distributive/Equity	Little or no EU impact: chemicals are produced outside the EU	A potential ban of boric acid and borax is likely to affect all manufacturers; no significant distributive impacts expected	No significant impact expected -	No significant impact expected -	No significant impact expected -

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
		-	-			

Source: ICF/AMEC Consultation

4.8 Scoping SEA: imidazolidine-2-thione; Ethylene Thiourea [ETU]

4.8.1 Introduction

This section covers the scoping level SEA for **imidazolidine-2-thione; Ethylene Thiourea (ETU; CAS No. 96-45-7)** and follows the structure defined in the introduction, concluding with the identification of considerations and elements to help ECHA and the Commission in the development of criteria for application of Article 68.2 for CMR substances in articles.

4.8.2 Regulatory status

ETU is classified as R1B. As a category 1B CMR substance, it cannot be used in toys, in components of toys or in micro-structurally distinct parts of toys, according to Annex II of directive 2009/48/EC. The substance is restricted by REACH Annex XVII Entry 28, which prohibits its direct use in consumer products. Therefore it is not allowed to be used in substances and preparations placed on the market for sale to the general public in individual concentrations equal to or greater than 0.1% w/w or other relevant concentration limit. This requirement, however, does not apply to articles (e.g. apparel) and there is a possibility that consumers may be exposed to products containing trace amounts of ETU, hence the potential need for restriction under Article 68.2. REACH Annex XVII Entry 30 bans the use of ETU in medicinal and veterinary products, motor fuels, cosmetics and artist' paints. Similarly, there are certain restrictions on use in food contact materials in compliance with Directive 2007/19/EC.

4.8.3 Uses of the substance

Ethylene thiourea (ETU) is a thiourea-based accelerator used mainly in the vulcanisation of chloroprene rubber (CR), more commonly known by the commercial name of Neoprene. Together with other ingredients it produces a high performance curing system for synthetic rubber that confers the material an excellent balance of vulcanization performance, resilience, compression set and heat aging which is hard to achieve with other accelerators. It also provides good adhesive properties, excellent flame resistance and low smoke emissions. This makes CR a popular material for outdoor use and those uses where strict fire regulations are in place (e.g. train driver cabins)

Toxicological experiments in rats and rabbits have shown that ETU is a potent teratogen that can cause abnormalities in the central nervous system and skeleton. Thus ETU has been classified as toxic for reproduction category 1B with Hazard statement H360D (may damage the unborn child) under the CLP Regulation.

4.8.3.1 Overall quantities manufactured and imported

Only three companies (one EU manufacturer and two importers) have registered ETU under REACH. The two importers have acquired letters of access from the EU manufacturer (lead registrant). It is not clear how much of this is used domestically versus how much is exported. The tonnage of imported ETU remains unclear. In any case the combined production and import of ETU in the EU is lower than 1,000 tonnes a year based on registration data. Consultees have suggested that there may be minor imports of ETU from the Far East not registered under REACH, and therefore not compliant with current regulation.

4.8.3.2 Use in articles

ETU is reported to be used in rubber manufacturing, particularly as a vulcanisation accelerator in making CR. Other minor reported uses include as an intermediate for antioxidants, insecticides, fungicides and pesticides, dyes and pharmaceuticals as well as in electroplating baths (Finnish Ministry of the Environment 2013). In terms of its use in articles, there are two main supply chains: industrial articles (which includes solid, dense rubber articles that are usually subject to particular conditions of use, such as exposure to

environmental conditions or repetitive compression) and the apparel sector (which uses CR foam, instead of dense rubber, and it is normally distributed and manufactured in sheets of variable thickness).

Regarding industrial rubber articles, registered uses of ETU cover manufacturing of articles for vehicles (e.g. joint boots, windscreen wiper blades), machinery, mechanical appliances (e.g. conveyor belts), electrical/electronic articles (e.g. underground and undersea cables) and general rubber articles (e.g. draught excluders). Consultation and literature have confirmed these uses.

Literature also suggests the use of ETU in the manufacture of chloroprene for the apparel industry (DuPont 2008, NTP 2011). This poses a higher potential for exposure to consumers than industrial articles due to the direct and prolonged contact with the skin. For its use in textiles, CR is compounded and vulcanized as closed-cell foam that is sliced into sheets of different thickness. CR foam sheets are a key material in the manufacture of wetsuits, constituting up to 99% of the final product. It is also used in footwear (Wellington boots) and specialized equipment. CR foam can also be found in a wide variety of accessories including laptop sleeves, knee pads and smell-trapping dog waste carriers. However, consultation has not been able to confirm the use of ETU for the manufacture of CR foam sheets. Two CR foam manufacturers supplying the European wetsuit industry were contacted, one in the EU and one in Taiwan. Due to the classification of ETU as a CMR, neither of them is using ETU as an accelerator for the vulcanization of CR foam. One of them uses 1,3-diethyl-2-thiourea (Diethyl thiourea / DETU CAS no.: 105-55-5) as an alternative accelerator.

There is little information available in the literature on the proportion of the total tonnage of the substance used in different types of articles. However, one industrial association consulted for this study suggests that the use of the substance in cables in the EU is between 10 and 50 tonnes per annum. Consultation suggests that no ETU is used in the EU for the manufacture of CR foam sheets for the apparel industry but its presence in imported sheets and apparel cannot be discounted.

The concentration of ETU used in the formulation of CR depends on the desired physico-chemical properties of the final article, usually ranging between 0.5 and 2 phr[118] (0.25% - 1% by weight approximately). A proportion of 0.5 phr of ETU dispersion (75%) is suggested for the manufacture of wetsuits (DuPont 2008). ETU reacts during the vulcanization but traces may remain in the final article. The concentration of ETU in the final consumer article remains unclear. Consultees were not able to provide an exact figure but declared it can be found only in traces. It was suggested that it is less than 0.1% but the real figure is likely to be lower. Tests mentioned by the US National Toxicology Program (NTP 2011) have shown that 0.01 mg of non-reacted ETU per square inch of CR surface could be extracted by water at 57°C over a period of seven days.

A recent study by the Danish EPA (2012) tested a number of CR foam consumer articles for thiourea-based compounds, including ETU. A total of 14 articles were tested including wetsuits, shoes, gloves, an iPad sleeve, etc. Surprisingly, ETU was not detected in any of them. The authors argue that this may be due to two reasons: either ETU was not used as an accelerator in any of the studied products, or ETU degrades completely during the curing process so that it is present in the final product in concentrations below the detection limit (2 mg/kg). It should be noted that all the products included in this study were apparel articles made from CR foam sheets and no technical articles made with “industrial” CR were tested.

The UN Comtrade database[119] suggests that 37 million pairs of “waterproof footwear with outer soles and uppers of rubber or plastics (Wellington boots, etc.)”, weighting some 33 kilotonnes (kt), were imported into the EU in 2012. Even assuming that this imported

[118] phr – Parts per hundred rubber. That is, parts in weight per one hundred parts of elastomer used in the composition.

[119] United Nations Commodity Trade Statistics Database (UN comtrade) http://comtrade.un.org/ (20/06/2013)

waterproof footwear is mostly comprised of neoprene and contains 0.1% of ETU as the maximum concentration reported in the stakeholder consultation, this suggests that a maximum of some 30 tonnes of ETU could enter the EU in imported footwear. In practice, the actual amount will be much lower as e.g. Wellington boots are typically mainly made from PVC or natural rubber (although linings and other parts may be neoprene) and the share of neoprene containing footwear is relatively small. Other uses of CR are likely to be larger users of ETU, but relevant data on imports of articles have not been identified. This is due to the lack of a specific article category in the consulted databases (e.g. wet suits are included in the Harmonized System category (HS code) of swimwear and track suits, representing probably only a small proportion of the imports within this commodity group).

4.8.3.3 Trends

Based on consultation for the current study, the global trend in the rubber industry during recent years has been to progressively abandon ETU due to its reprotoxic properties. This applies both to industrial article manufacturers and to the apparel sector. However, finding suitable alternatives seems to be easier for CR foam manufacturers for apparel than for industrial articles manufacturers. This is due to the fact that industrial articles require more specific technical properties that are difficult to achieve with other accelerators such as heat and ozone resistance and compression set.

4.8.4 Supply chains affected

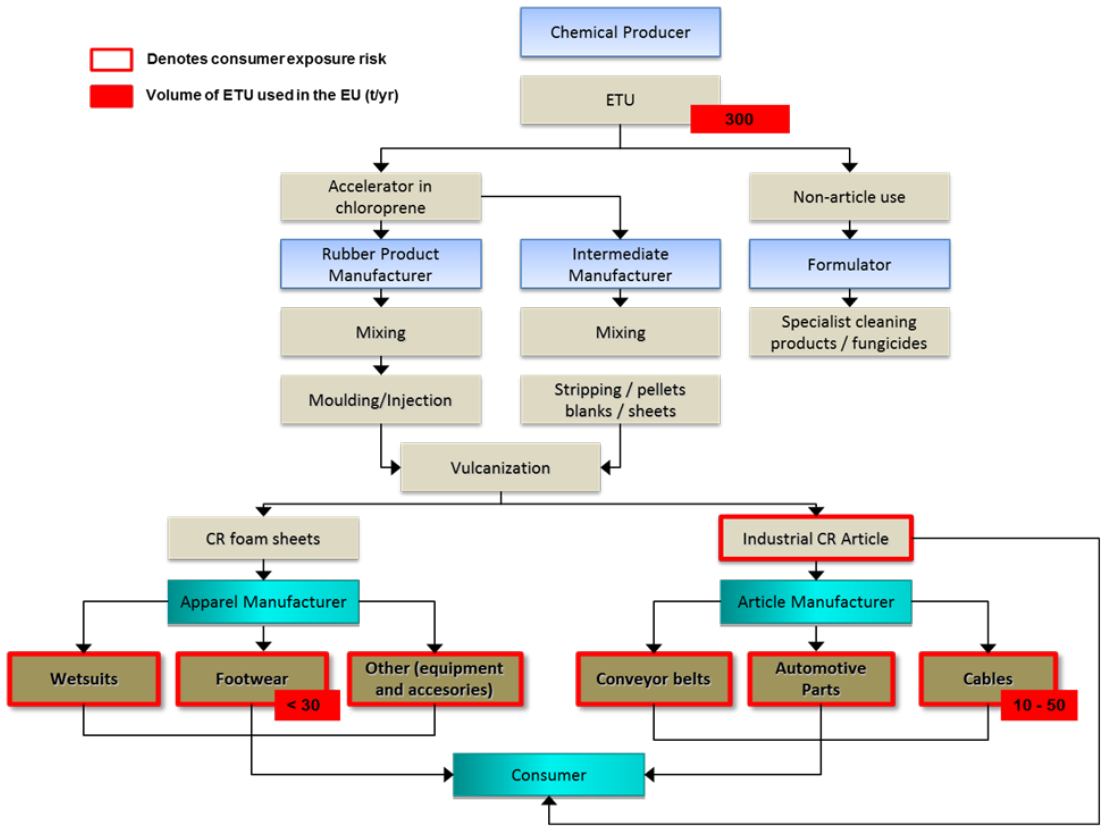
The figure below provides an overview of the key stages in the supply chain related to the use of ETU in consumer articles. This is clearly a simplification but does serve to highlight the key players in the supply chain. Those of particular importance for the scoping SEA are the ETU manufacturers, producers and importers of CR products including apparel, cable and automotive parts, and consumers.

The market for CR was estimated at approximately 70,000 tonnes and € 160 million in the EEA and approximately € 725 million world-wide in 2001 (EC, 2007). There are more than 6000 SMEs in the EU synthetic rubber industry and a significant proportion of them are expected to be involved in the CR supply chain. There is only one ETU manufacturer in the EU, but the number of manufacturers of CR products is expected to be high, including CR manufacturers (as a material) and manufacturers of final articles.

Rubber manufacturers mix ETU with other ingredients such as polymers, magnesium oxide, zinc oxide and colorants, to form an uncured rubber compound. Some companies act as intermediaries, acquiring and mixing the ingredients and selling the uncured rubber to rubber manufacturers. Uncured rubber is extruded or injected into the moulds and subjected to a vulcanization process. It is during vulcanization when ETU reacts with the rubber becoming bound into the matrix and conferring the rubber with the necessary physicochemical properties.

Industrial CR manufacturers usually mix and vulcanize the material to a specific shape, producing their own finalized articles. CR foam manufacturers usually produce large sheets that are then sold to apparel manufacturers for the production of a wide range of consumer articles (wetsuits, boots, gloves, computer sleeves, etc.).

Figure 4.13 Summary of supply chains for ethylene thiourea (ETU)



Source: ICF/AMEC Consultation

In summary, 300 tonnes (plus imports) of ETU (10 to 50 tonnes in cable and the rest in other CR articles) can be expected to be incorporated into articles manufactured within the EU. It is unclear how much ETU enters the EU in imported articles as CR pieces can be found in many different products (cars, elevators, machinery, etc.). This means that ETU can enter the EU as a standalone article (e.g. an imported CR joint boot that is used in the manufacture of a car within the EU) or incorporated in larger imported products (e.g. an imported car that contains CR pieces).

Regarding CR foam in apparel, no direct evidence was found of ETU being present in apparel imported into the EU. Although technical literature indicates that ETU is a popular accelerator in the manufacture of CR for apparel (DuPont 2008, NTP 2011), a recent chemical survey on CR apparel products (many of them assumed to be imported) did not detect ETU (Danish EPA 2012). Similarly, CR foam manufacturers that participated in our consultation (of which there were two) confirmed they do not use this substance. Although ETU is probably absent from many products or present in very low concentrations in those CR foam apparel articles where it is used, its presence cannot be completely discounted. Therefore, the following sections also consider the potential impacts on the apparel industry supply chain.

4.8.5 Expected non-use scenario

During the preparation of the scoping SEA, a consultation exercise with industry was undertaken to ascertain anticipated responses to a restriction on the use of ETU in consumer articles. Significant efforts were made to engage with the European manufacturers and importers of boots and cables, although limited substantial input was forthcoming from these. The number and type of stakeholders contacted during the consultation for ETU can be found in Table 4.26.

Table 4.26 Consultation exercise

	Type of industry/article	Stakeholders contacted	Valuable responses received
Trade/industry associations	Rubber manufacturers, apparel, cables, flooring and vehicles.	6 European	1 European
Private companies	Chemicals, industrial rubber articles, CR foam sheets, wetsuits, boots, CR accessories, specialized apparel and cables.	13 European 5 International	6 European 1 International

Source: ICF/AMEC Consultation

The non-use scenarios have been developed primarily based on the views of the manufacturers of ETU and alternative accelerators, industrial rubber manufacturers, CR foam manufacturers and wetsuit importers and manufacturers. This was supplemented by expert judgement taking into account the literature on the use of ETU in neoprene boots, cables and automotive parts.

The anticipated non-use scenarios at each key stage of the supply chain are described below, covering manufacturers of ETU, downstream users of ETU and consumers of the final products.

4.8.5.1 *Manufacturers of ETU*

In the case of a total restriction on the use/presence of ETU in rubber articles, the single ETU manufacturer in the EU would cease production of ETU and manufacture alternative substances in order to continue synthesizing accelerators for the CR industry. As a result of the classification of ETU as a CMR substance, the ETU manufacturer has developed a thiazole based accelerator as an alternative to ETU. This molecule (i.e. 5,5'-dithiobis(1,3,4-thiadiazole-2-thiol, also known as SD75) is used together with DPG 1,3-diphenylguanidine forming an accelerator system. The alternative accelerator is already on the market but requires further adjustments to be used as a fully functional substitute of ETU. Expenditure on administrative costs is also expected by the manufacturer as the substance still has to be registered under REACH. The manufacture estimated that SD75 still needs an investment of near €450,000 (including further R&D) in order to be fully developed and commercialized.

4.8.5.2 *Manufacturers of rubber articles*

Similarly to the ETU manufacturer, the EU CR sector has also been working to transition to safer alternatives, since the classification of ETU as a CMR substance. Therefore, in the case of a total restriction on the use/presence of ETU in rubber articles, it is assumed that manufacturers of industrial rubber articles containing ETU would substitute away from ETU in their products.

In addition to the alternative being developed by the ETU manufacturer, industrial rubber article manufacturers and rubber industry associations have formed a consortium called SafeRubber to develop an alternative to ETU for the vulcanisation of rubber (this is partially financed by the Commission through the Research Executive Agency (REA) under the Research for SME Associations Scheme FP7). The project has taken three years, and its findings are in the process of being published. At the time of writing this report, a summary of the findings was available. Further documentation is expected to be made public through the project website[120]. Consultation with the industry and review of the summary suggests that the project has been quite successful in that they have identified a substance with good

[120] www.saferubber.eu

technical capabilities and similar properties to ETU, which is not expected to be classified as CMR or SVHC. The substance, referred to as SRM102, seems to be commercially viable for general purpose and high-quality CR compounds, allowing for extrusion and moulding while keeping the desired physicochemical properties.

4.8.5.3 *Importers of rubber articles*

In the case of a total restriction on the use/presence of ETU in articles, importers of rubber articles are expected to import CR articles made without ETU, assuming that the alternatives are available to the non-EU manufacturers of these products.

The tonnage of industrial CR articles entering the EU market remains unclear. It can be imported as rubber articles or as part of larger devices, such as cars, trains or lifts. European rubber manufacturers are the priority users of the alternative substance developed by the SafeRubber consortium and it is not expected to be available for non-EU manufacturers in the short-term. However, proprietary substances that may replace ETU for many industrial uses are currently being manufactured outside the EU and are commercially available. These include dimethyl ammonium hydrogen isophthalate, commercialized under the name of Vanax CPA by the American chemical manufacturer R.T Vanderbilt. It is not clear if this substance can successfully replace ETU for all the possible final uses of CR rubber. Non-proprietary accelerators for CR rubber (e.g. DETU, DPTU, TMTM, Methylthiazolidinthion, Tributyl thiourea) can also be found on the international market but consultation suggested that they cannot achieve the same level of performance as ETU and are therefore unsuitable for some industrial uses.

Consultation also revealed that alternatives to ETU are already being used by non-EU manufacturers of CR foam that supply the EU apparel industry. The most relevant alternative substance (DETU) is not classified as CMR and is not an identified SVHC.

4.8.5.4 *Consumers*

CR is a well-established material with a unique combination of properties. Therefore, assuming that the CR articles can be manufactured with alternative substance(s) that can provide comparable technical capabilities to ETU, consumers would continue to purchase rubber articles without any change in their satisfaction levels.

4.8.6 Assessment of economic and social impacts

This section provides estimates of the likely economic impacts of the response (non-use) scenarios. The impacts are based on a review of information provided through industry consultation, as well as expert judgement informed by a review of literature sources.

4.8.6.1 *Screening of impacts*

The first step in the SEA is a screening of the impacts and stakeholders potentially affected by a possible restriction on the use/presence of ETU in consumer articles. This is so that the analysis is focussed on those stakeholders most affected by the possible restriction and considers the nature and scale of the impacts, following the SEA principles in relation to the possible costs and benefits. Categories of impact are shown in Section Table 4.27, which presents a first screening.

4.8.7 Economic impacts

4.8.7.1 *Manufacturers of ETU*

The single manufacturer of ETU in Europe has identified an alternative to ETU in rubber articles (SD75). Consultation with the manufacturer suggests that it is marketing the alternative internationally and has seen some of their customers use the alternative in place of ETU. However, it was pointed out that this substance still requires further adjustments to replace ETU in the majority of uses and it is not being produced at a fully commercial scale yet.

It is estimated that the economic impact of a potential restriction would be lower than these figures as an undetermined proportion of ETU may be exported to non-EU countries. In addition, a restriction on ETU may also increase the turnover from alternative accelerators that are also manufactured by the same company. However, with the development of another potential alternative to ETU by manufacturers of rubber articles themselves (i.e. the SafeRubber project), the ETU manufacturer may observe its market share reducing with a new market entrant.

4.8.7.2 *Manufacturers of rubber articles*

Some manufacturers of industrial rubber articles have been involved in the SafeRubber project which has claimed to have identified a suitable alternative to ETU. The SafeRubber consortium represents small and medium size enterprises (SMEs) within the synthetic rubber manufacturing and processing sector, equating to over 6,000 SMEs employing some 360,000 people and a turnover of €3.2 billion within Europe[121] (SafeRubber, 2013).

Consultation with a partner involved in the SafeRubber project suggests that a technically and commercially suitable alternative has been identified (SRM102). With this alternative, alongside another alternative being developed by the ETU manufacturer, European manufacturers of rubber articles would have greater options to choose which alternative would be most suitable for manufacturing their products.

It has been estimated that the manufacturing cost of a final rubber compound using SRM102 will be less than 105% of the equivalent compound using ETU. Due to the safer character of SRM102, there may be savings in health, safety and environmental costs. In any case, the cost increase is not expected to affect the competitiveness of rubber manufacturers using SRM102. Once this substance is fully available at industrial scale, it is expected that the ETU market within Europe would decrease due to safety concerns and the expectation of the industry that further restrictions will be put in place.

The SafeRubber project was aimed at increasing the competitiveness of SMEs in the CR sector after a cartel involving six of the main CR polymer manufacturers was revealed. The results achieved by the consortium are expected to position SMEs well in case of a restriction. This is expected to make European SMEs more competitive against big corporations and their products relatively more competitive compared to imported articles. According to consultation, access to SRM102 will be limited to the members of ETRMA, at least initially. The new substance will also be subject to intellectual property rights.

The only identified EU manufacturer of CR foam sheets for apparel would not be affected as it does not use ETU.

4.8.7.3 *Importers of rubber articles*

A restriction on the use/presence of ETU in articles is expected to have a negative impact on imports of industrial CR articles. However, quantification is not possible due to the wide range of devices containing CR components that may have been manufactured with ETU (e.g. cars, trains, lifts, cables, etc.).

As mentioned above, the new alternative developed by the SafeRubber consortium will not be available for non-EU manufacturers in the short term. Consultation also revealed that non-proprietary alternatives are not able to replace ETU for some specific uses of the final article (e.g. when high curing performance is required). This suggests that, if they wish to continue supplying the EU market, non-EU manufacturers may be forced to turn to more expensive proprietary alternatives, passing this cost to importers.

Companies importing rubber articles and then incorporating these into their own products would face increased material costs, which would either need to be borne by these

[121] Companies involved in manufacture of rubber using ETU will represent only a fraction of this total.

companies or passed on to consumers. Alternatively, non-EU manufacturers may choose not to continue supplying the EU market, resulting in a reduction in the volume of imports.

Regarding CR foam for the apparel industry, alternatives to ETU are already being used in imported sheets and apparel (e.g. imported wetsuits). The proportion of imported CR foam containing ETU over the detection limit remains unknown, although literature suggests it may be low (Danish EPA 2012). However, the fact that at least one major supplier is using DETU indicates that a migration to safer alternatives is technically and economically viable.

Although prices outside the EU may differ from these, substitution of ETU by DETU is expected to slightly increase manufacturing costs and have a limited impact on the price of imports. The increase in price of imported CR foam for apparel would depend on the proportion of this material currently being manufactured with ETU. There could be a change in the ETU price outside the EU after such a change, but there is insufficient data to predict what this could be.

For the case of CR foam sheets used in textiles, the UN Comtrade database suggests that 683 tonnes of rubberised textile fabrics were imported into the EU27 in 2012, having a total value of €4.7 million. Even assuming that CR was the only rubber used and 0.5% of ETU was added to the mixture (DuPont 2008), this suggests that 3.4 tonnes of ETU were used for the manufacture of these fabrics, with a cost of €23k – €31k. A replacement with DETU (1 to 1) would imply an increased cost between €3.2k and €12k for all the imports of this type of textiles. This means that substitution of ETU by DETU would result in a maximum increase of 0.25% of the fabric cost compared to the baseline. These calculations are a broad estimation related to only one product type, but illustrate that price increase in the final product is expected to be limited. It only represents the rubberised textile fabric and excludes imports of CR foam textile articles that are already manufactured such as wetsuits and boots.

4.8.7.4 Consumers

It is expected that the slight cost increase in EU manufacture of industrial CR articles, together with an increase in the price of imports, would have an effect on prices paid by consumers. However, industrial CR articles requiring ETU are not generally purchased directly by the general public, but are used in larger devices or in construction. Therefore, only a slight increase in prices is expected. A slight increase in the price of imported CR foam may also be expected. In the long term, as more alternative substances enter the market, competition may have a positive impact on final consumer products, reducing the price differential for CR articles made using alternatives to ETU.

4.8.7.5 Administrative costs

Both the ETU manufacturer and the SafeRubber consortium anticipate upcoming administrative costs. The single European ETU manufacturer expects to face costs over €300,000 for REACH registration and industrial certification of the new alternative substance. The SafeRubber consortium also expects certain administrative costs associated with compliance with REACH legislation. However, these REACH registration costs are expected to be borne regardless, and could not therefore be directly attributed to a possible new restriction on use/presence in consumer articles.

No further administrative costs for EU manufacturers are anticipated as a result of a restriction in articles.

Social impacts

It is expected that the current level of employment by European manufacturers of ETU and rubber articles containing ETU would not be significantly affected by a restriction on the use/presence of ETU in rubber articles. Specifically, according to consultation, no jobs would be lost by the ETU manufacturer as the workers involved in the ETU manufacturing line may be relocated to the production of alternative related substances. Testing, research and

certification of alternative substances may even have a limited temporary positive impact on the job market, as may any increase in EU-based rubber production arising from competitive advantage over non-EU firms, due to the likelihood that they will be more advanced in replacing ETU.

Smaller companies may be affected as they would require skilled professionals and resources to ensure compliance with the restriction. However, these efforts may be offset by the fact that SMEs are currently in a good position against a potential restriction, as they will soon have an affordable alternative available that does not require significant changes in the methods of production. It should be noted that the "SafeRubber" project is managed by and directed towards SMEs within the CR industry.

A potential restriction may also have a limited positive effect on gender equality in the workplace. Given the teratogenic properties of ETU, women of child bearing age are not allowed in industry to work with this compound. A restriction on the use of ETU and its associated switch to safer alternative substances should improve the access of women to employment in more steps in the CR manufacturing chain.

4.8.7.7 Potential human health and environmental benefits

Restriction of ETU used/present in consumer articles would result in human health and environmental benefits. Given that the highest exposure to ETU is through the inhalation of dust and the fumes released during vulcanization, the main health benefit would be to workers involved in the CR curing process.

The benefits to the general population remain unclear. Industry seems to be more concerned about improving occupational safety than minimizing potential consumer risks. According to consultation with industry, ETU reacts completely during vulcanization and the amount of ETU in the final product is negligible. Literature also seems to point in this direction. Further tests may be necessary in order to quantify the concentration of ETU in articles (not only apparel) and estimate the level of exposure of consumers.

Environmental benefits may also be expected, not only because of the decreased discharge of ETU to the environment but also because of a potential reduction in the use of associated substances during the curing process. According to the SafeRubber consortium, the use of the alternative SRM102 may lead to a reduction in scrap rubber compared to the use of ETU. Although more research is required from the industry, SRM102 may also allow for a reduction (or substitution) in the amount of hazardous metal oxides used during vulcanization.

4.8.8 Overall conclusions on potential costs and benefits

The most relevant economic impacts of a restriction on ETU in articles are anticipated for importers (including companies that import CR articles incorporating them into their own product) and, to a lesser extent, the single EU ETU manufacturer. EU rubber manufacturers are not expected to be significantly impacted as they have anticipated a potential restriction. Given the exclusive ownership of a commercially viable safe alternative, small EU rubber manufacturers may be positively affected by a potential restriction, being able to compete with bigger companies and importers. Long term impact on consumers is expected to be limited.

Health benefits for workers in the CR industry would be the most relevant benefit of a potential restriction. Benefits to the health of the general public are not clear as there is a lack of information regarding consumer exposure.

4.8.9 Substance-specific considerations for development of draft criteria to implement Art 68.2 to CMR 1A and 1B in consumer articles

This section firstly includes consideration of issues that are important in determining whether Article 68.2 restriction is potentially most appropriate, compared to other forms of restriction.

Following this, the identified socio-economic issues that it would be important to take into account in assessing the merits of a restriction are discussed.

With regard to the potential choice of Article 68.2 as a RMO (compared to other forms of restriction), the following considerations arise from this case study substance:

- ETU seems to be used (or have been used) in both consumer articles and in industrial rubber articles. Criteria should therefore take into account the extent to which there is clearly use in consumer articles, and the extent to which these can be distinguished from industrial articles. A key point that remains unknown is the level of exposure to ETU by the final consumer. According to consultation, ETU reacts during vulcanization, being incorporated into the matrix and there is subsequently minimal / no leaching from the final product. The amount of ETU in the final product is minimal (small traces) and there is virtually no exposure to consumers under normal circumstances. However, effects cannot be ruled out, even at low concentrations/exposure and there remain uncertainties about the levels of exposure. The potential for measuring/monitoring the presence of the substance in articles is therefore important to take into account in developing criteria. At present there is relatively little certainty on the degree of any risks to the consumer. Further research and testing would be required to assess the concentration of ETU in articles, and the associated exposure for the general public taking into account likely migration, as well as whether there is any "safe" threshold for exposure. Criteria may need to take into account whether there is a consumer risk that needs to be addressed, as well as the uncertainties in the current level of knowledge on the risks. However, the extent to which a risk may need to be demonstrated in the context of an Article 68.2 restriction is as yet unclear. ETU is used in both EU-produced and imported articles. In setting out *the wording of a potential restriction, it could be important to ensure that all of the articles entering the EU market are covered, not only those manufactured domestically (for example, by establishing a very low concentration limit instead of just restricting the use of ETU in the manufacture of consumer articles).*

Having determined that an Article 68.2 restriction is potentially suitable, there are a number of socio-economic issues arising from this case study that are relevant to deciding whether this simplified route is likely to be suitable:

- ETU seems to be a good example of how regulatory efforts may trigger research for new alternatives and promote domestic competitiveness. In this case, the classification of the substance has led to significant research efforts to identify alternatives. *Criteria clearly need to take into account the availability of technically suitable alternatives (including whether they are available in sufficient quantities and are affordable).*
- Efforts by industry to move towards safer alternatives have been driven by occupational health concerns related to the classification and hazards of the substance in the workplace. There is an existing move toward use of alternatives. A restriction on presence in consumer articles would have a co-benefit of also reducing worker exposure in industrial settings, even if the reduction in risk for the consumer may not be all that significant. *Criteria could therefore take into account whether there would be co-benefits in terms of risks at other stages in the supply chain.*
- EU industry seems to be well advanced in developing alternatives (potentially more so than non-EU industry). *Criteria may therefore need to take into account the EU's relative position compared to external companies in being able to move rapidly to use alternatives.*

Table 4.27 Identification of relevant impacts by stakeholder group, impact category and supply chain

✓ - Benefit or positive outcome
- No or insignificant anticipated impact
× - Cost or negative outcome

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS/ IMPORTERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
CR foam sheets and articles	Operating costs and conduct of business	No impact is anticipated as ETU is not used in the EU for the manufacture of CR foam sheets. -	No impact is anticipated for CR foam sheets manufacturers as ETU is not used in the EU for this purpose. -	If non-EU manufacturers wish to continue supplying the EU market, a restriction may have a marginal impact on production costs, possibly driving up prices of imports. CR foam article importers may need to check that their products do not contain ETU (certification/declaration or by undertaking their own testing). Substitution with alternative accelerators may also result in slightly increased costs. EU manufacturers that use CR foam sheets as a raw material (e.g. manufacturers of wetsuits) may have to demonstrate non-use of the substance, with its associated costs. A shift to alternatives abroad may also result in a marginal increased cost of imported CR foam sheets. However, the use of ETU in imported sheets has not been confirmed and it is expected to be low (if any). In any case, cost increase is expected to be passed on to consumers. ×	No major cost impacts so no specific issues identified for SMEs. SMEs may find it hard to exert pressure on suppliers to demonstrate compliance and/or to bear the costs of doing so themselves. -	Compliance and substitution costs may be passed on to consumers but It is expected that price increase resulting from the replacement of ETU would be limited in relation to the total cost of the finished product. ×
	Competitiveness, Trade and Investment	No impact is anticipated as ETU is not used in the EU for the manufacture of CR foam sheets. -	No impact is anticipated in this category. -	Importers and distributors of CR foam sheets and articles containing ETU will potentially lose competitive edge due to potential increased prices of final products and extra costs (testing, change of suppliers). However, the proportion of	No specific issues for SMEs have been identified. -	No impacts are anticipated. -

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS/ IMPORTERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
				imported CR foam containing ETU is expected to be low (if any). In addition article price increases as a result of accelerator substitution are not expected to be significant. ×		
	Competition and the internal market	No impact is anticipated as ETU is not used in the EU for the manufacture of CR foam sheets. -	No impact or a minimal positive impact is anticipated as the only CR foam EU manufacturer is not using ETU. In this sense, it could benefit from a competitive advantage. Given that all EU manufacturers and importers would be subject to assurance and traceability costs, no significant impact on internal competition is anticipated. -	EU importers may face a competitive disadvantage if their current imports of CR foam are found to contain ETU. Additional costs would be related to potential tests and changes in suppliers. Even so, the volume of the substance entering the EU in CR foam is assumed to be low and its restriction is unlikely to have a significant impact on internal competition ×	No specific issues for SMEs have been identified. -	Compliance and substitution costs may be passed on to consumers but It is expected that price increase resulting from the replacement of ETU would be negligible in relation to the total cost of the finished product. Higher prices of imported products are not expected to significantly induce substitution for articles that are locally-produced, thereby not restricting choice. -
	Innovation and research	No impact is anticipated as ETU is not used in the EU for the manufacture of CR foam sheets. -	No impact is anticipated as ETU is not used in the EU for the manufacture of CR foam sheets. -	No significant impact on innovation and research is expected. -	No specific issues for SMEs have been identified. -	No impacts are anticipated. -

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS/ IMPORTERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
	Distributive/ Equity	No impact is anticipated as ETU is not used in the EU for the manufacture of CR foam sheets. -	No impact is anticipated as ETU is not used in the EU for the manufacture of CR foam sheets. -	Larger impact on article importers than EU manufacturers due to additional costs (testing, supplier change). ×	SMEs are likely to face more difficulties to afford the costs resulting from a change in suppliers and from ensuring compliance, although they may be able to (partially) pass them on to consumers. ×	None identified. -
Industrial CR articles	Operating costs and conduct of business	Loss of turnover associated with sales of ETU but increased turnover associated with sales of alternative substances. The most recently developed alternative still requires further adjustments and REACH registration costs. ×	Manufacturing costs of industrial CR articles using alternatives are expected to be 5% more expensive than using ETU. Certification and assurance costs may apply. Lower health and safety expenses (e.g. compliance with occupational exposure controls) may partially compensate the investment. ×	Significant impacts on costs for non-EU manufacturers are expected (cost of alternatives, testing, certification, etc.), possibly driving up prices of imports. Additional testing and certification may also imply higher costs. However, most costs would be expected to be passed on to consumers ×	Smaller companies may be affected as they would require skilled professionals and resources to ensure compliance with the restriction. However, these efforts may be offset by the fact that SMEs already have an affordable alternative available that does not require significant changes in the methods of production. -	Compliance and substitution costs may be passed on to (industrial) consumers but, as CR articles are usually part of larger devices, it is expected that the price increase resulting from the replacement of ETU would be negligible in relation to the total cost of the finished product. -
	Competitiveness, Trade and Investment	Significant positive impacts are anticipated. Given that the only EU manufacturer has developed an alternative to ETU, this may offer a competitive advantage against non-EU	EU rubber article manufacturers have alternatives to choose including their own IP-protected alternative. This poses a competitive advantage against a potential restriction. However, companies that are	Importers of articles potentially containing ETU will potentially lose competitive edge due to potential increased prices of final products and extra costs (testing, change of suppliers). ×	EU rubber manufacturers SMEs have already developed their own IP protected alternative through the Safe Rubber consortium. This implies a possible competitive advantage in the event of a potential restriction. ✓	No impacts are anticipated. -

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS/ IMPORTERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
		chemical manufacturers. Additional turnover associated with sales of alternatives to non-EU manufacturers of rubber articles. ✓	not part of the SafeRubber consortium may not have access to one of the alternatives. ✓			
	Competition and the internal market	Increased competition is anticipated. The only three suppliers of ETU in the EU (a single EU manufacturer of ETU and two importers from the Far East) are likely to see their dominant position threatened by the emergence of an alternative substance developed by the article manufacturers. ✓	Increased competition. EU manufacturers of rubber articles, that currently purchase ETU from the single manufacturer of ETU in the EU (or the two non-EU importers)), should have greater choice due to the alternative supplied by the ETU manufacture and also the alternative developed via the SafeRubber project. Manufacturers outside the SafeRubber consortium may have less choice than those that are part of this consortium. ✓	EU importers of articles would face a competitive disadvantage due to the probable lack of non-proprietary alternatives to ETU abroad (i.e. compared to local producers, who already have a suitable alternative). This may limit the number of CR article suppliers. Additional costs would be related to potential tests and changes in suppliers. ×	Smaller manufacturers of rubber articles, which currently purchase ETU from the single manufacturer of ETU in the EU (or one of the importers), should have greater choice due to the alternative supplied by the ETU manufacturer and also the alternative developed via the SafeRubber project. ✓	Compliance and substitution costs may be passed on to (industrial) consumers. However, industrial CR articles are usually sold as part of larger devices (e.g. trains, cars). Therefore, it is expected that the price increase resulting from the replacement of ETU would be negligible in relation to the total cost of the finished product. Higher prices of imported products may induce substitution with articles that are - produced in the EU, thereby restricting choice. However, this is expected to be compensated by increased domestic competition. -

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS/ IMPORTERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMEs	CONSUMERS
	Innovation and research	A restriction on the use/presence of ETU in articles is expected to encourage the full development of the alternative accelerator synthesized by the ETU manufacturer. ✓	Although the majority of research has already been conducted, a potential restriction may improve the development at industrial scale of the alternative created by the SafeRubber consortium. ✓	No significant impact on innovation and research. -	Although the majority of research has already been conducted, a potential restriction may improve the development at industrial scale of the alternative created by the SafeRubber consortium, all of whom are SMEs. ✓	Benefit through greater certainty around safety of imported products. ✓
	Distributive/ Equity	Given that only one manufacturer and two importers of ETU operate within the EU, impacts on this step of the chain are expected to be concentrated on these three players. ×	No specific issues are anticipated. -	Larger impact on article importers than EU-based manufacturers due to additional costs (testing, supplier change. ×	Due to support from the Commission, European SME manufacturers have developed their own alternative to ETU. No equity adverse issues are anticipated. Small importers are likely to face more difficulties to afford the costs resulting from a change in suppliers and from ensuring compliance, although they may be able to pass them on to consumers -	No significant effects expected. -

Source: ICF/AMEC Consultation

4.9 Scoping SEA: Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate [CI Direct Black 38]

4.9.1 Introduction

This section covers the scoping-level SEA for **Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (CI Direct Black 38; CAS No. 1937-37-7)** and follows the structure defined in the introduction, concluding with the identification of considerations and elements to help ECHA and the Commission in the development of criteria for application of Article 68.2 for CMR substances in articles.

4.9.2 Regulatory status

Direct Black 38 is a benzidine-based azo dye. Under certain conditions, such substances are known to cleave metabolically at the azo bond to benzidine, a carcinogenic amine in category 1A according to its harmonised classification. Direct Black 38 itself has been classified as carcinogenic category 1B with hazard statement H350 ("may cause cancer") under the CLP regulation.

Direct Black 38 is being proposed by the Netherlands to be identified as a substance meeting the criteria of Article 57 (a) of REACH owing to its classification as carcinogen category 1B. The corresponding Annex XV SVHC dossier was published in August 2013.

The substance is already restricted by REACH Annex XVII Entry 28. Therefore it is not allowed to be used in substances and preparations placed on the market for sale to the general public in individual concentrations equal to or greater than 0.1% w/w or other relevant concentration limit. This restriction does not apply to the use of the substance in articles, hence the potential need for restriction under Article 68.2).The use of Direct Black 38 is also prohibited in cosmetic products[122], as well as restricted in leather and textile articles through REACH Annex XVII Entry 43 which restricts the use of azo dyes that could led to the presence of benzidine in final articles under certain conditions (detailed in section 4.9.3.2.2).

4.9.3 Uses of the substance

4.9.3.1 Overall quantities manufactured and imported

EU manufacture and import of the substance and mixtures containing the substance is assumed to be relatively limited as the substance has not been registered under REACH, despite the relevant registration deadline having passed (Annex XV SVHC Dossier, 2013). The Annex XV SVHC dossier (2013) on Direct Black 38 indicates that several companies supplying Direct Black 38 have been consulted. Two companies confirmed that the substance is not manufactured in the EU but imported into the EU, with the total amount less than 500 kg. Therefore the primary route into the EU mainly relates to potential import in articles coloured with the substance.

4.9.3.2 Use in articles

4.9.3.2.1 Overview

C.I. Direct Black 38 has historically been used for the dyeing of textiles (i.e. cotton, silk, wool and jute), leather and paper. Use in plastics, inks, wood, biological materials, and hair dyes

[122] Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

is also mentioned in the literature (Annex XV SVHC Dossier, 2013). Environment Canada (2009b) reports that Direct Black 38 has been primarily used in the textile industry.

Since Direct Black 38 can be used to dye articles available to consumers and there is potential for consumer exposure through dermal or oral contact with such dyed articles. In particular, Direct Black 38 is characterized by high water solubility and free benzidine may be metabolically released by reductive cleavage of the azo bond (Annex XV, 2013).

One public agency has indicated through consultation that the typical concentration of Direct Black 38 in articles is estimated to be below 0.1%.

The extent to which Direct Black 38 is currently used and imported in articles is unknown, although it is expected to be low (Annex XV SVHC Dossier, 2013) due to existing restrictions and increased awareness of its CMR properties. According to information received from the ETAD, Direct Black 38 is expected to be no longer on the European market, either as such or in the form of finished articles available to consumers. However, it should be noted that products dyed with Direct Black 38 may be imported unknowingly into the EU in manufactured items, or may be commercialised in small quantities which hinder the collection of data. In this sense, data from the ECHA classification and labelling inventory suggest that the substance could still be used by a considerable number of European companies, because there are several notified classifications (Annex XV SVHC Dossier, 2013).

Available literature indicates that main applications of Direct Black 38 are the dyeing of textiles, leather and paper, with other minor uses such as plastics also being mentioned (Annex XV, 2013). Information on usage of the substance in such types of articles is presented in the following sections.

4.9.3.2.2 Textiles and leather

Direct Black 38 has been mainly used in the dyeing of textile and leather articles. In particular, it has been typically used to dye cotton and other cellulosic fibres due to its high affinity for cellulose (Environment Canada, 2009b). In this sense, it was reported that in Japan about 60% of Direct Black 38 was used for dyeing fibres and 20% for dyeing leather (IARC, 1982 as cited in RIVM, 2008).

Over recent decades, health concerns linked to the potential cleavage of Direct Black 38 to the carcinogenic amine benzidine in final textile/apparel articles have encouraged a shift to other dyes and led to the implementation of legislative measures that restrict its usage in such articles.

In the EU, the use of Direct Black 38 in textiles and leather is already restricted through REACH Annex XVII Entry 43, which repealed the Azo colorants Directive 2002/61/EC. Previously, benzidine-based azo dyes had been restricted in Germany from 1994 as well as in Austria and the Netherlands (RIVM, 2008). According to Entry 43, textile and leather articles produced or imported into the EU that may come into direct and prolonged contact with the skin or oral cavity are not allowed to contain azo dyes, which by reductive cleavage may release certain aromatic amines, including benzidine. The threshold limit for the detection of the prohibited amines, allowed to be found in the article or in the dyed parts thereof is 30 ppm for each amine (i.e. above 30 mg/kg). Imported textiles are controlled by retailers and authorities with the results being communicated via the RAPEX system. According to the Ministry of Foreign Affairs of the Netherlands (2012) most of the textile products, placed on the EU market comply with the restriction on azo dyes with test institutes reporting that the vast majority of samples tested today are compliant (Centre for the Promotion of Imports from developing countries (CBI), Ministry of Foreign Affairs of the Netherlands, 2012).

The Regulation does not give a list with the names of dyestuffs that are prohibited. This means that azo dyes which do not release one of the listed amines above the regulatory thresholds in final articles are allowed to be used. In addition, those textiles that are not in

direct or prolonged contact with skin are not covered by the regulation. Consumer exposure to textiles and leather coloured with Direct Black 38 may, in theory, therefore still occur in the EU. As European manufacturers have moved away from this substance, it is expected that the main route of exposure is through articles imported from other countries with less strict regulations/controls. In this sense RAPEX is still reporting the presence (sometimes above regulatory thresholds) of benzidine in textile and leather products (Annex XV, 2013).

However, restrictions on the use of benzidine-based dyes in textiles have also been introduced in other jurisdictions outside the EU (SGS Consumer Testing Services, 2012), including mayor exporters of textile products into the EU such as China[123] and India[124] with regulations dating back to 2005 and 1993 respectively. The European Apparel and Textile Confederation has indicated that, due to the fact that Direct Black 38 is restricted under the OEKO-TEX® Standard 100, it is likely that this dye is no longer present/in use in the EU textile market, although it notes that it might be in use outside the EU and present in imported textiles.

4.9.3.2.3 Paper and other minor uses

With regards to the use of Direct Black 38 in other articles, such as paper, limited information has been identified, although it suggests that that it is likely to be barely used. Literature suggests that benzidine-based dyes are not used in paper applications such as diapers, handkerchiefs and toilet paper (COWI, 2003). The EUPIA has published a voluntary exclusion list for printing inks and related products, which includes azo dyes which can decompose in the body to bio-available carcinogenic aromatic amines of category 1A and 1B according to the CLP Regulation (EC) No. 1272/2008, including benzidine. Through consultation they have confirmed that Direct Black 38 is not used by the European printing ink industry (i.e. for inks produced in the EU).

In addition, Direct Black 38 does not appear to be used in the Toy Industry by their members for the manufacture of toys. Other packaging associations such as FEFCO (European Corrugated Board Manufacturer) indicate that Direct Black 38 is not of relevance for their industries. They note that due to its CMR properties it is unlikely that this substance is used in the food packaging sector. In this sense European Resolution AP 89(1)[125] on the use of colorants in plastic materials coming into contact with food states that the content of benzidine singly or in total should not exceed 10mg/kg.

4.9.3.3 Trends

As is clear from the data in Section 4.9.3.2, there has been a significant trend away from the use of Direct Black 38. According to Environment Canada (2009b), manufacturers began moving away from the use of benzidine-based dyes such as Direct Black 38 in the mid to late 1970s and replacing them with other dyes due to human health concerns. In particular, industry seemed to be particularly concerned about occupational safety. In this sense, one of the EU associations contacted in the consultation indicates that the substance was phased out in view of the occupational hazards in the late 1980s regardless the end application.

Although, the extent of the presence of the substance in articles, and the associated potential for exposure of consumers is unknown, evidence reviewed in the preceding section suggests that the global use of the substance in consumer articles is expected to be limited and in decline (Annex XV, 2013; Environment Canada, 2009b). Given that Direct Black 38

[123] Consultation has revealed that, although the substance is used and supplied in China (at least 36 suppliers), its use has been prohibited in the Chinese textile industry since 2005. Azo dyes releasing carcinogenic amines are currently banned through the GB 18401-2010 “National general safety technical code for textile products“.

[124] The handling of Direct Black 38 and 41 other benzidine-based dyes has been prohibited since 1993 in India, with an additional 70 azo dyes being prohibited since 1997 (Environment Canada, 2009).

[125] Resolution AP (89) 1 on the use of colourants in plastic materials coming into contact with food. http://www.coe.int/t/e/social_cohesion/soc-sp/public_health/food_contact/RESOLUTION%20AP%20-%2089%201%20ON%20COLOURANTS.pdf

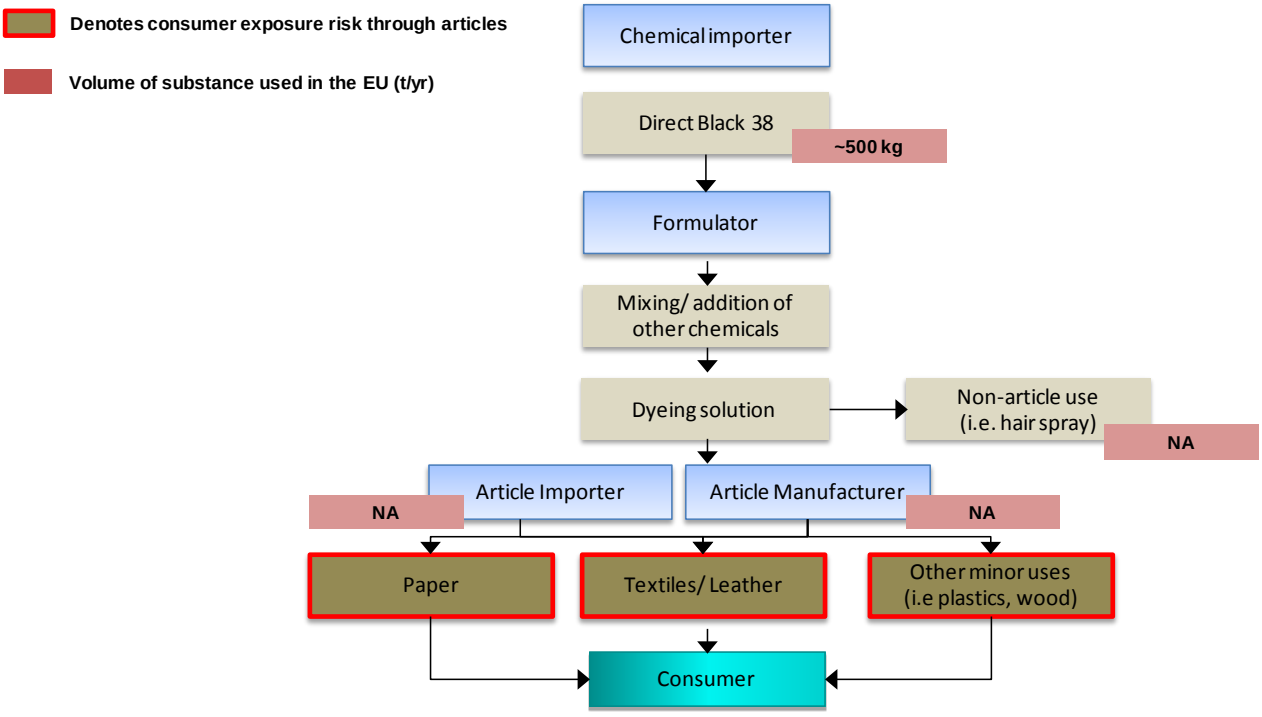
has been mainly marketed for textile applications its use is likely to have decreased substantially, not only at EU level but also worldwide, due to the introduction of regulations limiting the use of azo dyes that can cleave to benzidine in several jurisdictions. Its CMR properties and the proposal to identify it as SVHC are likely to drive a further replacement of Direct Black 38 in consumer articles over the coming years. In this sense (as mentioned above) it has been reported that several international companies have benzidine based dyes listed in their internal lists of restricted substances even if they are not covered by specific regulations.

4.9.4 Supply chains affected

The figure below provides an overview of the key stages in the supply chain related to the use of Direct Black 38 in consumer articles. This is clearly a simplification but does serve to highlight the key players in the supply chain. Those of particular importance for the scoping SEA are the potential importers of the substance; producers or importers of articles coloured with Direct Black 38; and consumers. As indicated previously Direct Black 38 is not manufactured in the EU and is only imported in small quantities. Although the extent to which the substance is currently used is likely to be low, there remains a possibility that a number of companies are producing or importing goods that may have been dyed with Direct Black 38. However, no robust data on quantities can be identified.

Direct Black 38 is formulated to contain additional chemicals to maintain the desired properties of the dye and to ensure effectiveness in the dying process. These can include de-dusting agents (e.g., hydrocarbon oils) as well as diluents to standardise dye strength, wetting agents and bacteriostats (ETAD 1995 as cited in Environment Canada, 2009b). The final content of the active dye can therefore differ across formulations. As this information is usually confidential it may explain why there is limited information on the physical and chemical properties of Direct Black 38 (Environment Canada, 2009b).

Table 4.28 Summary of supply chains of Direct Black 38 [~500kg]



Source: ICF/AMEC Consultation

4.9.5 Expected non-use scenario

During the preparation of the scoping SEA, a consultation exercise with industry was undertaken to ascertain anticipated responses to a restriction on the use/presence of use of Direct Black 38 in consumer articles. A number of key stakeholders were selected from the 171 organisations contacted during the first round of consultation. This was done according to the answers provided and their expertise. Relevant organisations that were not previously considered were also included in phase 2 of the study in order to close identified knowledge gaps. In total 19 organizations were contacted for detailed consultation on Direct Black 38, as detailed below. The number of respondents and the amount of information gathered through consultation was limited, despite making numerous requests for information.

Table 4.29 Consultation exercise

	Type of industry/article	Stakeholders contacted	Valuable responses received
Trade/industry associations	Dyes, paper, packaging, textiles, inks, plastics, toys.	10 European 4 International	6 European 1 International
Private companies	Colorant manufacturers/importers.	5 all with EU representation	No responses.

Source: ICF/AMEC Consultation

The non-use scenarios have been developed primarily based on the views of relevant industry associations, supplemented by expert judgement taking into account the literature on the use of Direct Black 38. The literature review has indicated that the main applications and thus the sources with greatest potential for exposure of consumers relate to dyed textiles, leather and paper (Annex XV SVHC Dossier, 2013).Taking this into account and acknowledging existing restrictions covering dyed leather and textile articles, the analysis has been mainly focused on potential scenarios restricting Direct Black 38 in these articles.

The anticipated non-use scenarios at each key stage of the supply chain are described below, covering importers of Direct Black 38, downstream users of Direct Black 38 and consumers of the final articles.

4.9.5.2 Importers of Direct Black 38

Available information (Annex XV SVHC Dossier, 2013) and REACH registration data suggest that Direct Black 38 is only imported in small quantities. Therefore it would be reasonable to assume that a total restriction on Direct Black 38 in all types of articles is unlikely to cause a major impact on such importers in terms of job losses. These will seek to import alternative colorant substances for use in articles.

4.9.5.3 Producers of articles dyed with Direct Black 38

In the case of a total restriction on Direct Black 38 in the production of consumer articles, producers of these articles are expected to avoid the use of Direct Black 38 and its related formulations (i.e. inks). Manufacturers will have to replace the substance with alternatives and might be required to demonstrate that it is not present in the final article. The limited quantities involved and the presence of existing prohibitions elsewhere suggest that suitable alternatives are available.

4.9.5.4 Importers of articles dyed with Direct Black 38

In the case of a total restriction on Direct Black 38 in articles, importers of such articles are expected to introduce mechanisms to ensure that these are not dyed with Direct Black 38. The fact that Direct Black 38 has been subjected to restrictions for a long time in the EU and in other jurisdictions such as India (since 1993) suggests that alternatives are readily available worldwide.

European firms importing coloured articles might face additional costs associated with the need to demonstrate that their imported products are compliant with the restriction. Generally, this can be done by requiring their non-EU suppliers to provide evidence of non-use (e.g. certificate, declaration or documented test results); but in certain cases importers may decide to test themselves for the presence of the substance (e.g. if suppliers do not collaborate or for certain products directly sold to consumers such as textiles).

A key issue would be the wording of any restriction. If the restriction only limits use of Direct Black 38 in manufacture of consumer articles, without restricting the presence of Direct Black 38 in articles, imports of articles containing the substance could potentially increase (i.e. if non-EU companies are not affected by the restriction).

4.9.5.5 *Consumers*

Assuming that relevant articles can be dyed with alternative substance(s) that can provide comparable technical capabilities to Direct Black 38, consumers will continue to purchase articles without any change in their satisfaction levels. However, the extra costs resulting from compliance with the restriction (including administrative and testing costs) may be passed on to consumers.

4.9.6 Assessment of economic and social impacts

This section provides estimates of the likely economic impacts of responses to the non-use scenarios. The impacts are based on a review of information provided through industry consultation, as well as expert judgement informed by a review of literature sources.

4.9.6.1 *Identification of main impacts*

The first step in the SEA is the identification of the main impacts and stakeholders potentially affected by a possible restriction on Direct Black 38 in all types of consumer articles. Analysis is focussed on those stakeholders most affected by the possible restriction and considers the nature and scale of the impacts, following the SEA principles in relation to the possible costs and benefits. Categories of impact are shown in Annex 1. The following sections provide an appraisal of potential impacts for the identified stakeholders.

4.9.6.2 *Economic impacts*

4.9.6.2.1 *Importers of Direct Black 38*

One source (OECD, 2005 as cited in Annex XV SVHC Dossier, 2013) indicates a price of around $US 3 per kg for Direct Black 38. If there was a total prohibition on its use/presence in articles there is likely to be a negative impact on sales of the importers of Direct Black 38 which may be in the order of a few hundred or thousand Euros per year, based on an estimated quantity of 500 kg of Direct Black imported into the EU each year. The loss of these sales would potentially be offset by sales of alternatives.

4.9.6.2.2 *Manufacturers of articles dyed with Direct Black 38*

Following existing restrictions on the use of CMR substances and azo dyes, especially in leather and textile articles, the EU manufacturing sector has moved towards safer alternatives (Annex XV SVHC Dossier, 2013). Therefore, in the case of a total restriction on the use of Direct Black 38 in all types of articles, it is assumed that manufacturers of such articles (e.g. paper) containing Direct Black 38 would substitute away from the presence of this substance in their products.

Currently it is clear that the substance has been replaced by alternative dye products for EU textile dying products (Annex XV SVHC Dossier, 2013), although there is relatively little information on specific alternatives. The synthesis of trisazo dyes derived from 4,4′-diaminodiphenylsulphide is mentioned in the literature (Zhang, Cheng and Yang, 1999) as a substitute to Direct Black 38. One source (OECD, 2005 as cited in Annex XV SVHC Dossier, 2013) indicates that Direct Black 38 can be substituted by Direct Black 22, which does not

contain benzidine although it can be about 2-3 times more expensive. The cost of Direct Black 38 was around $US 3 per kg whereas the cost of Direct Black 22 was around $US 8-10 per kg at the time of that publication (Annex XV SVHC Dossier, 2013). The relative prices may have changed in the intervening years but more recent data are not available. One consultation document on the implementation of the European Azo colorants directive 2002/61/EC developed by the UK DTI and DEFRA (2003) indicates that substitutes for azo dyes that could cleave to aromatic amines in textile and leather articles, which includes those based on benzidine, were already available at little extra cost and concluded that any company still using the restricted azo dyes would experience little difficulty or expense in switching to alternatives.

With regards to other applications there is little information on alternatives available, although it is reasonable to assume that alternatives are probably widely used in non-textile uses, as is the case with textile and leather articles, given the small quantities of Direct Black 38 currently imported into the EU. Therefore it is considered likely that the implications of a restriction would be limited for manufactures of other type of articles, at least in terms of the total market.

4.9.6.2.3 *Importers of articles dyed with Direct Black 38*

Existing restrictions on Direct Black 38 across several jurisdictions suggest that there are suitable alternatives worldwide to this substance at least in textile and leather articles. These being the main reported uses of Direct Black 38 it is likely that it has also been substituted with regards to other applications such as paper. In this sense the international colorant association ETAD, has indicated in the consultation that Direct Black 38 will not be marketed by ETAD companies for consumer applications.

Nonetheless, there remains a possibility that Direct Black 38 may be present in imported goods from other parts of the world in cases where dyes are not supplied by ETAD members or where not covered by any restrictions. In addition, it is unclear how rigorously existing restrictions in other countries are being enforced. In this sense, nearly all textile and leather articles for which RAPEX alerts were issued in 2009-2012 because of too high levels of benzidine came from China or India, despite existing restrictions on the use of benzidine based dyes such as Direct Black 38 in textiles (Annex XV SVHC Dossier, 2013) (see section 4.9.3.2). Even so, the volume of the substance entering the EU is considered to be low and its total prohibition is unlikely to cause significant impact although it may cause some modest additional costs. Some firms may need to find alternative suppliers if their current imports of dyed goods are found to contain Direct Black 38. In this sense, compliance costs to demonstrate that imported products are free from Direct Black 38 could also increase, especially if it is necessary to carry out tests.

With regards to this, the consultation document on the implementation of the European Azo colorants directive 2002/61/EC (currently REACH Annex XVII Entry 43) developed by the UK DTI and DEFRA (2003) indicates that if EU importers cannot secure reliable evidence from their overseas suppliers that their products do not contain azo dyes affected by the prohibition (such as Direct Black 38) then they will need to conduct tests themselves in line with methods developed by the Commission. According to this study the costs of these tests can be in the order of £105 and £126 per test and involve the destruction of the sample of material tested (at current 2013 prices this would be around €180 and 220€[126]).

Based on the information available, which suggests that Direct Black 38 is used in annual volumes below 1 tonne by several European companies, it is possible that small companies are the ones that would be most affected by a ban on Direct Black 38. These companies are likely to face more difficulties to afford the costs resulting from a change in suppliers and

[126] These have been calculated using an exchange rate (2003) of 0.701 and HICP statistics for 2003 and 2013.

from ensuring compliance, although they may be able to pass them on to consumers (UK DTI and DEFRA, 2003).

4.9.6.2.4 Consumers

Consumers may face additional costs if companies raise the prices of the final articles in order to compensate for more expensive alternative dyes or increasing compliance costs (i.e. running tests). However, with regards to its main applications on textiles and leather, the consultation carried out by the UK government on the implementation of the European Azo colorants directive 2002/61/EC concluded that any price increase resulting from the azo dye substitution would be negligible in relation to the total cost of the finished product. It is likely that this statement is also valid for other applications.

4.9.6.3 Social impacts

It is expected that the current level of employment by European manufacturers of articles that could be dyed with Direct Black 38 would not be significantly affected by a restriction on Direct Black 38 in paper, textile and leather articles, due to the small share of the overall markets and the availability of alternative substances

However, if there are any impacts, it is worth noting that smaller companies may be more significantly affected as they would require skilled professionals and resources to ensure compliance with the restriction. If they cannot afford to channel resources, time and effort to implementing alternative dyes, they may be driven out of business in the longer term, which would potentially result in job losses. However, the number of companies potentially affected is likely to be very small due to the low quantities of Direct Black 38 involved.

It is of note that Entry 28 of REACH Annex XVII, which prohibits its direct use in consumer products (preventing supply of the substance itself and mixtures), does not apply to the use of the substance in imported articles. A restriction could therefore serve to improve the competitive position of EU firms as compared to non-EU firms, as they would both then only supply o-anisidine-free articles onto the EU market, which could have associated benefits in terms of jobs.

4.9.6.4 Administrative costs

Due to the fact that Direct Black 38 is already subject to strict controls in its main applications (textiles and leather) it is not expected that a total ban would result in significant additional administrative costs. The main costs are likely to be in demonstrating compliance e.g. monitoring reports to authorities if requested. Procedures and test methods currently listed by the Commission to demonstrate compliance with existing requirements covering azo dyes in leather and textiles may need to be modified or extended to cover other applications.

4.9.6.5 Human health and environmental impacts

In the light of existing azo dyes restrictions, any usage of articles dyed with Direct Black 38 in the EU is thought to be minimal, especially in the textile and leather industry. However, if goods dyed using the substance are still being commercialised in the EU, a total restriction of Direct Black 38 in consumer articles would result in human health and environmental benefits through reduced exposure levels.

4.9.6.5.1 Environmental impacts

No EU risk assessment has been identified for Direct Black 38, but the Canadian Government (Environment Canada, 2009b) has developed a screening risk assessment related to the environment. Relevant conclusions are:

- Potential releases of Direct Black 38 to the Canadian environment during the formulation and consumer use of products containing this substance are estimated to be 15% to sewers and 85% transferred to waste disposal sites.
- Direct Black 38 has high water solubility.

- Dyes have an inherently high affinity to substrates, and a potentially large proportion can be removed during sewage treatment as a result of such substances being adsorbed to sludge.
- Direct Black 38 will persist in aerobic environments (water, soil, sediment) but exposure to aquatic organisms would be limited. In addition, experimental toxicity data for Direct Black 38 and other disulfonated acid dyes suggest that this substance is not expected to cause acute harm to aquatic organisms at low concentrations.

Under a conservative exposure scenario in which an industrial operation discharges this substance into the aquatic environment through a single sewage treatment plant and where the reporting threshold of 100 kg was used to conservatively estimate release and exposure levels, the study concluded that "*Direct Black 38 is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, or that constitute or may constitute a danger to the environment on which life depends*".

In view of the small quantities of Direct Black 38 that seem to enter the EU market, we could assume similar conclusions for the EU. The baseline environmental impacts are therefore likely to be minimal and so the potential reduction in risks (i.e. environmental benefits) through a restriction is also likely to be minimal.

4.9.6.5.2 Health impacts

Consumers may be exposed through dermal and oral contact with articles dyed with the substance (Annex XV SVHC Dossier, 2013). RIVM (2008) indicates that the critical effects observed in animals for benzidine based dyes were bladder cancer and liver cancer; although this does not necessarily mean that these types of cancer will be observed in humans.

The Annex XV SVHC report (2013) includes "indicative" worst-case exposure estimates and risk characterization ratios (RCR) derived using ECETOC-TRA and Consexpo software:

- Clothing: 37 mg/kg/day (dermal) and 0.16 mg/kg/day (oral) with an RCR of 2.5×10^{7}
- Leather furniture: 5.5 mg/kg/day (dermal) with an RCR of 3.7×10^{6}
- Printed paper: 3.3×10^{-4} mg/kg/day (dermal plus oral) with an RCR of 220

This "indicative" risk characterisation then considered a NSRL (No Significant Risk Level) from the California OEHHA Toxicity Criteria Database of 1.5×10^{-6} mg/kg bw/day (oral) as a basis for comparison with the exposure estimates. Based on this, the report concludes that "it is clear that this screening level risk assessment indicates potential exposure significantly higher than established no significant risk levels. However, the above should be treated with caution given that NSRL values are based on a risk level of 1 in 10^{5}, so the RCRs could never in practice be as high as those calculated here. This suggests that, if there is a real indication that the substance is still used in the EU, further refinement of the exposure and potentially hazard data would be required before any robust conclusions could be drawn on the likely scale of such risks. It should be noted that there is minimal information available on current uses in consumer products, and that the exposure and hazard elements of the risk characterisation have not been refined."

In addition, RIVM (2008) has developed a health IA focusing on benzidine based dyes. The aim of the study was to quantify the (potential) health gains resulting from an implemented policy measure (in this case the EU restrictions on azo dyes in textiles articles through REACH Annex XVII) in terms of 'Disability Adjusted Life Years' (DALY) which is equivalent to the number of healthy life years lost by disease in a population. Different measured or estimated (assumed) data on the amount of substance in the product, frequency and duration of exposure, among others, were used. The size of the exposed target population

was also estimated. For benzidine based dyes, the DALY calculations resulted in high values. Before the restriction on azo dyes in textiles and leather articles 280,000 DALYs were calculated assuming a prevalence ratio in textiles of 25% and a target population of 16 million subjects. This means that, when exposure to benzidine azo dyes is ultimately eliminated the maximal health risk reduction would be around 280,000 DALYs.

However, the study notes that the uncertainty in the derivation of the DALYs is large, mainly in relation to the exposure assessment and the toxicology of the compounds. Any reduction in DALYs from a restriction on Direct Black 38 in consumer articles is likely to be only a very small fraction of the numbers estimated above.

4.9.7 Overall conclusions on potential costs and benefits

Overall, whilst use of the substance in articles commercialised in the EU cannot be ruled out, evidence reviewed and consultation suggests that actual use of Direct Black 38 is likely to be minimal. In this context, it is unlikely that the prohibition of Direct Black 38 would cause a major economic impact and extra costs to EU companies or consumers. If some of the current imports of goods have been dyed using Direct Black 38, the prohibition will reduce the negative health and environmental impact due to exposure to these products and also result in a more level playing field between EU and non-EU companies, who would both only sell articles free of the substance on the EU market.

4.9.8 Substance specific considerations for development of draft criteria to implement article 68.2 to CMR 1A and 1B substances in consumer articles

This section firstly includes consideration of issues that are important in determining whether Article 68.2 restriction is potentially most appropriate, compared to other forms of restriction. Following this, the identified socio-economic issues that it would be important to take into account in assessing the merits of a restriction are discussed.

With regard to the potential choice of Article 68.2 as a RMO (compared to other forms of restriction), the following considerations arise from this case study substance:

- Direct Black 38 can cleave to carcinogenic amine benzidine in final articles and there is a potential for exposure of consumers. If there were no exposure possible, it would presumably be difficult to justify any restriction. *Criteria could therefore take into account whether the available evidence indicates that consumer exposure cannot be ruled out, because if this is not the case, it may be difficult to justify this restriction.*
- The presence of Direct Black 38 in articles available to consumers on the EU market cannot be ruled out and, based on data from RAPEX; it is present in imported articles, even in uses where it is already restricted. *Criteria could therefore take into account whether the substance is actually present within articles available to consumers and commercialised in the EU.*
- *Criteria for the application of Article 68.2 clearly need to take into account the level of uncertainty related to use, exposure and risks to the consumers with a substance. Amongst any group of substances, there will always be some with more information than others.*
- It is important to note that the substance is already subject to general and specific restrictions under REACH Annex XVII, including a restriction that covers its main application in leather and textile articles, limiting the use, import and marketing of manufactured or imported textile and leather articles dyed with the substance. Under Article 68.2 these restrictions could be potentially extended, preventing the use of all type of articles dyed with the substance. However, given that the extent of actual use (as well as exposure) of the substance in manufactured or imported articles is unknown and likely to be limited, an additional restriction could potentially impose extra costs on EU companies and authorities (e.g. by way of testing the presence of the substance) with

potential little benefit if the substance is barely used both in the EU and abroad. Such restriction might therefore not be cost-effective. *Criteria could therefore also take into account the additional benefits of a restriction compared to other restrictions already in place.*

Having determined that an Article 68.2 restriction is potentially suitable, there are a number of socio-economic issues arising from this case study that are relevant to deciding whether this simplified route is likely to be suitable:

- Techniques are available to detect the presence of benzidine based dyes such as Direct Black 38 in articles (including imported articles). *Criteria for selection of the Article 68.2 restriction route would presumably need to take this into account to ensure that non-compliance can be identified (and compliance demonstrated).*
- The substance is not manufactured in the EU and its use by EU companies appears to be minimal. Therefore, putting forward Direct Black 38 for a restriction under Article 68.2 would likely have a relatively limited impact upon the EU industry in in terms of economic activity and employment. *Criteria could therefore take into account situations such as this where there is a reasonable expectation that there would be a negligible impact on EU industry.*
- Information available and existing restrictions in third countries (i.e. China, India) suggest that the global colorant industry has moved away from the use of the substance (especially in the leather and textile industry) due to health concerns and that suitable alternatives are available worldwide. In addition it has been voluntarily included in several international company "black-lists" of restricted substances even if final article use is not covered by legislation. *Criteria could therefore take into account whether there is a need to address an already reducing (or eliminated) risk to ensure future consumer health protection by avoiding any future increase in use or import of articles containing the substance.*
- It is also clear from the extent of the presence of restricted dyes (or its resulting carcinogenic amines) in uses that are already restricted (e.g. textiles) that ensuring compliance with restrictions for imported articles can be problematic. This is evidenced by information from RAPEX (which shows that benzidine is still identified in textile articles) and is just as true for 'standard' restrictions as it is for restrictions under Article 68.2. In particular, based on the information gathered which shows that the substance is only imported in small quantities (below 1 tonne) it is speculated that a total restriction on Direct Black 38 is likely to affect the most small companies which may not be aware of REACH requirements or may not have the knowledge or resources to identify if the products that are importing are compliant with the regulation. *Criteria should therefore take into account whether there are any characteristics of the industry sectors affected (e.g. large numbers of SMEs) that would potentially lead to disproportionate costs.*

Table 4.30 Identification of relevant impacts by stakeholder group, impact category and supply chain

✓ - Benefit or positive outcome;
- No or insignificant anticipated impact;
× - Cost or negative outcome.

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS/IMPORTERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMES	CONSUMERS
Textiles and leather	Operating costs and conduct of business	No or insignificant impact is anticipated as production of Direct Black 38 has ceased in Europe and only minimal quantities appear to be imported. Alternative colorant substances for use in articles are available for import. -	No or insignificant impact anticipated as evidence suggests that the EU manufacturing sector has moved towards safer alternatives in production lines of textiles/leather (minimal import). Potential increase in costs could be related to the need to demonstrate compliance; however manufacturers are already required to demonstrate that they comply with existing restrictions under Annex XVII on textiles. -	Potential impact on costs. A ban would exert pressure to check whether products they supply comply, either through obtaining information from suppliers (certification/declaration or test results) or by undertaking their own testing. They would also need to bear (and pass on to consumers) any potential increase in costs of articles using alternatives. However, due to the fact that Direct Black 38 is already subject to strict controls in textiles and leathers it is not expected that a total ban will result in significant additional costs (i.e. already used to testing methods). ×	Due to existing restrictions on textile and leather articles, no major cost impacts are expected and so no specific issues identified for SMEs. However, SMEs may find it more hard to exert pressure on suppliers to demonstrate compliance and/or to bear the costs of doing so themselves, although they may be able to pass them on to consumers. -	Compliance and substitution costs may be passed on to consumers but It is expected that price increase resulting from the replacement of Direct Black 38 would be negligible in relation to the total cost of the finished product. -
	Competitiveness, Trade and Investment	No impact for producers anticipated as production has ceased in the EU. Importers could offset the loss of sales with more	Evidence suggests that the EU manufacturing sector has moved towards safer alternatives. A restriction may close the gap (under the baseline) between	Article importers potentially containing Direct Black 38 will potentially lose competitive edge due to potential increased prices of final products and extra costs (testing, change of suppliers). However, the volume of the substance entering the EU is	No specific issues for SMEs identified.	Not applicable.

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS/IMPORTERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMES	CONSUMERS
		expensive alternatives. -	domestic manufacturers and non-EU exporters regarding the use of Direct Black 38 in articles, potentially leading to improved competitiveness. However, there could also be a negative impact on competitiveness for EU companies if they can no longer supply articles to global markets while non-EU companies can. ✓ and ✗	considered to be low due to existing restrictions in third countries and its total prohibition is unlikely to cause significant impact (companies are already used to tests). In addition increase in article prices as a result of dye substitution are not expected to be significant. ✗		
	Competition and the internal market	No impact for producers of Direct Black 38 is anticipated as production has ceased in Europe. Importers may face a competitive disadvantage while they search for potential suppliers of alternative dyes. Due to small quantities involved impact is expected to be insignificant. -	Evidence suggests that the EU manufacturing sector has moved towards safer alternatives in production lines of textiles and leather. In the event of a total restriction, they could benefit from a competitive advantage. ✓	EU importers of articles would face a competitive disadvantage if their current imports of dyed goods are found to contain Direct Black 38. Additional costs would be related to potential tests and changes in suppliers. Even so, the volume of the substance entering the EU in textiles is considered to be low due to existing restrictions in third countries and its total prohibition is unlikely to cause significant impact on internal competition. ✗	No specific issues for SMEs identified. -	No significant impacts for consumers identified.

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS/IMPORTERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMES	CONSUMERS
	Innovation and research	No or insignificant impact is anticipated as production has ceased in Europe and only small quantities appear to be imported. -	No or insignificant impact anticipated as evidence suggests that the EU manufacturing sector has moved towards safer alternatives in production lines of textiles and leather. -	Although alternatives seem to be readily available, importers may explore new dyeing possibilities. Impact of redirection of research activities towards regulatory compliance (as opposed to genuine search for market driven innovations) is not expected to be significant due to existing restrictions (i.e. already subject to regulatory controls). ✓	No specific issues for SMEs identified. -	No impacts anticipated. As the use of benzidine based dyes in textiles is already restricted the benefit of innovation compared to the baseline is expected to be noticeable or marginal. -
	Distributive/Equity	No impact is anticipated as production of Direct Black 38 has ceased in Europe and only small quantities appear to be imported. -	Evidence suggests that the EU manufacturing sector has moved towards safer alternatives in production lines of textiles and leather. A restriction could improve competitiveness of EU firms compared to non-EU companies that may currently use Direct Black 38 ✓	Importers are probably the most impacted stakeholder due to additional costs (demonstrating compliance, passing on price of alternatives, supplier change). However, all costs would be expected to be passed on to consumers. ×	SMEs are likely to face more difficulties to afford the costs resulting from a change in suppliers and from ensuring compliance, although they may be able to pass them on to consumers. ×	No impacts are anticipated
Paper	Operating costs and conduct of business	No or insignificant impact is anticipated as production of Direct Black 38 has ceased in Europe and only small quantities appear to be imported. Alternative colorant	No significant impact anticipated as quantities of Direct Black 38 used by the EU industry are expected to be minimal. EU article manufacturers are already using alternatives in	Potential impact on costs. A ban would exert pressure to check whether products they supply comply, either through obtaining information from suppliers (certification/declaration or test results) or by undertaking their own testing. They would also need to bear (and pass on to consumers)	No major cost impacts are expected due to small quantities involved and so no specific issues identified for SMEs. However, SMEs may find it more hard to exert pressure on suppliers to demonstrate compliance and/or to bear	Compliance and substitution costs may be passed on to consumers but It is expected that price increase resulting from the replacement of Direct Black 38 would be negligible in relation

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS/IMPORTERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMES	CONSUMERS
		substances for use in articles seem to be available for import. -	production lines. However, a ban would exert pressure to demonstrate compliance which may involve additional costs for manufacturers; ✗	any potential increase in costs of articles using alternatives. ✗	the costs of doing so themselves, although they may be able to pass them on to consumers. -	to the total cost of the finished product. -
	Competitiveness, Trade and Investment	No impact for producers anticipated as production has ceased in the EU. Importers could offset the loss of sales with more expensive alternatives. -	Evidence suggests that the EU manufacturing sector has moved towards safer alternatives in production lines of ink for paper. A restriction may close the gap (under the baseline) between domestic manufacturers and importers regarding the use of Direct Black 38 in articles, potentially leading to improved competitiveness. However, there could also be a negative impact on competitiveness for EU companies if they can no longer supply articles to global markets while non-EU companies can. ✓ and ✗	Article importers potentially containing Direct Black 38 will potentially lose competitive edge due to potential increased prices of final products and extra costs (testing, change of suppliers). However, article price increases as a result of dye substitution are not expected to be significant and cost may be passed on to consumers. ✗	No specific issues for SMEs identified.	Not applicable.

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS/IMPORTERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMES	CONSUMERS
	Competition and the internal market	No impact for producers of Direct Black 38 is anticipated as production has ceased in Europe. Importers may face a competitive disadvantage while they search for potential suppliers of alternatives but this expected to be minimal due to small quantities involved.	Evidence suggests that the EU manufacturing sector has moved towards safer alternatives in production lines. In the event of a total restriction, they could benefit from a competitive advantage. ✓	EU importers of articles would face a competitive disadvantage if their current imports of dyed goods are found to contain Direct Black 38. Additional costs would be related to potential tests and changes in suppliers, although these may be passed on to consumers. ×	No specific issues for SMEs identified.	No significant impacts for consumers identified..
	Innovation and research	No or insignificant impact is anticipated as production has ceased in Europe and only small quantities appear to be imported. -	No or insignificant impact anticipated as quantities of Direct Black 38 used by the EU industry are expected to be minimal. EU manufacturers of articles appear to be already using alternatives to Direct Black 38 in production lines. -	Although alternatives seem to be readily available, importers may explore new dyeing possibilities. Impact of redirection of research activities towards regulatory compliance (as opposed to genuine search for market driven innovations) is not expected to be significant due to small quantities involved and availability of alternatives. ✓	No specific issues for SMEs identified. -	No impacts anticipated.
	Distributive/Equity	No impact is anticipated as production of Direct Black 38 has ceased in Europe and only small quantities appear to be	Evidence suggests that the EU manufacturing sector has moved towards safer alternatives in production lines of textiles and leather. A	Importers are probably the most impacted stakeholder due to additional costs (demonstrating compliance, passing on price of alternatives, supplier change). However, all costs would be expected to be passed on to	SMEs are likely to face more difficulties to afford the costs resulting from a change in suppliers and from ensuring compliance, although they may be able to pass them on to	No impacts are anticipated

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS/IMPORTERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMES	CONSUMERS
		imported. -	restriction would reduce the potential loss in competitiveness arising from the manufacture of articles dyed with more expensive alternatives to Direct Black 38. ✓	consumers. ×	consumers. ×	

Source: ICF/AMEC Consultation

4.10 Scoping SEA: Bis(2-ethylhexyl)phthalate (DEHP)

4.10.1 Introduction

This section covers the scoping-level SEA for **bis(2-ethylhexyl)phthalate (DEHP, CAS No. 117-81-7)** and follows the above structure, concluding with the identification of considerations and elements to help ECHA and the Commission in the development of criteria for application of Article 68.2 for CMR substances in articles.

4.10.2 Regulatory status

In terms of regulatory status, DEHP is classified as R1B. The use of DEHP (as well as DBP and BBP) is restricted in toys and childcare articles at concentrations of greater than 0.1 % by mass of the plasticised material. As a CMR substance, it cannot be used in toys, in components of toys or in micro-structurally distinct parts of toys, according to Annex II of directive 2009/48/EC.

Similarly, there are certain restrictions on use in food contact materials in compliance with Directive 2007/19/EC. In particular, DEHP can only be used in non-fatty food contact materials for repeated use (e.g. tubes and conveyor belts) and as a technical support agent in concentrations up to 0.1 %, provided the migration of the plasticiser does not exceed the SML of 1.5 mg/kg food. DEHP is banned in cosmetics according to Directive 2004/93/EC.

Significantly in the context of the current study, DEHP is included in the authorisation list under REACH (Annex XIV), with a sunset date of 21/02/2015 and a latest application date of 21/08/2013[127].

4.10.3 Use in combination with other phthalates

DEHP is often used in articles in combination with other phthalates, particularly DBP, DIBP and DINP. An example can be found in the flooring industry. Data from the European Resilient Flooring Manufacturers Institute cited in the Restriction Proposal (Denmark 2011) is included in Table 4.31. It should be noted that this data is from 2005 and the EU resilient flooring industry has moved away from use of phthalates in Annex XIV.

Table 4.31 Concentrations of selected phthalates in average flooring products

	DEHP %	BBP %	DIBP %	Other unspecified phthalate
Homogeneous PVC	0.57			
Heterogeneous PVC	3.0	0.89	1.59	
PVC with foam Backing		0.44	0.65	
Laminated PVC	None	None	None	None
Cushioned PVC	1.36	0.64	5.71	
Safety PVC				1.4
Semi Flexible PVC	1.54			

Source: 2005 data from ERFMI, cited in Danish EPA, 2011.

[127] Exempted uses are in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC.

Similarly, the RAPEX database includes numerous records of products containing a number of different phthalates at the same time. An illustrative example is a toy set consisting of a doll and a pony made in soft plastic that was detected in Sweden in May 2013. The plastic arms and legs of the doll contained by mass 10-11% DBP, 0.30-0.32% of DEHP and 5.9-6.3% of DIBP while the pony contained 29-35% of DEHP, 0.21-0.22% of DBP and 0.22-0.23% of DINP (Ref No. A12/0652/13). Additional recent examples in RAPEX are Ref. No. A12/0355/13, A12/0046/13 and A12/0143/13 among others.

4.10.4 Focus areas for the scoping-level SEA

Depending upon the scope of REACH authorisations that are granted, use of DEHP in production of certain types of articles may no longer be allowed in the EU. However, the scope of (non)authorisation does not extend to articles imported from outside the EU. There may therefore be a need to introduce restrictions on imported articles containing DEHP under Article 68.2, potentially in line with those applications for which authorisations have not been granted, so as to 'close the loop' in terms of protection of human health for consumers exposed to DEHP from such articles. Such a restriction would also help to ensure equal treatment of EU and non-EU article producers.

It should be noted that it appears to be possible to define a toxicological threshold for the reproductive toxicity effects of DEHP. This means that, if the risk to human health is adequately controlled, an authorisation will be granted (and, if not, an authorisation *may* be granted, via the socio-economic route) (ECHA 2009).

DEHP was selected for more detailed analysis in (phase 2 of) this project on the basis that authorisation applications were expected to be received for the substance. The main focus of the present analysis is to help understand the potential implications of Article 68.2 restriction after the sunset date to regulate imported articles. The Commission indicated that it would be useful to obtain information on the economic value of imported articles and on the main product types and uses of the substance in articles.

4.10.5 Uses of the substance

4.10.5.1 Overall quantities manufactured and imported

Production of DEHP in Europe[128] fell from 666kt to 247kt over the period 1997 to 2004, while consumption fell from 476kt to 221kt over the same period (Annex XV SVHC Dossier =, 2008). The Danish EPA (2011) estimated that consumption (EU production and import used for production of articles, minus exports) was 282kt in 2007 and 171kt in 2009-10.

4.10.5.2 Use in articles

4.10.5.3 Overview

In 2007, 97% of DEHP consumption was estimated to be for use as a PVC plasticiser, with the remainder used in non-polymer applications including adhesives and sealants, paints and lacquers, printing inks and capacitors, as well as advanced ceramic materials for electronic and structural applications (Sweden, 2008).

An estimate of the quantity of DEHP in articles marketed in the EU is provided in a report for ECHA (2009a). This is reproduced in the table below. The total quantity of imported articles containing DEHP in articles intended for indoor use or contact with human skin was around 40,000 tonnes in 2007, representing around 17% of all such DEHP-containing articles used in the EU, or around 14% of total articles used in the EU (the latter figure includes those for outdoor uses).

Whilst these data are the most recent available, it is understood that EU industry has already moved away from use of DEHP to a significant degree in recent years, due to the inclusion

[128] EU15 plus Norway, Iceland, Switzerland, Turkey, Cyprus and Malta.

on the REACH candidate list and its CMR status. The figures below are therefore likely to be overestimates compared to the current (2013) position.

Table 4.32 Estimated DEHP tonnage in end-products marketed in the EU based on EU manufacture, import, export data

End-product use area	Tonnage, t/y				% of total use
	EU Manufacture	Import	Export	End-product use	
Indoor uses					
Flooring	33,000	2,000	4,800	30,200	10.6
Wall covering	11,000	700	1,600	10,100	3.5
Film/sheet and coated products made by calendaring	44,000	13,600	16,400	41,200	14.5
Wires and cables	52,000	6,200	5,600	52,600	18.5
Hoses and profiles	31,000	1,600	3,000	29,600	10.4
Coated fabric and other products from plastisol.	31,000	2,200	1,400	31,800	11.2
Moulded products	3,000	2,700	700	5,000	1.8
Other polymer applications	12,300	10,900	3,100	20,100	7.1
Non polymer applications:					
Adhesives and sealant	4,000	n.d.	n.d.	4,000	1.4
Lacquers and paints	500	n.d.	n.d.	500	0.2
Printing ink	1,000	n.d.	n.d.	1,000	0.4
Other non-polymeric	20	n.d.	n.d.	20	0.0
Outdoor uses					
Calendared roofing material	600	n.d.	n.d.	600	0.2
Coil coated roofing material	3,000	n.d.	n.d.	3,000	1.1
Wire and cables - air	2,400	n.d.	n.d.	2,400	0.8
Wire and cables - soil	9,700	n.d.	n.d.	9,700	3.4
Coated fabric	12,800	n.d.	n.d.	12,800	4.5

End-product	Tonnage, t/y				% of total use
Car undercoating	4,000	n.d.	n.d.	4,000	1.4
Hoses and profiles	3,700	n.d.	n.d.	3,700	1.3
Shoe soles	19,400	n.d.	n.d.	19,400	6.8
Non polymer applications:					
Lacquers and paints	400	n.d.	n.d.	400	0.1
Adhesives and sealant	3,300	n.d.	n.d.	3,300	1.2
Total end-product use (round)	282,000	40,000	37,000	285,000	100

Source: COWI, IOM and Entec, 2009a.

The above obviously represents a very high-level view of the article types which may contain DEHP. The number and diversity of article types notified to ECHA under Article 7(2)[129] highlights the huge range of different products in which the substance is used. The characteristics of each of these, as well as the socio-economic merits compared to the potential impacts of a possible restriction, will vary. Clearly it is not feasible to assess all of these in a scoping-level SEA such as this and the analysis has focused on some of the major applications by use quantity. These are not necessarily the uses most likely to be covered by applications for authorisation (at the time of writing, details of uses applied for were not available).

4.10.5.4 *Market value for articles*

The table below provides an estimate of the market value for key types of DEHP-containing articles, including differentiation between EU produced and imported articles where possible.

Table 4.33 Estimated market value for selected article types

Article type	EU manufacture / import (tonnes DEHP)	Quantity and value of articles
Flooring	33,000t / 2,000t	• Quantity of DEHP-containing flooring on EU market estimated as 175,000t based on 20% concentration (Danish EPA, 2011) and therefore 10,000t imported. • EU production plus import of DEHP-containing flooring = €280 million (Danish EPA, 2011) • Imported DEHP-containing flooring therefore estimated as €16 million per year.
Wall covering	11,000t / 700t	• Quantity of DEHP-containing wall covering on EU market estimated as 37,000t based on 30% concentration (Danish EPA, 2011) and therefore 2,300t imported. • No data on value of final articles available
Film/sheet	44,000t / 13,600t	• Quantity of DEHP-containing film/sheet on EU market estimated as 150,000t based on 30% concentration (Danish EPA, 2011) and therefore 55,000t imported. • No data on value of final articles available (Danish EPA,

[129] DEHP, ECHA Data on Candidate List Substances in Articles. http://echa.europa.eu/documents/10162/24e96360-d320-4b26-b7a4-0172ef9f4913

Article type	EU manufacture / import (tonnes DEHP)	Quantity and value of articles
		2011).
Wire/cable	52,000t / 6,200t	• Quantity of DEHP-containing wire/cable on EU market estimated as 230,000t based on 22.5% concentration (Danish EPA, 2011) and therefore 28,000t imported. • EU production plus import of DEHP-containing cables and wires on EU market = €2.15 billion. • Imported DEHP-containing cables and wires therefore estimated as €0.2 billion per year.
Hose/profile	31,000t / 1,600t	• No data
Fabric, etc.	31,000t / 2,200t	• Quantity of DEHP-containing fabric and other plastisol-based products on EU market estimated as 100,000t based on 30% concentration (Danish EPA, 2011) and therefore 7,000t imported. • Value of EU-produced DEHP-containing articles estimated as €340 million and imported articles estimated as €24 million per year based on average price for tablecloths, curtains, shower curtains and similar items (not industrial uses) of €3.1/kg (Danish EPA, 2011).
Moulded products	3,000t / 2,700t	• No data
Other polymers	12,300t / 10,900t	• No data
Notes: Data based primarily on Denmark (2011). Data on uses in this source document relate to uses and imports in 2007, with a downward trend in use expected (not taken into account here).		

Notes: Data based primarily on Denmark (2011). Data on uses in this source document relate to uses and imports in 2007, with a downward trend in use expected (not taken into account here).

Table 4.35 below gives an estimate of the proportion of imported articles that contain DEHP compared to the total quantity of articles imported within selected category group. The proportion of DEHP-containing articles varies substantially. While the vast majority of imported PVC films and sheets contained DEHP, less than 6% of the cables and wires imported into the EU contained this substance.

Table 4.34 Proportion of imported articles containing DEHP by type of article

Article type	Imported articles containing DEHP (tonnes of articles)	Total imported articles (tonnes or articles)	Percentage of DEHP-containing articles by article type
Flooring of vinyl and heavy style wall covering	12,300t	99,324t	12%
PVC film, sheet	55,000t	57,161t	96%
PVC fabrics	7,000t	22,682t	31%
Wires and cables	28,000t	500,325t	6%

Note: Data on DEHP containing articles was estimated from Denmark (2011). Data on total imported articles from Danish EPA (2012). All data refers to 2007.

4.10.5.5 *Overall data on manufacture and import of articles potentially containing DEHP*

The table below provides information on quantities of various PVC articles imported into the EU27 and quantities manufactured in the EU27, in 2007 and 2011. These data do not provide information on the quantities or proportions that may contain DEHP. However, they do provide an indication of (a) relative quantities of imported articles compared to EU manufactured articles and (b) trends over the period 2007 to 2011, both of which provide useful context on the potential significance of imported PVC articles that *may* contain DEHP in the context of a restriction under Article 68.2.

Table 4.35 PVC articles manufactured and imported into the EU27 in 2007 and 2011

Article type	Manufactured in EU27 (t)		Imported into EU27 (t) (% of EU manufacture)	
	2007	2011	2007	2011
Flooring of vinyl and heavy style wall covering	1,163,848	1,129,299	99,324 (9%)	192,427 (17%)
Insulated wire and cable	3,774,741	3,427,628	500,325 (13%)	471,246 (14%)
Bags, briefcases, etc.	1,029,333	1,014,601	686,961 (67%)	638,656 (63%)
Tablecloths, curtains, shower curtains, etc.	1,859,862	1,596,853	79,844 (4%)	86,859 (5%)
Waterbeds and air mattresses	5,456	12,972	9,315 (171%)	8,413 (65%)
Sandals, slippers	99,439	87,209	124,106 (125%)	137,825 (158%)
Bathing equipment	453,848	387,803	218,153 (48%)	202,512 (52%)
Balls, etc.	15,268	12,127	41,585 (272%)	10,797 (89%)

Source: Based on Danish EPA, 2012.

It can be seen that the article types for which imports represent the most significant volumes compared to EU manufacture are footwear, balls, bags and waterbeds/air mattresses.

The only uses where there has been a change of more than 25% between 2007 and 2011 are: imports of flooring/wall covering (94% increase), manufacture of waterbeds and air mattresses (c. 140% increase) and imports of balls, etc. (decrease by c. 75%). The reasons for these changes are unknown but it should be borne in mind that there may be some anomalies in the underlying data (e.g. the figure for balls was fairly steady between 2007 and 2010 but dropped very sharply in 2011).

4.10.5.6 *Trends*

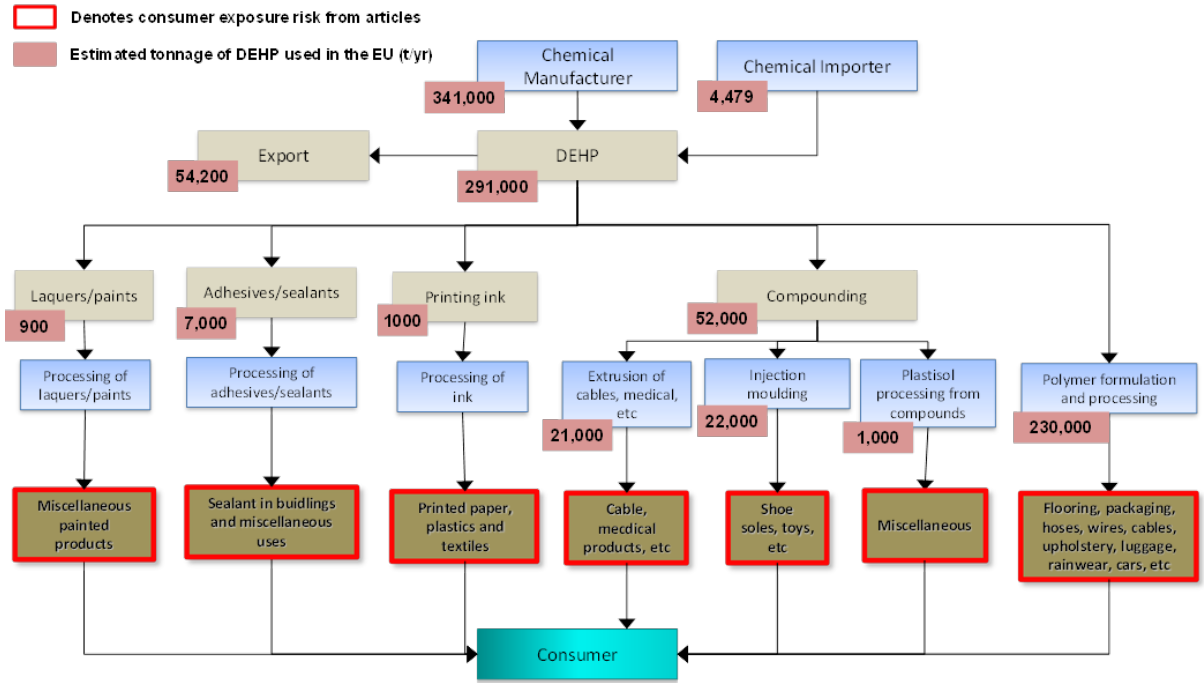
As is clear from the data in the section on overall quantities (above), there has been a significant trend away from the use of DEHP in the EU. Given the sunset date in 2015 for uses without a REACH authorisation, it is likely that this downward trend will continue (the extent to which this is true will depend on which uses are granted authorisations).

Data in the preceding section also provide an overview of some high-level trends in the manufacture and import of the types of PVC products in which DEHP is used. It is clear that the move away from use of DEHP does not seem to have been accompanied by any significant trend away from the use of PVC (which is important in the context of the likely response scenario in the event of a restriction).

4.10.6 Supply chains affected

The figure below provides an overview of the key stages in the supply chain related to the use of DEHP in consumer articles. This is clearly a simplification but does serve to highlight the key players in the supply chain.

Figure 4.14 Summary of supply chains of DEHP (COWI, IOM and Entec, 2009a)



Source: ICF/AMEC Consultation.

4.10.7 Expected non-use scenario

During the preparation of the scoping SEA, a consultation exercise with industry was undertaken to ascertain anticipated responses to a restriction on the use of DEHP in the production of consumer articles. A number of key stakeholders were selected from the 171 organisations contacted during the first round of consultation. This was done according to the answers provided and their expertise. Relevant organisations that were not previously considered were also included in phase 2 of the study in order to close identified knowledge gaps. In total 15 organizations were contacted for detailed consultation on DEHP, as detailed below. The number of respondents and the amount of information gathered through consultation was limited, despite making numerous requests for information.

Table 4.36 Consultation exercise

	Type of industry/article	Stakeholders contacted	Valuable responses received
Trade/industry associations	Chemical producers, plastic manufacturers, footwear, outdoors accessories, toys, flooring	10 European 1 Non-EU	4 European
Private companies	Chemicals, cables, healthcare products and equipment.	4 European	2 European

Source: ICF/AMEC Consultation.

The non-use scenarios have been developed primarily based on the views of a small number of industry associations (the response from industry to consultation on this substance was very limited overall). This was supplemented by expert judgement taking into account the literature on the use of DEHP, such as the restriction proposal for several phthalates from Denmark (2011).

It is clear from the large number of notified uses of DEHP in articles (which may represent only a proportion of all uses), that it is unlikely to be feasible within considerations for a "fast track" restriction under Article 68.2 to consult widely with the full range of actors involved in production and use of each article type. However, depending on the extent of authorisations granted, it may be more feasible to consult with supply chains for the presumably smaller group of uses that will be authorised beyond the sunset date (as well as article importers).

The anticipated non-use scenarios at each key stage of the supply chain are described below, covering manufacturers/importers of DEHP, polymer processing companies, article producers, article importers and consumers.

It should be noted that the analysis has been developed using the assumption that the scope of a restriction under Article 68.2 would apply to imported articles containing DEHP (primarily PVC) i.e. in order to close the gap for uses of DEHP where an authorisation is not granted for use in the EU but for which consumers (and the environment) may still be exposed through imported articles. For the baseline situation, it is therefore assumed that authorisations are granted for some but not necessarily all current uses.

4.10.7.1 Manufacturers and importers of DEHP

In the event of a restriction on the use of DEHP in articles that focused on non-authorised uses of the substance, it is assumed that manufacturers and importers of DEHP would not be directly affected, since the restriction would only target imports of articles.

4.10.7.2 Polymer processors

Polymer processors are taken to include the diverse range of companies involved in e.g. PVC compounding; plastisol and master batch production; and PVC processing (moulding, calendaring, etc.). As with manufacturers and importers of DEHP itself, it is assumed that these companies would not be directly affected by a restriction targeting imported articles containing DEHP (their current uses would either be authorised or not authorised beyond the sunset date and impacts on imported articles would have no direct impact).

4.10.7.3 Article producers

This analysis considers a situation whereby articles containing DEHP in non-authorised uses would be restricted (after the sunset date). In the *absence* of a restriction on imported articles, EU producers of PVC articles where DEHP is not authorised could see an erosion of their sales through the ability of non-EU article producers to sell DEHP-containing products on the EU market. A restriction on relevant imported articles would presumably allow EU-based article producers to compete more evenly with non-EU article producers (both would need to use substitute plasticisers or alternative materials), which is likely to lead to increased EU article production using alternatives compared to the baseline situation[130].

The overall response scenario, therefore, is that article producers will use alternative plasticisers or alternative materials to produce articles already, as a result of (non) authorisation. A restriction would mean that non-EU producers would need to use alternatives (in non-authorised uses) in the same way that EU producers would, if they wish to continue selling onto the EU market.

[130] The baseline situation is assumed to be the case whereby the sunset date has passed and uses of DEHP are either authorised or not, and there is no restriction on import of articles containing DEHP under Article 68.2.

It is relevant to note that, in the 10 years to 2010, 950,000t of PVC was recycled in Europe, of which 45% was plasticised PVC, particularly cables, flooring and fabrics[131]. Depending on the scope of a restriction under Article 68.2, recyclers of PVC and producers/suppliers of recycled articles could be negatively affected, if they could no longer supply products that contained DEHP. They would also be likely to bear costs of testing products to ensure that DEHP is not present.

4.10.7.4 Article importers

Importers of articles would no longer be able to import products containing DEHP for restricted uses. Instead, they would need to import articles based on alternatives to DEHP. Based on information from consultation for the current study, as well as literature such as the Danish (2011) restriction proposal and data on imports and manufacture of PVC products (Danish EPA, 2011), it is considered most likely that the alternatives used would mainly be other plasticisers, rather than alternative materials.

Consultation for the current study highlighted a view within certain industry sectors that there remain significant imports of articles into the EU which contain phthalates (including DEHP) in uses that are already restricted (e.g. toys and childcare articles). One trade association has highlighted a view that lack of extensive monitoring of the content of imported articles allows articles containing restricted phthalates to be imported in significant quantities. This is borne out by findings from a review of the RAPEX database for DEHP which highlights the large number of toys containing this substance. Since 2005, more than 400 toys were found to have phthalates over 0.1%, 164 in 2012 alone. DEHP is one of the most commonly reported phthalates in toys within RAPEX, being found in teddy bears, dolls, crayons, pencils, bath toys, toy vehicles, etc.

4.10.7.5 Consumers

Under the baseline situation – non-authorisation for certain uses of DEHP but imports of relevant articles still permitted – it is likely that consumers could purchase increased volumes of imported articles that still contain DEHP from outside the EU, particularly if these are less expensive or have greater technical performance than articles using alternatives. This would be at the expense of EU-produced goods.

In the event of a restriction that covered imported articles for uses which are not authorised, it is more likely that consumers would purchase greater proportions of EU-produced articles (relative to the baseline situation), given that non-EU producers would no longer be able to differentiate themselves from EU producers by still being able to use DEHP.

4.10.8 Assessment of economic and social impacts

4.10.8.1 Overview

This section provides a discussion of the likely economic impacts of the response (non-use) scenarios described above.

Given that the main impacts of a restriction on use in articles would presumably affect only imported articles for non-authorised uses, it seems to make sense to consider the economic impacts of a restriction in terms of a number of different product types. The following sections therefore provide an appraisal of potential economic impacts for producers, importers and consumers of articles, for a few of the main broad article types (those of greatest volume).

In the absence of much relevant information from consultation during the course of the current study, the information set out in the following sections is based mainly on literature sources.

131 http://www.plasticisers.org/misconceptions/factsandfigures/3/18/Flexible-PVC-can-be-recycled/.

Overall, it was estimated in ECHA (2009a) (see above) that there is around 40,000t of DEHP in imported articles each year. Denmark (2011) estimate that the costs of using alternatives relate primarily to the price differential between DEHP and alternatives (with reformulation/R&D costs being less significant). They suggest that the additional costs of alternatives could be in the region of 11% to 21% higher when using alternatives such as DINP and DIDP respectively (assuming a cost for DEHP of €1/kg). Considered purely in terms of the imported articles containing DEHP, and assuming that all prices would be passed on to consumers, this would increase the price paid by consumers in the region of €4-8 million per year[132].

However, the cost associated with a potential Article 68.2 restriction that would only additionally affect imported articles is not so straightforward and relevant issues are considered in the following sections.

4.10.8.2 Economic impacts

4.10.8.2.1 Costs of using alternative plasticisers

The table below provides estimates of the potential additional costs of using alternative plasticisers for a number of the biggest article types based on DEHP. It is based on the analysis by Danish EPA (2011) and only includes the difference in purchase price of alternative plasticisers to DEHP, which it is assumed would be passed on from polymer processors to article producers and, ultimately, to consumers.

Table 4.37 Estimated increased prices for use of alternative plasticisers in imported articles

Article type	Quantity of DEHP in imported articles (t)	Alternative used (price difference)	Increased cost of purchasing alternative (€/yr for total quantity)
Flooring	2,000	DINP (+11%)	€220,000
Wall covering	700	DINP (+11%)	€80,000
Insulated wire and cable	6,200	DIDP (+21%)	€1,300,000
Film / sheet	13,600	DINP (+11%)	€1,500,000
Coated fabric	2,200	DINP (+11%)	€240,000

Note: Costs relate to the total volume of PVC imported into the EU currently assumed to contain DEHP and increased costs only relate to the price differential between purchasing DEHP and the alternative.

By way of example, the Danish EPA (2011) estimated the additional cost of flooring containing DINP compared to DEHP as around €200,000 per year, based on imports of 2,000t per year and an increased price of DINP compared to DEHP of 11% over the €1/kg for DEHP.

Assuming no other changes, an increase in the price paid for the plasticiser could be passed on to the EU consumer, resulting in increased costs compared to the baseline of €200,000 per year. However, a restriction on use of DEHP in imported articles could mean that there would be positive economic benefits to EU article producers i.e. consumers would be (relatively) more likely to buy EU-produced articles if imported articles could no longer include DEHP, putting them on a more level playing field with domestic articles.

Overall, purchasing imported articles containing PVC would become more expensive compared to the baseline situation (i.e. consumers would need to pay more for DEHP-free articles because non-EU firms would need to use more expensive plasticisers and pass

[132] Note that the restriction proposal (Danish EPA, 2011) assumed that imports would be only 30,000t by 2015 so the costs then would be 25% lower i.e. €3-6 million per year.

these costs on, in order to sell on the EU market). However, a restriction would serve to offset the competitive advantage that non-EU article producers would gain by being able to continue using DEHP while domestic producers could not (following the sunset date for uses where no authorisation is granted).

For example, based on the data for a subset of article categories in Table 4.37, for all of the article categories combined, EU production of articles represented around 7.7 million tonnes in 2011, compared to imports of around 1.7 million tonnes. In the worst-case situation, refused authorisation for all product types could lead to EU consumers purchasing an equivalent amount to current EU production (7.7 million tonnes) from non-EU producers. It is this type of effect that would be offset, including the associated loss of EU jobs.

Taking only those uses for which estimates are available on the values of EU-produced articles containing DEHP from Table 4.37, the value of these articles could be of the order of €2.6 billion per year (€264m for flooring, €1.95 billion for wire/cable, and €340 million for fabric, etc.). Non-authorisation of use of DEHP while still permitting import of articles containing the substance could in theory lead to all of these articles being imported from outside the EU. In reality, it is likely that only a modest proportion of articles currently produced in the EU would instead be purchased from outside the EU due to the reduced article cost afforded by DEHP's price compared to its alternatives. Nonetheless, even with a relatively small proportion of sales affected, a restriction on DEHP in imported articles could provide an economic benefit by levelling the playing field for EU producers, and could therefore result in potentially significant savings

4.10.8.2.2 Other costs

The above analysis only includes the costs associated with the price differential between DEHP and phthalate-based alternatives. There would also be other costs to the producers of articles (mainly non-EU), through R&D and reformulation of products to use the alternatives. It has not been possible to quantify these, though they are likely to be of a comparable magnitude to the costs faced by EU companies in developing alternatives for uses which are not granted authorisation beyond the sunset date, and would likewise be passed on to EU consumers if these non-EU companies wish to continue supplying the EU market.

It should also be borne in mind that, in the event of a restriction, it is likely that there would be some replacement of DEHP with other types of plasticisers than those considered here (e.g. non-phthalates) as well as other types of polymeric or other materials. These have not been examined in detail here.

4.10.8.2.3 Administrative costs

Due to the complexity of the supply chain, the huge variety of articles involved and the number of importers, distributors, etc., it is very difficult to estimate administrative costs. It is assumed that EU-produced articles would be less costly to monitor than imported ones. It has been roughly estimated that administrative costs associated with monitoring phthalates in imported articles would be in the range of €6-12 million per year (Denmark 2011) for all of the four phthalates in Annex XIV (DEHP, DBP, BBP and DIBP). As DEHP accounted for the majority of the phthalates incorporated into articles (~93%), most of the monitoring costs could be associated with this substance.

4.10.8.3 Social impacts

Non-authorisation of certain uses of DEHP in article production could potentially lead to significant impacts upon employment in the EU amongst DEHP manufacturers/importers, polymer processing companies and article producers. If non-EU-produced articles (containing DEHP) become preferable to EU-produced articles (based on alternatives), there is the potential for significant economic activity and associated employment to be lost from the EU. A restriction on use in all articles (including imported articles) would provide a more level playing field and potentially avoid such significant employment losses for EU firms.

4.10.8.3.1 Potential human health and environmental benefits

The restriction proposal for four phthalates (Danish EPA, 2011) related to combined exposure of DEHP and three other phthalates. In its opinion of 15 June 2012, ECHA's Risk Assessment Committee acknowledged that, based on biomonitoring data from before 2008, there could be a risk from the combined exposure to the four phthalates, both for children and for adults, although the risk ratios calculated were not much above 1. They indicated that, while it is difficult to quantify the present day risk, the steady recent decline in both tonnages used in Europe and their body burden, plus the clear indications for a continuation of this decline would result in considerably lower RCRs.

Therefore, the Committee concluded that the data available did not indicate that currently (2012) there was a risk from combined exposure to the four phthalates (and therefore by definition not from DEHP). The RAC therefore did not support the restriction proposed by Denmark.

Based on the above, it appears that there would be minimal (or negligible) benefit for consumers of restricting the use of DEHP in any (or all) articles. Therefore, the same is assumed to be true for remaining articles restricted under article 68.2.

It should be noted that, despite it being a CMR substance, there is a threshold for effects of DEHP. Taking into account exposure related to migration, there are a number of uses that do not pose an unacceptable risk, including most consumer uses of articles.

In terms of potential environmental benefits, it is of note that the EU RAR (2008) concluded that environmental risks were mainly related to the vicinity of polymer processing sites. These risks related to the aquatic and terrestrial environments and to man exposed via the environment. However, since polymer processing sites in the EU would have no additional changes (beyond the authorisation decisions) it is assumed that there would be no additional impact on the environment.

4.10.9 Overall conclusions on potential costs and benefits

It was estimated that 1.7 million tonnes of articles containing DEHP are imported into the EU every year. If non-authorisation of certain uses within the EU is not followed by a similar restriction on the corresponding imported articles, this figure could increase to the detriment of domestic manufacturers using alternatives.

The potential price increase due to substitution of DEHP in articles is expected to be relatively low (on average) (taking only price differentials of different phthalates into account), while monitoring costs are anticipated to be the most significant expense associated with a restriction in articles based on Denmark's restriction proposal. It was roughly estimated that the substitution costs for imported flooring articles would be around €200,000 per year in terms of increased price of articles. The overall increased costs of using alternatives could thus be up to around 10 times this value, taking account the relative share of flooring compared to total DEHP use. Additional costs for non-EU manufacturers may include reformulation, R&D, etc. which could be passed on to EU firms. Administrative costs for monitoring phthalates in imported articles were estimated by Denmark (2011) to be much higher at €6-12 million per year, the majority of which is assumed to be related to DEHP.

The most relevant benefits relate to a more level playing field for EU-based companies compared to non-EU article manufacturers and so avoidance of loss of employment.

There could also be improved consumer health benefits, although it is not clear that there is any remaining unacceptable risk to consumers through use of DEHP. Reduced use in consumer products would also lead to reduced migration during the service life of articles, helping to contribute to the aim of the water framework directive (2000/80/EC) to achieve a cessation of discharges, emissions and losses of DEHP.

Overall, taking the requirement for authorisation as part of the baseline, the economic and other benefits of a restriction on (non-authorised) use in articles are expected to outweigh the costs. A restriction on DEHP in imported articles is expected to close the gap between importers and domestic manufacturers, allowing the latter to sell their articles in equal market conditions.

4.10.10 Substance-specific considerations for development of draft criteria to implement Art 68.2 to CMR 1A and 1B in consumer articles

This section firstly includes consideration of issues that are important in determining whether Article 68.2 restriction is potentially most appropriate, compared to other forms of restriction. Following this, the identified socio-economic issues that it would be important to take into account in assessing the merits of a restriction are discussed.

With regard to the potential choice of Article 68.2 as a RMO (compared to other forms of restriction), the following considerations arise from this case study substance:

- For substances on Annex XIV, such as DEHP, restrictions on related consumer articles could be very important in ensuring that EU industry is not disadvantaged compared to non-EU companies for uses that are not authorised after the sunset date. Without such a restriction, it is possible that substantial quantities of articles currently bought from EU producers could instead be bought from non-EU companies, as they could still contain DEHP. *Criteria could therefore take into account the need for and potential for levelling the playing with non-EU article producers. There would need to be current or historical uses of the substance for which no authorisation is (expected to be) granted.*
- DEHP is clearly present in articles on the EU market and, based on data from RAPEX, it is present in imported articles, even in uses where it is already restricted. *Criteria could therefore take into account whether the Annex XIV substance is actually present within imported articles, because if this is not the case, it may be difficult to justify any restriction.*
- DEHP can clearly migrate from polymeric articles and consumers can therefore be exposed. If there were no exposure possible, it would presumably be difficult to justify any restriction. *Criteria could therefore take into account whether the available evidence indicates that consumer exposure cannot be ruled out.*
- Notwithstanding the above, ECHA's risk assessment and SEA committees recently concluded that the current risks arising from exposure to DEHP are not unacceptable, provided that exposure of consumers does not increase[133]. This builds on the ESR risk assessment for DEHP (EC, 2008) which concluded that there was no need to limit the risks associated with DEHP for consumers other than for toys/childcare articles and medical equipment (uses that are now already addressed through other EU restrictions. These issues arise because of the threshold for effects associated with the substance. Whilst it is not necessarily required to demonstrate an unacceptable risk to introduce a restriction under Article 68.2, the presence of evidence suggesting no unacceptable risks could lead to a restriction being viewed internationally as protectionist, in the context of international trade rules. Criteria could therefore take into account (a) whether the substance has a threshold for effects and (b) whether evidence exists suggesting no unacceptable risks for consumers, either of which may indicate more detailed consideration (e.g. Article 69 restriction) is appropriate.

Having determined that an Article 68.2 restriction is potentially suitable, there are a number of socio-economic issues arising from this case study that are relevant to deciding whether this simplified route is likely to be suitable:

[133] It should be noted that other Annex XIV substances are unlikely to have as much readily-available information as DEHP.

- Techniques are available to detect the presence of DEHP in (imported articles). *Criteria for selection of the Article 68.2 restriction route would presumably need to take this into account.*
- DEHP is a very high volume substance, both in terms of EU manufacture/use and in terms of import of articles into the EU. There are complex supply chains involved, many thousands of companies and hundreds of different uses, although many companies have moved away from use of DEHP in recent years. In the context of a potential restriction on articles to close the gap left after non-authorisation following the sunset date[134], it is problematic to target consultation to identify relevant stakeholders' views on likely implications of a restriction. *Criteria may therefore need to take into account whether the complexity of supply chains could be a barrier to understanding the socio-economic impacts of a 'fast track' restriction under Article 68.2. In this case there were relatively good data available on uses and the complexity of the supply chains.*
- Notwithstanding the above, since a restriction is likely to benefit EU industry by levelling the playing field with companies outside the EU, the extent of negative impacts on EU industry from a restriction is likely to be minimal. *Criteria could therefore take into account situations such as this where there is a reasonable expectation that there would not be negative impacts on EU industry. No specific information was needed for DEHP to conclude that this is the case here, and this is likely to be true for other Annex XIV substances.*
- It is clear from the extent of the presence of restricted phthalates in uses that are already restricted (e.g. DEHP in toys) that ensuring compliance with restrictions for imported articles can be problematic. This is evidenced by information from RAPEX, as well as consultation for the current study, and is just as true for 'standard' restrictions as it is for restrictions under Article 68.2 (compliance is an issue upon which MS are working). *Criteria could therefore take into account the extent to which such non-compliance for the substance in question has the potential to limit the extent to which the playing field is levelled between EU and non-EU article producers, as well as whether there are other potential RMOs that could be more effective (which seems unlikely). If this is likely to be a significant issue, this may be a sign that a more detailed investigation is required.*
- It seems clear that a restriction would benefit EU firms to a greater extent than non-EU firms, levelling the playing field. While it is likely to be able to conclude this for most Annex XIV substances, the available information on imports and domestic production of relevant articles provided additional corroboration in this case. *Criteria could therefore take into account whether a restriction would benefit EU firms to a greater or lesser extent than non-EU firms.*
- Flexible PVC products are widely recycled and there could therefore be important issues related to placing recycled consumer articles containing DEHP on the market. Whilst this does not necessarily imply a more detailed restriction process is required, *criteria could take into account whether recycled articles are likely to be relevant, as this may be relevant to the wording of the restriction.*

[134] And hence a restriction would, in practice, only additionally affect imported articles, compared to the baseline. It would also level the playing field for companies within the EU who have moved away from use of the substance in advance of (impending) regulation, as has occurred in the EU with DEHP.

Table 4.38 Screening of relevant impacts by stakeholder group, impact category and supply chain

✓ - Benefit or positive outcome;
- No or insignificant anticipated impact;
× - Cost or negative outcome.

IMPACT CATEGORY/ STAKEHOLDER	POLYMER PROCESSORS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMES	CONSUMERS
Operating costs and conduct of business	No impacts beyond those attributable to the authorisation process. -	No impacts beyond those attributable to the authorisation process. - Depending on scope of restriction, if recycled articles are covered, potentially negative impacts for companies producing articles from recycled PVC (lost turnover or demonstrating DEHP not present) ×	Potential impact on costs. A ban would exert pressure to check whether products they supply comply, either through obtaining information from suppliers (certification/declaration or test results) or by undertaking their own testing. They would also need to bear (and pass on to consumers) the likely increased costs of articles using alternatives. ×	No major cost impacts so no specific issues identified for SMEs. SMEs may find it hard to exert pressure on suppliers to demonstrate compliance and/or to bear the costs of doing so themselves. -	Cost increase due to substitution by more expensive alternatives (by non-EU firms) is likely to be passed on to consumers. Potentially more likely to buy from EU firms compared to the baseline. ×
Competitiveness, Trade and Investment	No impacts beyond those attributable to the authorisation process. -	A restriction in articles may close the gap (under the baseline) between domestic manufacturers and importers regarding the use of DEHP in products, potentially leading to improved competitiveness. ✓	Importers of articles potentially containing DEHP will potentially lose competitive edge due to potential increased prices of final imported products (from substitution of DEHP) and extra costs (demonstrating compliance, change of suppliers). ×	No specific issues for SMEs identified -	Not applicable -

IMPACT CATEGORY/ STAKEHOLDER	POLYMER PROCESSORS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMES	CONSUMERS
Competition and the internal market	No impacts beyond those attributable to the authorisation process. -	A restriction in articles could provide an economic benefit by levelling the playing field for EU manufacturers and encouraging equal competition. ✓	EU importers of articles will face a competitive disadvantage if their current imports of articles are found to contain DEHP. Additional costs will be related to potential tests and changes in suppliers. ×	No specific issues for SMEs identified -	Compliance and substitution by non-EU firms expected to be passed on to consumers. ×
Innovation and research	No impacts beyond those attributable to the authorisation process. -	No impacts beyond those attributable to the authorisation process. -	Importers may explore new possibilities to cover consumer needs other than traditional DEHP-containing articles. ✓	No specific issues for SMEs identified -	No impacts anticipated. -
Distributive/Equity	No impacts beyond those attributable to the authorisation process. -	EU article manufacturers are expected to be the most positively impacted stakeholder. A restriction for articles would reduce the potential loss in competitiveness arising from (non) authorisation under REACH. ✓	Importers are probably the most impacted stakeholder due to additional costs (demonstrating compliance, passing on price of alternatives, supplier change). ×	SMEs are likely to face more difficulties to afford the costs resulting from a change in suppliers and from ensuring compliance, although they may be able to (partially) pass them on to consumers. ×	No impacts anticipated. -

Source: ICF/AMEC Consultation.

4.11 Scoping SEA: Dibutyl phthalate [DBP]

4.11.1 Introduction

This section covers the scoping-level SEA for **dibutyl phthalate (DBP), CAS No. 84-74-2)** and follows the structure defined in the introduction, concluding with the identification of considerations and elements to help ECHA and the Commission in the development of criteria for application of Article 68.2 for CMR substances in articles.

4.11.2 Regulatory status

In terms of regulatory status, DBP is classified as a category 1B reproductive toxin. The use of DBP (as well as DEHP and BBP) is restricted in toys and childcare articles at concentrations greater than 0.1 % by mass of the plasticised material. As a 1B CMR substance, it cannot be used in toys, in components of toys or in micro-structurally distinct parts of toys, according to Annex II of directive 2009/48/EC. The substance is restricted by REACH Annex XVII Entry 28, which prohibits its direct use in consumer products. Therefore it is not allowed to be used in substances and preparations placed on the market for sale to the general public in individual concentrations equal to or greater than 0.1% w/w or other relevant concentration limit. This requirement, however, does not apply to articles and there is a possibility that consumers may be exposed to products containing DBP, hence the potential need for restriction under Article 68.2). REACH Annex XVII Entry 30 bans the use of DBP in medicinal and veterinary products, motor fuels, cosmetics and artist' paints. Similarly, there are certain restrictions on use in food contact materials in compliance with Directive 2007/19/EC.

Significantly in the context of the current study, DBP is included in the authorisation list under REACH (Annex XIV), with a sunset date of 21/02/2015 and a latest application date of 21/08/2013[135].

4.11.3 Use in combination with other phthalates

DBP is often used in articles in combination with other phthalates, particularly DEHP, DIBP and DINP. An example can be found in the flooring industry. Data from the European Resilient Flooring Manufacturers Institute cited in the Restriction Proposal (Denmark 2011) is included in Table 4.39. It should be noted that this data is from 2005 and the EU resilient flooring industry has moved away from use of phthalates included in Annex XIV.

Table 4.39 Concentrations of selected phthalates in average flooring products

	DEHP %	BBP %	DIBP %	Other unspecified phthalate
Homogeneous PVC	0.57			
Heterogeneous PVC	3.0	0.89	1.59	
PVC with foam Backing		0.44	0.65	
Laminated PVC	None	None	None	None
Cushioned PVC	1.36	0.64	5.71	
Safety PVC				1.40
Semi Flexible PVC	1.54			

Source: 2005 data from ERFMI, cited in Denmark 2011.

[135] Exempted uses are in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC.

Similarly, the RAPEX database includes numerous records of products containing a number of different phthalates at the same time. An illustrative example is a toy set consisting of a doll and a pony made in soft plastic that was detected in Sweden in May 2013. The plastic arms and legs of the doll contained by mass 10-11% DBP, 0.30-0.32% of DEHP and 5.9-6.3% of DIBP while the pony contained 29-35% of DEHP, 0.21-0.22% of DBP and 0.22-0.23% of DINP (Ref No. 22 A12/0652/13).

The case of the toy mentioned above is an example of an imported article containing restricted phthalates that should have been withdrawn from the market. DBP (as well DEHP and DBP) is restricted in toys and childcare articles in concentrations above 0.1% according to REACH Regulation Annex XVII, entry 51 and 52.

Depending upon the scope of REACH authorisations that are granted, use of DBP in production of certain types of articles may no longer be allowed in the EU. However, the scope of (non)authorisation does not extend to articles imported from outside the EU. There may therefore be a need to introduce restrictions on imported articles containing DBP under Article 68.2, potentially in line with those applications for which authorisations have not been granted, so as to 'close the loop' in terms of protection of human health for consumers exposed to DBP from such articles. Such a restriction would also help to ensure equal treatment of EU and non-EU article producers.

DBP was selected for more detailed analysis in (task 2 of) this project on the basis that authorisation applications were expected to be received for the substance. The main focus of the present analysis is to help understand the potential implications of Article 68.2 restriction after the sunset date to regulate imported articles. The Commission indicated that it would be useful to obtain information on the economic value of imported articles and on the main product types and uses of the substance in articles are of interest.

4.11.4 Uses of the substance

4.11.4.1 Overall quantities manufactured and imported

DBP represented less than 1% of the phthalates produced in the EU in 2007. Manufacture of DBP in the EU fell from 28,000 tonnes in 1998 to less than 10,000 tonnes in 2004 (COWI, IOM and Entec, 2009b). Denmark (2011) estimated that consumption (EU production and import used for production of articles, minus exports) for DBP, BBP and DIBP combined was 27,000 tonnes in 2007 and 13,000 tonnes in 2009-10. The distribution of these substances is not specified. However, for 2007, it was estimated that 8,250 tonnes of DBP were being marketed in articles within the EU, of which 5,230 were used in articles intended for indoor use and/or with human skin contact (Denmark 2011). In any case there is a clear trend towards the reduction of the use of phthalates in the EU, including DBP.

4.11.4.2 Use in articles

4.11.4.2.1 Overview

In 1997, 76% of DBP was used as a plasticizer in polymers, 14% in adhesives, 7% in printing inks and the remaining 3% of DBP is used in miscellaneous other applications (DBP EU RAR, 2003). Consultation also revealed the use of this substance as an intermediate, not incorporated into articles or other consumer products. In particular, DBP is used as a solvent in the manufacture of maleic anhydride.

Table 4.40 below details the estimated use of DBP for 2007 and the reported one in 1997 for several use categories. It was estimated that a total of 8,250 tonnes of DBP were entering the EU market in 2007 incorporated into articles, including domestic manufacture and imports.

Whilst these data are the most recent available, it is understood that EU industry has already moved away from use of DBP to a significant degree in recent years, due to the inclusion on

the REACH candidate list and its CMR status. The figures below are therefore likely to be overestimates compared to the current (2013) position.

Table 4.40 Estimated DBP tonnage in end-products marketed in EU27 in 2007

End-product use area	Tonnage, tonnes /year				% of total use
	EU Manufacture	Import	Export	End-product use	
Polymers (incl. fibreglass), interior use	2,930	n.d.	n.d.	2,930	36
Polymers (incl. fibreglass), exterior use	2,930	n.d.	n.d.	2,930	36
Non polymer applications:					
Paint	160	n.d.	n.d.	160	2
Adhesives	1,900	n.d.	n.d.	1,900	23
Grouting agents	80	n.d.	n.d.	80	1
Other non-polymeric (e.g. propellants, catalyst, etc.)	250	n.d.	n.d.	250	3
Total end-product use (round)	8,250	n.d.	n.d.	8,250	100

Source: ECHA, 2009.

According to consultation for the current study, the main present-day use (and probably the use with the most challenging substitution requirements) of DBP in the manufacture of plastic articles within the EU is use as a plasticizer for PVC articles that have to be subject to drastic changes in temperature. In particular, it is used in the automotive and aerospace industry as part of the braking system (e.g. in cold weather conditions the braking system turns rapidly from below zero temperatures to more than one hundred degrees). It may also be used in car air conditioning and cables.

Another important use of this substance in Europe is the manufacture of explosives and ammunition for military, security forces and civil use (e.g. sporting and hunting ammunition, mining, demolitions).

The above obviously represents a relatively high-level view of the article types which may contain DBP. The number and diversity of article types notified to ECHA under Article 7(2)[136] highlights the wide range of different products in which the substance is used. The characteristics of each of these, as well as the socio-economic merits compared to the potential impacts of a possible restriction, will vary. Clearly it is not feasible to assess all of these in this scoping-level SEA. No information has been found regarding total tonnage of DBP entering the EU market in imported articles. As DBP is used only for a minor part of the products within the different commodity groups, the import/export of DBP cannot be determined on the basis of available data on import or export of articles.

4.11.4.2.2 Overall data on manufacture and import of articles potentially containing DBP

The table below provides information on quantities of various PVC articles imported into the EU27 and quantities manufactured in the EU27, in 2007 and 2011. These data do not provide information on the quantities or proportions that may contain DBP. However, they do provide an indication of (a) relative quantities of imported articles compared to EU manufactured articles and (b) trends over the period 2007 to 2011, both of which provide

[136] DBP, ECHA data on Candidate List Substances in Articles. http://echa.europa.eu/documents/10162/ee4b5cc6-facb-4686-9d17-c69350c2e138

useful context on the potential significance of imported PVC articles that *may* contain DBP in the context of a restriction under Article 68.2.

Table 4.41 PVC articles manufactured and imported into the EU27 in 2007 and 2011

Article type	Manufactured in EU27 (t)		Imported into EU27 (t) (% of EU manufacture)	
	2007	2011	2007	2011
Flooring of vinyl and heavy style wall covering	1,163,848	1,129,299	99,324 (9%)	192,427 (17%)
Insulated wire and cable	3,774,741	3,427,628	500,325 (13%)	471,246 (14%)
Bags, briefcases, etc.	1,029,333	1,014,601	686,961 (67%)	638,656 (63%)
Tablecloths, curtains, shower curtains, etc.	1,859,862	1,596,853	79,844 (4%)	86,859 (5%)
Waterbeds and air mattresses	5,456	12,972	9,315 (171%)	8,413 (65%)
Sandals, slippers	99,439	87,209	124,106 (125%)	137,825 (158%)
Bathing equipment	453,848	387,803	218,153 (48%)	202,512 (52%)
Balls, etc.	15,268	12,127	41,585 (272%)	10,797 (89%)

Source: Based on Danish EPA (2012)

It can be seen that the article types for which imports represent the most significant volumes compared to EU manufacture are footwear, balls, bags and waterbeds/air mattresses.

The only uses where there has been a change of more than 25% between 2007 and 2011 are: imports of flooring/wall covering (94% increase), manufacture of waterbeds and air mattresses (c. 140% increase) and imports of balls, etc. (decrease by c. 75%). The reasons for these changes are unknown but it should be borne in mind that there may be some anomalies in the underlying data (e.g. the figure for balls was fairly steady between 2007 and 2010 but dropped very sharply in 2011).

4.11.4.3 Trends

As is clear from the data in the section on overall quantities (above), there has been a significant trend away from the use of DBP in the EU. Given the sunset date in 2015 for uses without a REACH authorisation, it is likely that this downward trend will continue (the extent to which this is true will depend on which uses are granted authorisations). Furthermore, it is understood that recently-submitted authorisation applications may not have included any applications for use of DBP in plasticisation of PVC, meaning that there may be a further trend away from use of the substance.

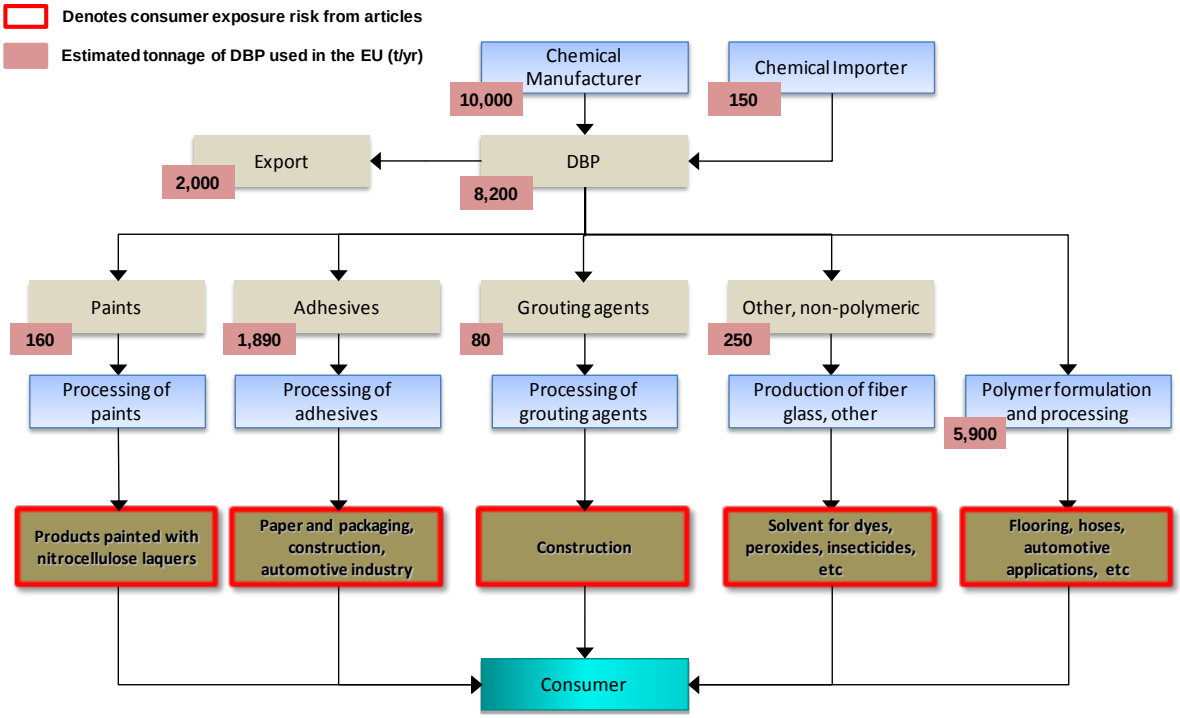
Data in the preceding section also provide an overview of some high-level trends in the manufacture and import of the types of PVC products in which DBP is used. It is clear that the move away from use of DBP does not seem to have been accompanied by any significant trend away from the use of PVC (which is important in the context of the likely response scenario in the event of a restriction).

4.11.5 Supply chains affected

The figure below provides an overview of the key stages in the supply chain related to the use of DBP in consumer articles. This is clearly a simplification but does serve to highlight

the key players in the supply chain. Those of particular importance for the scoping SEA are polymer processors, article manufacturers, article importers and consumers.

Figure 4.15 Summary of supply chains of DBP in 2007.



Source: Based on ECHA, 2009.

4.11.6 Expected non-use scenario

During the preparation of this scoping SEA, a consultation exercise with industry was undertaken to ascertain anticipated responses to a restriction on the use of DBP in the production of consumer articles. A number of key stakeholders were selected from the 171 organisations contacted during the first round of consultation. This was done according to the answers provided and their expertise. Relevant organisations that were not previously considered were also included in phase 2 of the study in order to close identified knowledge gaps. In total 15 organizations were contacted for detailed consultation on DEHP, as detailed below. The number of respondents and the amount of information gathered through consultation was limited, despite making numerous requests for information.

Table 4.42 Consultation exercise

	Type of industry/article	Stakeholders contacted	Valuable responses received
Trade/industry associations	Chemicals, flexible PUF, rigid PUF, adhesives	6 European	2 European
Private companies	Chemicals	2 European	0

Source: ICF/AMEC Consultation.

The non-use scenarios have been developed primarily based on the views of a small number of industry associations (the response from industry to consultation on this substance was very limited overall). This was supplemented by expert judgement taking into account the literature on the use of DBP, such as the restriction proposal for several phthalates from the Danish EPA (2011).

The range of uses of DBP in the manufacture of articles within the EU confirmed during consultation were relatively limited. However, a much larger number of uses have been notified to ECHA (which may represent only a proportion of all uses). Similarly, the RAPEX database provides a number of examples of imported toys containing DBP. Although not as prevalent as the case of DEHP, the high number of notified uses of DBP in articles suggests that it is unlikely to be feasible within considerations for a "fast track" restriction under Article 68.2 to consult widely with the full range of actors involved in production and use of each article type. However, depending on the extent of authorisations granted, it may be more feasible to consult with supply chains for the presumably smaller group of uses that will be authorised beyond the sunset date (including article importers).

The anticipated non-use scenarios at each key stage of the supply chain are described below, covering manufacturers/importers of DBP, polymer processing companies, article producers, article importers and consumers.

It should be noted that the analysis has been developed using the assumption that the scope of a restriction under Article 68.2 would apply to imported articles containing DBP (primarily PVC) in order to close the gap for uses of DBP where an authorisation is not granted for use in the EU but for which consumers (and the environment) may still be exposed through imported articles. For the baseline situation, it is therefore assumed that authorisations are granted for some but not necessarily all current uses.

4.11.6.1 Manufacturers and importers of DBP

In the event of a restriction on the use of DBP in articles that focused on non-authorised uses of the substance, it is assumed that manufacturers and importers of DBP would not be directly affected, since the restriction would only target imports of articles.

4.11.6.2 Polymer processors and manufacturers of other DBP containing mixtures

Polymer processors are taken to include the diverse range of companies involved in, for example, propellant manufacturing, PVC compounding, plastisol production and PVC processing (moulding, calendaring, etc.). As with manufacturers and importers of DBP itself, it is assumed that these companies would not be directly affected by a restriction targeting imported articles containing DBP (their current uses would either be authorised or not authorised beyond the sunset date and a restriction in imported articles would not have a direct impact).

4.11.6.3 Article producers

This analysis considers a situation whereby articles containing DBP in non-authorised uses would be restricted (after the sunset date). In the *absence* of a restriction on imported articles, EU producers of DBP-containing articles (e.g. some PVC articles) where DBP is not authorised could see an erosion of their sales through the ability of non-EU article producers to sell DBP-containing products on the EU market. A restriction on relevant imported articles would presumably allow EU-based article producers to compete more evenly with non-EU article producers (both would need to use substitute plasticisers or alternative materials), which is likely to lead to increased article production using alternatives compared to the baseline situation[137].

The overall response scenario, therefore, takes into account that article producers will use alternative plasticisers or alternative materials to produce articles already, as a result of (non) authorisation. A restriction would mean that non-EU producers would need to use alternatives (in non-authorised uses) in the same way that EU producers would, if they wish to continue selling onto the EU market. An example of this point, involving resilient flooring, was revealed during consultation. The EU flooring industry seems to have recently moved

[137] The baseline situation is assumed to be the case whereby the sunset date has passed and uses of DBP are either authorised or not, and there is no restriction on import of articles containing DBP under Article 68.2.

completely from phthalates on the authorisation list. This required substantial investments and they hope a restriction in imported articles would help them recover the costs by promoting fair competition.

It is relevant to note that, in the 10 years to 2010, 950,000t of PVC was recycled in Europe, of which 45% was plasticised PVC, particularly cables, flooring and fabrics (Plasticisers, 2011). Depending on the scope of a restriction under Article 68.2, recyclers of PVC and producers/suppliers of recycled articles could be negatively affected, if they could no longer supply products that contained DBP. They would also be likely to bear costs of testing products to ensure that DBP is not present.

4.11.6.4 Article importers

Importers of articles would no longer be able to import products containing DBP for restricted uses. Instead, they would need to import articles based on alternatives to DBP. Based on information from consultation for the current study, as well as literature such as the Danish (2011) restriction proposal and data on imports and manufacture of PVC products (Danish EPA, 2011), it is considered most likely that the alternatives used would mainly be other plasticisers, rather than alternative materials.

Consultation for the current study highlighted a view within certain industry sectors that there remain significant imports of articles into the EU which contain phthalates (including DBP) in uses that are already restricted for certain uses (e.g. childcare articles). One trade association has highlighted a view that lack of extensive monitoring of the content of imported articles allows articles containing restricted phthalates to be imported in significant quantities. This is borne out by findings from a review of the RAPEX database, which highlights the presence of phthalates in restricted articles, particularly toys. In 2012, more than 160 toys and childcare articles containing restricted phthalates were detected by the authorities and recorded in the database. In the case of DBP, it was found in dolls, school pencil cases, toy guns and toy medical instruments among others.

Consultation also highlighted the case of imported ammunition and explosives as a specific issue for DBP. European ammunition manufacturers classify their products as mixture in a container, being out of the scope of this study. However, it was suggested that some importers classify them as articles in order to avoid registration under REACH. In this case, they would be DBP containing articles and a potential restriction may force ammunition importers to change the classification of their products and adhere to regulations regarding mixtures in containers.

4.11.6.5 Consumers

Under the baseline situation – non-authorisation for certain uses of DBP but imports of relevant articles still permitted – it is likely that consumers could purchase increased volumes of imported articles that still contain DBP from outside the EU, particularly if these are less expensive or have greater technical performance than articles using alternatives. This would be at the expense of EU-produced goods.

In the event of a restriction that covered imported articles for uses which are not authorised, it is more likely that consumers would purchase greater proportions of EU-produced articles relative to the baseline situation, given that non-EU producers would no longer be able to differentiate themselves from EU producers by still being able to use DBP. Consumers may face slightly higher prices due to substitution and assurance costs.

4.11.7 Assessment of economic and social impacts

4.11.7.1 Overview

This section provides a discussion of the likely economic impacts of the response (non-use) scenarios described above.

Given that the main impacts of a restriction on use in articles would presumably affect only imported articles for non-authorised uses, the economic impacts of a restriction in terms of a number of different product types should be considered. However, lack of information on the amount of DBP in imported articles precludes the assessment of economic and social impacts based on product types. Instead, a higher level approach has been adopted, using PVC imports and estimations on the four phthalates in Annex XIV as a reference.

In the absence of much relevant information from consultation during the course of the current study, the information set out in the following sections is based mainly on literature sources.

Overall, it was estimated by ECHA in 2009 that around 8,250 tonnes of DBP in articles are incorporated each year in the EU market. The proportion of DBP in imported articles versus domestically manufactured ones remains unknown. The Danish EPA (2011) estimated that the costs of using alternatives relate primarily to the price differential between potentially restricted phthalates and alternatives (with reformulation/R&D costs being less significant). In 2015, a total extra cost of € 3-6 million is anticipated for the four phthalates in Annex XIV due to their substitution in imported articles with more expensive alternatives. DBP would only contribute to a small proportion of this figure.

However, the cost associated with a potential Article 68.2 restriction that would only additionally affect imported articles is not so straightforward to estimate and relevant issues are considered in the following sections.

4.11.7.2 Economic impacts

The lack of data on volume of DBP entering the EU in imported articles precludes a reliable quantitative estimation of the potential costs of a restriction in articles for this specific phthalate. It has been estimated that the extra cost associated with price increase in imported articles for the four phthalates in Annex XIV (DEHP, DBP, BBP, DIBP) will be € 3 – 6 million in 2015, assuming imports of 30,000 tonnes of these phthalates in articles (Danish EPA, 2011).

Overall, purchasing imported articles containing PVC would become more expensive compared to the baseline situation (i.e. consumers would need to pay more for DBP-free articles). This is due to non-EU manufacturers having to use more expensive plasticisers and passing these costs on, in order to sell on the EU market. Non-EU manufacturers may also opt to cease exporting their products into the EU, which would result in a decrease in competition and a potential price increase. However, a restriction would serve to offset the competitive advantage that non-EU article producers would gain by being able to continue using DBP while domestic producers could not (following the sunset date for uses where no authorisation is granted).

Non-authorisation of use of DBP while still permitting import of articles containing the substance could lead to an increasing number of articles being imported from outside the EU. In reality, it is likely that only a modest proportion of articles currently produced in the EU would instead be purchased from outside the EU due to the reduced cost afforded by DBP's price compared to its alternatives. Nonetheless, even with a relatively small proportion of sales affected, a restriction on DBP in imported articles could provide an economic benefit by levelling the playing field for EU producers, and could therefore result in potentially significant savings

4.11.7.2.1 Other costs

The above analysis only includes the costs associated with the price differential between DBP and phthalate-based alternatives. There would also be other costs to the producers of articles (mainly non-EU), through R&D and reformulation of products to use the alternatives. It has not been possible to quantify these, though they are likely to be of a comparable magnitude to the costs faced by EU companies in developing alternatives for uses which are

not granted authorisation beyond the sunset date and would likewise be passed on to EU consumers if these non-EU companies wish to continue supplying the EU market.

It should also be borne in mind that, in the event of a restriction, it is likely that there would be some replacement of DBP with other types of plasticisers than those considered here (e.g. non-phthalates) as well as other types of polymeric or other materials. These have not been examined in detail here.

4.11.7.2.2 Administrative costs

Due to the complexity of the supply chain, the amount of articles involved and the number of importers, distributors, etc., it is very difficult to estimate administrative costs. It is assumed that EU-produced articles would be less costly to monitor than imported ones. It has been roughly estimated that administrative costs associated with monitoring phthalates in imported articles would be in the range of € 6-12 million per year (Denmark 2011) for all of the four phthalates in Annex XIV (DEHP, DBP, BBP and DIBP). As DBP only accounts for a small proportion of the phthalates incorporated into articles (<7%), the monitoring costs exclusively associated with DBP would be much lower. DBP is also often found in combination with other phthalates, which makes estimating the cost of monitoring this individual phthalate highly uncertain.

4.11.7.3 Social impacts

Non-authorisation of certain uses of DBP in article production could potentially lead to impacts upon employment in the EU amongst DBP manufacturers/importers, polymer processing companies and article producers. If non-EU-produced articles (containing DBP) become preferable to EU-produced articles (based on alternatives), there is the potential for economic activity and associated employment to be lost from the EU. A restriction on use in all articles (including imported articles) would provide a more level playing field and potentially avoid such employment losses.

4.11.7.3.1 Potential human health and environmental benefits

According to Denmark's restriction proposal (Danish EPA, 2011), for a large part of the population risks are not sufficiently controlled and the exposure to DBP should be reduced. This relates to combined exposure of DBP and three other phthalates. In its opinion of 15 June 2012, ECHA's Risk Assessment Committee acknowledged that, based on biomonitoring data from before 2008, there could be a risk from combined exposure to the four phthalates, both for children and for adults, although the risk ratios calculated were not much above 1. However, they indicated that, while it is difficult to quantify the present day risk, the steady recent decline in both tonnages used in Europe and their body burden, plus the clear indications for a continuation of this decline would result in considerably lower RCRs.

Therefore, the Committee concluded that the data available did not indicate that currently (2012) there was a risk from combined exposure to the four phthalates (and therefore by definition not from DBP). The RAC therefore did not support the restriction proposed by Denmark. Based on the above, it appears that there would be minimal (or negligible) benefit for consumers of restricting the use of DBP in any (or all) articles. Therefore, the same is assumed to be true for remaining articles restricted under article 68.2.

In terms of potential environmental benefits, it is of note that the EU RAR (in its addendum of 2004) anticipated a risk for plants due to atmospheric exposure of DBP. However, this risk was mainly related to the vicinity of processing sites (PVC production, adhesive production, printing ink usage and glass fibre production. However, since processing sites in the EU would have no additional changes (beyond the authorisation decisions) it is assumed that there would be no additional impact on the environment.

4.11.8 Overall conclusions on potential costs and benefits

DBP is only used in a minor part of the products within each commodity group and it is often found in combination with other phthalates. This makes quantitative assessment of costs and benefits directly attributable to a restriction on DBP in imported articles highly uncertain. In any case, it can be concluded that costs associated with possibly more expensive imports (due to substitution, assurance, certification, etc.) would be relatively limited. The domestic (EU) cost of a restriction would presumably be negligible, if the restriction only covers uses that are not authorised in the EU. Due to the high volume of imported articles containing phthalates, the overall administrative costs are expected to be high.

The most relevant benefits relate to improved competitive conditions for domestic article producers compared to the baseline scenario, with potential for avoided loss of employment. Non-EU manufacturers would need to replace phthalates with more expensive alternatives and demonstrate that their articles are free of DBP. This cost may be passed on to importers and, eventually, to consumers. There could also be improved consumer health benefits, although it is not clear that there is any remaining unacceptable risk to consumers through use of DBP.

Overall, taking the requirement for authorisation as part of the baseline, the economic and other benefits of a restriction on (non-authorised) use in articles are expected to outweigh the costs. A restriction on DBP in imported articles is expected to close the gap between importers and domestic manufacturers, allowing the latter to sell their articles in equal market conditions and so avoiding loss of employment.

4.11.9 Substance-specific considerations for development of draft criteria to implement Art 68.2 to CMR 1A and 1B in consumer articles

This section firstly includes consideration of issues that are important in determining whether Article 68.2 restriction is potentially most appropriate, compared to other forms of restriction. Following this, the identified socio-economic issues that it would be important to take into account in assessing the merits of a restriction are discussed.

With regard to the potential choice of Article 68.2 as a RMO (compared to other forms of restriction), the following considerations arise from this case study substance:

- For substances on Annex XIV, such as DBP, restrictions on related consumer articles could be very important in ensuring that EU industry is not disadvantaged compared to non-EU companies for uses that are not authorised after the sunset date. Without such a restriction, it is possible that substantial quantities of articles currently bought from EU producers could instead be bought from non-EU companies, as they could still contain DBP. *Criteria could therefore take into account the need for and potential for levelling the playing field with non-EU article producers. There would need to be current or historical uses of the substance for which no authorisation is (expected to be) granted.*
- DBP is clearly present in articles on the EU market. Based on data from RAPEX, it is present in imported articles, even in uses where it is already restricted. *Criteria could therefore take into account whether the Annex XIV substance is actually present within imported articles, because if this is not the case, it may be difficult to justify any restriction.*
- DBP can clearly migrate from polymeric articles and consumers can therefore be exposed. If there were no exposure possible, it would presumably be difficult to justify any restriction. *Criteria could therefore take into account whether the available evidence indicates that consumer exposure cannot be ruled out.*

Having determined that an Article 68.2 restriction is potentially suitable, there are a number of socio-economic issues arising from this case study that are relevant to deciding whether this simplified route is likely to be suitable:

- Techniques are available to detect the presence of DBP in (imported articles). *Criteria for selection of the Article 68.2 restriction route would presumably need to take this into account.*
- Although DBP is not produced in quantities as large as other substances in Annex XIV (i.e. DEHP) and many companies have moved away from this substance in recent years, supply chains involved are complex, with many actors involved and dozens of different uses. In addition, DBP is often used in combination with other phthalates, being present sometimes in specific parts of the product. In the context of a potential restriction on articles to close the gap left after non-authorisation following the sunset date[138], it is problematic to target consultation to identify relevant stakeholders' views on likely implications of a restriction. *Criteria may therefore need to take into account whether the complexity of supply chains could be a barrier to understanding the socio-economic impacts of a 'fast track' restriction under Article 68.2.*
- Notwithstanding the above, since a restriction is likely to benefit EU industry by levelling the playing field with companies outside the EU, the extent of negative impacts on EU industry from a restriction is likely to be minimal. *Criteria could therefore take into account situations such as this where there is a reasonable expectation that there would not be negative impacts on EU industry. No specific information was needed for DBP to conclude that this is the case here, and this is likely to be true for other Annex XIV substances.*
- It is clear from the extent of the presence of restricted phthalates in uses that are already restricted (e.g. DBP in toys) that ensuring compliance with restrictions for imported articles can be problematic. This is evidenced by information from RAPEX, as well as consultation for the current study, and is just as true for 'standard' restrictions as it is for restrictions under Article 68.2 (compliance is an issue upon which MS are working). *Criteria could therefore take into account the extent to which such non-compliance for the substance in question has the potential to limit the extent to which the playing field is levelled between EU and non-EU article producers, as well as whether there are other potential RMOs that could be more effective (which seems unlikely). If this is likely to be a significant issue, this may be a sign that a more detailed investigation is required.*
- It seems clear that a restriction would benefit EU firms to a greater extent than non-EU firms, levelling the playing field. While it is likely to be able to conclude this for most Annex XIV substances, the available information on imports and domestic production of relevant articles provided additional corroboration in this case. *Criteria could therefore take into account whether a restriction would benefit EU firms to a greater or lesser extent than non-EU firms.*
- Flexible PVC products are widely recycled and there could therefore be important issues related to placing recycled consumer articles containing DBP on the market. Whilst this does not necessarily imply a more detailed restriction process is required, *criteria could take into account whether recycled articles are likely to be relevant, as this may be relevant to the wording of the restriction.*

[138] And hence a restriction would, in practice, only additionally affect imported articles, compared to the baseline. It would also level the playing field for companies within the EU who have moved away from use of the substance in advance of (impending) regulation, as has occurred in the EU with DBP.

Table 4.43 Screening of relevant impacts by stakeholder group, impact category and supply chain

✓ - Benefit or positive outcome;
- No or insignificant anticipated impact;
× - Cost or negative outcome.

IMPACT CATEGORY/ STAKEHOLDER	POLYMER PROCESSORS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMES	CONSUMERS
Operating costs and conduct of business	No impacts beyond those attributable to the authorisation process. -	No impacts beyond those attributable to the authorisation process. - Depending on scope of restriction, if recycled articles are covered, potentially negative impacts for companies producing articles from recycled PVC (lost turnover or demonstrating DEHP not present) ×	Potential impact on costs. A ban would exert pressure to check whether products they supply comply, either through obtaining information from suppliers (certification/declaration or test results) or by undertaking their own testing. They would also need to bear (and pass on to consumers) the likely increased costs of articles using alternatives. ×	No major cost impacts so no specific issues identified for SMEs. SMEs may find it hard to exert pressure on suppliers to demonstrate compliance and/or to bear the costs of doing so themselves. -	Cost increase due to substitution by more expensive alternatives (by non-EU firms) is likely to be passed on to consumers. Potentially more likely to buy from EU firms compared to the baseline. ×
Competitiveness, Trade and Investment	No impacts beyond those attributable to the authorisation process. -	A restriction in articles may close the gap (under the baseline) between domestic manufacturers and importers regarding the use of DBP, in products and potentially leading to improved competitiveness... ✓	Importers of articles potentially containing DBP will likely lose competitive edge due to potential increased prices of final imported products (from substitution of DBP) and extra costs (demonstrating compliance, change of suppliers). ×	No specific issues for SMEs identified -	Not applicable. -

IMPACT CATEGORY/ STAKEHOLDER	POLYMER PROCESSORS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMES	CONSUMERS
Competition and the internal market	No impacts beyond those attributable to the authorisation process. -	No negative impacts are expected apart from those attributable to the authorisation process. A restriction in articles could provide an economic benefit by levelling the playing field for EU manufacturers and encouraging equal competition. ✓	EU importers of articles will face a competitive disadvantage if their current imports of articles are found to contain DBP. Additional costs will be related to potential tests and changes in suppliers. ×	No specific issues for SMEs identified -	Compliance and substitution costs by non-EU firms expected to be passed on to consumers. ×
Innovation and research	No impacts beyond those attributable to the authorisation process. -	No impacts beyond those attributable to the authorisation process. -	Importers may explore new possibilities to cover consumer needs other than traditional DBP-containing articles. ✓	No specific issues for SMEs identified -	No impacts anticipated. -
Distributive/Equity	No impacts beyond those attributable to the authorisation process. -	EU article manufacturers are expected to be the most positively impacted stakeholder. A restriction in articles would reduce the potential loss in competitiveness arising from (non) authorisation under REACH. ✓	Importers are probably the most impacted stakeholder due to additional costs (testing, demonstrating compliance, passing on price of alternatives, supplier change). ×	SMEs are likely to face more difficulties to afford the costs resulting from a change in suppliers and from ensuring compliance, although they may be able to (partially) pass them on to consumers. ×	No impacts anticipated.

Source: ICF/AMEC Consultation.

4.12 Scoping SEA: Tris (2-chloroethyl) phosphate [TCEP]

4.12.1 Overview

This section covers the scoping-level SEA for **tris (2-chloroethyl) phosphate (TCEP, CAS No. 115-96-8)** and follows the structure defined in the introduction, concluding with the implications for development of criteria to help ECHA and the Commission in the prioritisation of substances in articles.

4.12.2 Regulatory status

TCEP is classified as Reprotoxic 1B and Carcinogenic 2. As a category 1B CMR substance, it cannot be used in toys, in components of toys or in micro-structurally distinct parts of toys, according to Annex II of directive 2009/48/EC. The substance is restricted by REACH Annex XVII Entry 28, which prohibits its direct use in consumer products. Therefore it is not allowed to be used in substances and preparations placed on the market for sale to the general public in individual concentrations equal to or greater than 0.1% w/w or other relevant concentration limit. This requirement, however, does not apply to articles and there is a possibility that consumers may be exposed to products containing TCEP, hence the potential need for restriction under Article 68.2). REACH Annex XVII Entry 30 bans the use of TCEP in medicinal and veterinary products, motor fuels, cosmetics and artist' paints. Similarly, there are certain restrictions on use in food contact materials in compliance with Directive 2007/19/EC.

TCEP is included in the authorisation list under REACH (Annex XIV), with a sunset date of 21/08/2015 and a latest application date of 21/02/2014. Depending upon the uses for which authorisations are granted, use of TCEP in production of certain types of articles may no longer be allowed in the EU. However, the scope of authorisation does not extend to articles imported from outside the EU. There may therefore be a need to introduce restrictions on imported articles containing TCEP under Article 68.2, potentially in line with those applications for which authorisations have not been granted, so as to 'close the loop' in terms of protection of human health for consumers exposed to TCEP from such articles. Such a restriction would also help to ensure equal treatment of EU and non-EU article producers.

TCEP was selected for more detailed analysis in (task 2 of) this project on the basis that authorisation applications may be received for the substance. The main focus of the present analysis is to help understand the potential implications of Article 68.2 restriction after the sunset date to regulate imported articles.

4.12.3 Uses of the substance

TCEP is mainly used as a flame retardant in the manufacture of PUF and unsaturated polyester resins. It is also used in acrylic resins, adhesives and coatings. The main industrial sectors in which TCEP has been used are the building industry (e.g. roofing insulation), the furniture and the textile industry (e.g. back-coatings for carpets and upholstery). It has also been used in the manufacture of vehicles (cars, trains and aeroplanes).

Although no TCEP is expected to be used in consumer paints, in 2004 it was still used in the manufacture of industrial paints. Use in paints and coatings for construction works and the offshore industry are the only uses registered under REACH. TCEP is also known to be used as an intermediate in the chemical industry for the manufacture of wax additives. This last use would be out of the scope of this study as the substance is not incorporated in articles.

The breakdown of quantities by type of article is uncertain. However, before the classification of TCEP as a CMR it was suggested that 94% (940 tonnes/year) of this substance within the EU was used in the manufacture of polymers, 5% (50 tonnes/year) as an intermediate substance and 1% (10 tonnes/year) in industrial paints (Annex XV SVHC Dossier, 2009).

4.12.3.1 Overall quantities manufactured and imported

Manufacture of TCEP in Western Europe (EU15) was 2,000 tonnes per year in 1998. In 2002, there was no manufacture in EU15 and use was estimated to be 1,007 tonnes/year, with 1,150 tonnes imported and 143 tonnes exported per year. In 2005, there was reportedly one manufacturer within the EU25, which manufactured between 300 and 500 tonnes, most of which was exported. In 2010, it was estimated that the domestic production within EU27 was 400 tonnes and, due to import and some export, the final use of the substance amounted to around 1,000 tonnes per year (ECHA 2010).

Currently, TCEP is registered under REACH under a joint submission for the tonnage band of 10-100 tonnes per year, being solely used in paints and coatings for the building and offshore industry.[139] Evidence suggests there is only one manufacturer of TCEP in the EU. According to information on uses provided during consultation and previous data on manufacture and import, we estimate that the current total consumption of TCEP in the EU is lower than 60 tonnes per year. There is no recent data on imports of TCEP but it is expected to be much lower than figures from 2001/2002 (if any). The reduction compared to 2010 estimates may reflect companies moving to alternatives due to the addition of the substances to the candidate list and Annex XIV of REACH.

4.12.3.2 Use in articles

Before the classification of this substance as a CMR, the vast majority of TCEP within the EU was used as an additive plasticiser and viscosity regulator with flame-retarding properties, particularly for polyesters, PUF and other polymers (e.g. PVC and polyisocyanurate).

TCEP is known to have been used in several materials including plastics, textiles, adhesives, building insulation, coatings, paints and varnishes (EU RAR 2009, RCOM 2010). In terms of consumer exposure, the most relevant articles are those containing PUF, such as furniture, beds and mattresses. TCEP can also be found in textiles, carpeting, upholstery, childcare goods and electronic casing (FIRA 2012). TCEP has also been used historically as a replacement for now-restricted substances such as pentarythritol-BDE.

Studies have confirmed the presence and concentration of TCEP in articles. The Danish EPA reported this substance in a soft cube toy for children made of textile, plastic and foam rubber at levels ranging from 4,900 to 6,500 mg/kg (Danish EPA 2006). In 2009 the Canadian Health Authorities conducted a study analysing the content of flame retardants in several PUF products including 14 sofas, 4 mattresses, 10 children's products including toys, 4 acoustic panels and a seat from a car. TCEP was present in 4 of the sofas, the seat and 2 children's products (a PUF book and a sleep positioner with 13,000 mg/kg and 21,000 mg/kg of TCEP respectively). (Canadian Department of Health 2012).

A similar study in the US, but focused on children's articles, was published in 2012. TCEP was identified in 17 out of 101 PUF children's products tested, including sleep positioners, nursing pillows, portable mattresses and baby carriers. The concentration ranged between 1,080mg/kg and 5,940 mg/kg with an average concentration of 5,910 mg/kg (Stapleton, et al., 2011).

Consultation for the current study revealed that TCEP is no longer being used in Europe for the manufacture of either rigid PUF (for insulation) or flexible PUF (for cushioning). According to the main trade associations in the industry (PU-Europe), manufacturers have moved to alternative flame retardants (mainly TCPP[140]) due to health and regulatory concerns. This suggests that, at least in the EU, TCEP has been replaced for its main use and is currently limited to specialized applications.

[139] According to records in ECHA's database on registered chemicals (http://echa.europa.eu/search-chemicals) as of 13 November 2013.

[140] Tris(2-chloro-1-methylethyl) phosphate (TCPP), CAS No: 13674-84-5 / EC No: 237-158-7

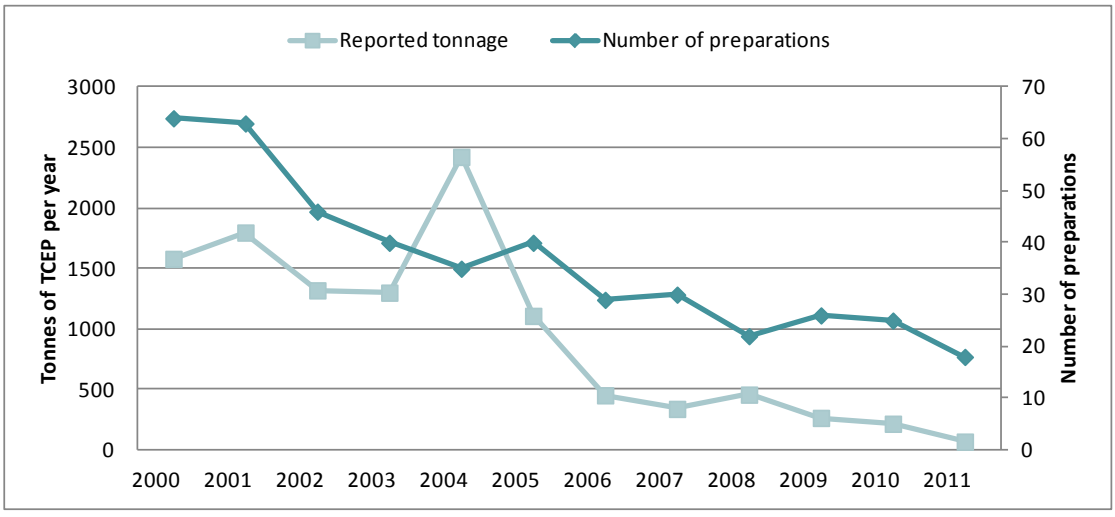
Records of Substances in Articles (SiA) in ECHA databases confirm this point. There are only two notifications of SiA for TCEP, as a coating in metal articles and a coating for stone, plaster, cement, glass and ceramic articles. The exact function and availability of these articles remains unclear but, according to ECHA's Notification of Substances in Articles (SiA) use seems to be limited to the construction and offshore industry, which makes them unlikely to be available for most consumers. TCEP has reportedly been used in the formulation of specialized flame resistant paints and varnishes (e.g. for polyvinyl acetate or acetyl cellulose) in concentrations between 5 and 16% (EU RAR 2009). It is assumed that no TCEP is formulated into consumer paints. Total use in industrial paints is estimated to be less than 10t/y in the EU.

4.12.3.3 Trends

Over recent decades, there is a clear trend in the reduction of the use of TCEP due to health and regulatory concerns. This has been highlighted by the RAR and the Annex XV SVHC dossier. Since the classification of TCEP as a CMR substance and its inclusion in the authorisation list, industry seems to be moving away from using TCEP at a higher pace. This is illustrated by the fact that in 2010 the estimated EU production was 400 tonnes while currently it is less than 100 tonnes.

Data from the SPIN database also illustrates the decline in use of TCEP. Figure 4.17 shows the combined reported use of TCEP in the Scandinavian countries (Sweden, Finland, Norway and Denmark). It is evident that both the tonnage of TCEP and the number of preparations containing the substance have substantially decreased in these countries over the last decade.

Figure 4.16 Tonnage of TCEP and number of preparations containing it in Scandinavian countries



Source: SPIN database

At an international scale, the only plant producing TCEP in North America ceased production in 2009 although manufacture is likely to still occur in Asia. Global consumption of TCEP peaked at over 9,000 tonnes in 1989 and decreased to below 4,000 tonnes in 1997. By 2005 it was estimated to be less than 1,000 tonnes, declining to near 150 tonnes in 2010 (Canadian Department of Health, 2012). This indicates that current consumption of TCEP in the world is less than 2% of what it was 20 years ago.

4.12.4 Supply chains affected

The figure below provides an overview of the key stages in the supply chain related to the use of TCEP in consumer articles. This is clearly a simplification but does serve to highlight the key players in the supply chain. Those of particular importance for the scoping SEA are the manufacturer of TCEP, manufacturers of articles and importers of articles. Given the

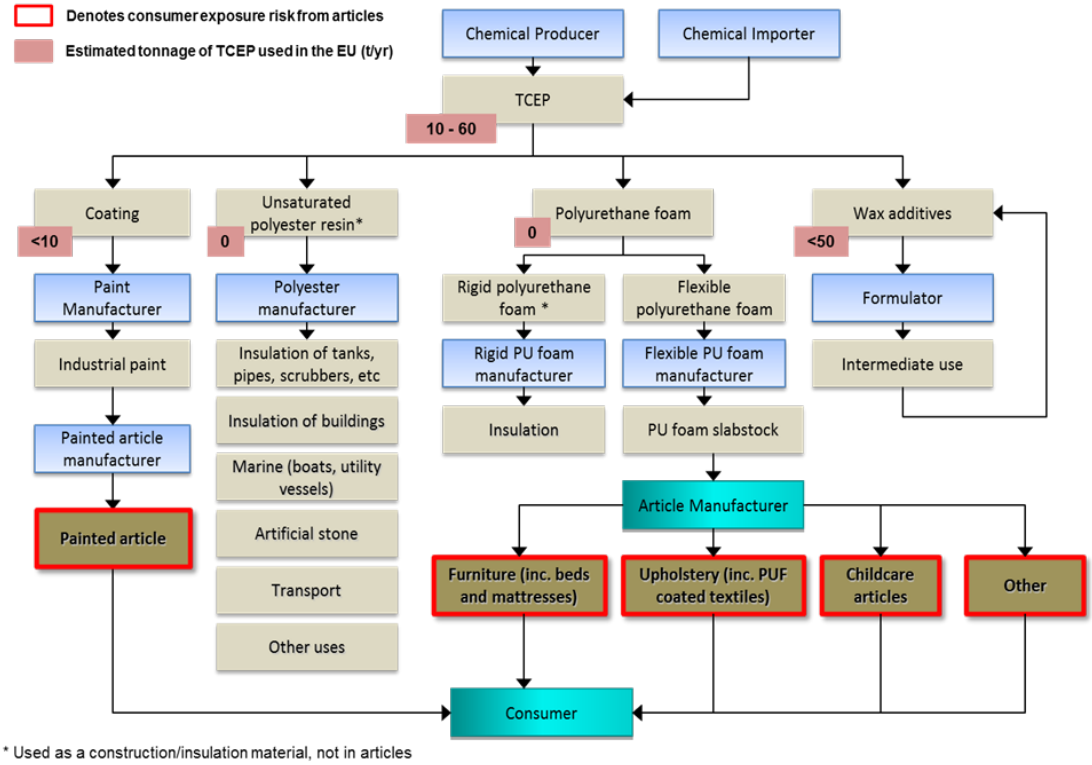
exposure potential and the historical records of presence of TCEP, articles containing PUF are the main concern for this study. Other minor uses mentioned in general literature but with no further evidence or references (like the use of TCEP in electronic casings) have not been included in the figure below.

There is only one TCEP manufacturer in the EU, but there are a large number of manufacturers of PUF products. PUF manufacturers mix TCEP with the polymers to improve the fire-retardant properties of the material and commercialize it in slabs. PUF slabstock is then used in the manufacture of consumer articles such as furniture, upholstery, childcare articles, coated textiles, etc. Although, according to consultation, TCEP is no longer used in PUF in the EU it still may be imported in articles containing this material. Consultation also revealed that direct import of PUF slabs is very limited. This is due to the high volume/weight ratio of this material (97% of air by volume), which makes its transport very costly.

As mentioned above, TCEP may be present in specialized flame retardant paints but not in consumer paints. TCEP is formulated into the paint and then applied to the article. The nature of the final article is not clear, nor is the degree to which general public might be exposed, although exposure is likely to be minimal, as compared to substances in paints that are directly applied by consumers.

Regarding rigid PUF and unsaturated polyester resin, these materials are used in construction and insulation and are not expected to be incorporated in consumer articles. In any case, consultation confirmed that no TCEP is used in rigid PUF in the EU and evidence suggests the same for polyester resin. Similarly, the use of TCEP as an intermediate in the manufacture of wax additives is outside the scope of this study.

Figure 4.17 Summary of supply chains of tris (2-chloroethyl) phosphate (TCEP)



Source: ICF/AMEC Consultation

4.12.5 Expected non-use scenario

During the preparation of the scoping SEA, a consultation exercise with industry was undertaken to ascertain anticipated responses to a restriction on the use/presence of TCEP

in the production of consumer articles. The number and type of stakeholders contacted during the consultation for ETU can be found in Table 4.44.

Table 4.44 Consultation exercise

	Type of industry/article	Stakeholders contacted	Valuable responses received
Trade/industry associations	Chemicals, flexible PUF, rigid PUF, adhesives	6 European	2 European
Private companies	Chemicals	2 European	0

Source: ICF/AMEC Consultation

It should be noted that the analysis has been developed using the assumption that the scope of a restriction under Article 68.2 would only practically affect imported articles containing TCEP (primarily PUF and painted articles) i.e. in order to close the gap for uses of TCEP where an authorisation is not granted for use in the EU but for which consumers (and the environment) may still be exposed through imported articles. The restriction would be assumed to apply to all articles, but EU-produced articles would already be covered by (non) authorisation. For the baseline situation, it is therefore assumed that authorisations are granted for some but not necessarily all current uses.

4.12.5.1 *Manufacturers and importers of TCEP*

In the event of a restriction on the use of TCEP in articles that focused on non-authorised uses of the substance, it is assumed that manufacturers and importers of TCEP would not be directly affected (beyond existing requirements under REACH authorisation), since the restriction would only target imports of articles.

4.12.5.2 *Paint formulators*

Although consultation could not confirm this point, evidence suggests that flame-retardant paints may be a critical use of TCEP. There seems to be an internal debate within industry regarding the availability of alternatives to this use.

4.12.5.3 *Manufacturers of PUF*

According to consultation, EU manufacturers of PUF, both rigid and flexible, have already moved to alternatives and therefore would not take further actions in a non-use scenario.

4.12.5.4 *Manufacturers of articles*

According to consultation with industry imports of PUF are negligible and domestic PUF is TCEP-free so EU PUF article manufacturers would not be affected in a non-use scenario.

Regarding manufacturers of articles coated in flame retardant paint containing TCEP, it is not clear whether they would use an alternative substance or cease production. However, it seems more likely that alternatives would be applied although the performance of the final articles may be affected. No further information is available, however.

4.12.5.5 *Importers of articles*

Importers of articles would no longer be able to import products containing TCEP. Instead, they would need to import articles based on alternatives to TCEP. Based on information from consultation for the current study, as well as literature such as the Austrian (2011) Annex XV SVHC dossier, the most common substitute for TCEP is TCPP (Tris (2-chloroethyl) phosphate, CAS No. 13674-84-5).

TCPP offers good technical characteristics and has a similar price. It is manufactured in the EU in volumes above 30,000 t/y, having increased in recent years due to the substitution of TCEP. Although not classified as CMR, there has been some public concern regarding the

safety of TCPP. A risk assessment in 2008 (EU RAR 2008) concluded that the substance was a borderline case for classification for effects on fertility and developmental toxicity but no further classification was proposed. No need for further risk reduction measures for consumers were recommended.

4.12.5.6 Consumers

Even under the baseline situation – non-authorisation for certain uses of TCEP but imports of relevant articles still permitted – it is unlikely that consumers would purchase increased volumes of imported articles that still contain TCEP from outside the EU. This is due to the global decline in the use of the substance and the minimal (if any) difference in price and technical performance between articles manufactured with TCEP and with the alternative TCPP. No changes in consumer behaviour are expected due to a restriction in articles.

4.12.6 Assessment of economic and social impacts

4.12.6.1 Screening of impacts

The first step in the SEA is a screening of the impacts and stakeholders potentially affected by the restriction. This ensures that the analysis is focussed on those stakeholders most affected by the proposed restriction and considers the nature and scale of the impacts, following the SEA guidance in relation to the possible costs and benefits. Categories of impact are shown in section Table 4.45 along with a qualitative assessment of impacts.

4.12.6.2 Economic impacts

4.12.6.2.1 Manufacturers and importers of TCEP

This study assumes a situation whereby articles containing TCEP in non-authorised uses would be restricted (after the sunset date). Therefore, no further impacts than those attributable to the authorisation process are anticipated.

4.12.6.2.2 Manufacturers of alternative flame retardants

As mentioned above, the production of TCPP has increased notably during recent years as a substitute to TCEP. A restriction on TCEP in imported articles may encourage non-EU manufacturers to move to this alternative and, indirectly, increase exports of TCPP from EU flame retardant producers to non-EU article manufacturers. However, TCPP is also produced in non-EU countries and the potential increase in exports of TCPP is expected to be limited.

4.12.6.2.3 Paint formulators

No additional impacts to those attributable to the authorisation process are anticipated.

4.12.6.2.4 Manufacturers and importers of articles

A ban implies that article manufacturers and importers would have to demonstrate that their products do not contain TCEP before they are placed on the internal market. This could be accomplished by providing a certification detailing the source and contents of the PUF or testing the articles in a laboratory, with its associated cost increase.

However, given the global decline in the use of TCEP in PUF and the movement of industry to alternative flame retardants, the costs for article manufacturers, importers, distributors and retailers is expected to be limited.

The application of Article 68.2 to articles would close the gap for uses of TCEP where an authorisation is not granted for use in the EU but for which consumers (and the environment) may still be exposed through imported articles. In this sense, a restriction in articles could provide an economic benefit by levelling the playing field for EU manufacturers, being able to commercialize their products under the same conditions.

If authorisation is not granted, manufacturers of articles coated in flame retardant paint containing TCEP may face additional costs associated with substitution of TCEP for other alternatives. However, this impact should be assessed during the authorisation process and would not be a direct result of a restriction in articles. The volume of imported paint and painted articles containing TCEP remains unclear although it is estimated to be low. Importers of articles coated in TCEP paints are expected to face additional costs due to change of suppliers and the requirement to provide assurance that the substance is not present. It is not clear if current alternatives are able to substitute TCEP in flame retardant paints achieving the same level of performance. If this is the case, the European offshore and construction industry may lose some competition capacity and face higher fire risks. However, given the low volume of TCEP used and the specialized use of this substance, the overall impact is expected to be limited.

4.12.6.2.5 Consumers

A restriction on the use/presence of TCEP in articles may result in a decreased exposure to this substance and associated lower health risks. Consumers may face slightly increased costs when buying articles containing PUF that has been certified as TCEP free. However, these are anticipated to be minimal. With the exception of paints, which have a specialized use and are unlikely to be part of consumer products, TCEP has been satisfactorily replaced in general consumer articles. Therefore no reduction in the choice of articles for the general population is anticipated.

4.12.6.3 Administrative costs

EU authorities may face increased cost in implementation, monitoring, sampling, testing and enforcement. These costs would decline over time as non-compliant products are removed from the marketplace. The use of existing alert systems (e.g. RAPEX) may help reduce information and compliance costs as well as contributing to effective enforcement at EU level.

4.12.6.4 Social impacts

Given the limited production and use of TCEP in the EU, impacts on employment are expected to be minimal.

4.12.6.4.1 Potential human health and environmental benefits

A large proportion of consumer exposure to TCEP occurs through the intake of indoor dust from articles. The exposure of babies due to sucking of articles is of special concern (EU RAR 2010). Therefore, a restriction in articles is expected to bring benefits to human health.

Releases to watercourses and air have also been estimated. However, environmental risk and human exposure through the environment are not considered to be significant (EU RAR 2010).

The RAR (EU RAR 2010) concluded that there is a need for limiting the risks of workers regarding TCEP, although a restriction in imported articles is not intended to tackle this issue.

4.12.6.4.2 Overall conclusions on potential costs and benefits

As TCEP is included in Annex XIV under REACH, any impact of a refused authorisation on the EU industry would be attributable to the authorisation process. Nevertheless, a restriction on use/presence of TCEP in imported articles could mean that there would be positive economic benefits to EU article producers i.e. consumers would be (relatively) more likely to buy EU-produced articles if imported articles could no longer include TCEP in the same way as domestic articles. Consumers are expected to benefit on one hand from mitigation of any risks to the environment and human health, or on the other may face slightly higher prices for imported consumer articles due to certification for fire safety standards, traceability and compliance costs. The choice of consumer articles is not expected to be affected.

4.12.7 Substance-specific considerations for development of draft criteria to implement Art 68.2 to CMR 1A and 1B in consumer articles

This section firstly includes consideration of issues that are important in determining whether Article 68.2 restriction is potentially most appropriate, compared to other forms of restriction. Following this, the identified socio-economic issues that it would be important to take into account in assessing the merits of a restriction are discussed.

With regard to the potential choice of Article 68.2 as a RMO (compared to other forms of restriction), the following considerations arise from this case study substance:

- Legal status: Like DEHP and DBP, TCEP is currently included in Annex XIV of REACH. This has relevant implications in the potential impacts of a restriction in articles i.e. closing the gap for uses that are not granted an authorisation. A notable aspect is that, as long as the restriction in articles matches the non-authorised uses of the substance, no additional impacts should be expected for the manufacturers of the substance and producers/users of articles. *Criteria could therefore take into account the need for and potential for levelling the playing field with non-EU article producers.*
- Another important point is that any critical use of the substance in articles could be addressed during the authorisation process and would therefore not need to be directly assessed in the application of Article 68.2. *Criteria could therefore take into account whether other controls on use of a substance give indications of uses that should be exempt from a restriction under Article 68.2, particularly (time-limited) REACH authorisation. Criteria for Annex XIV substances may therefore not need to take into account issues such as use of critical raw materials in the same way as other CMRs, because such issues should already be picked up through authorisation.*
- An issue for TCEP is that it has been used in CR for both industrial and consumer uses. As far as use for industrial articles goes, a possible issue is that some articles might subsequently be incorporated into other articles that are sold to consumers. Choice of an Article 68.2 restriction should therefore take into account knowledge of what the different uses are, and whether this is sufficient to understand which products may ultimately be sold to consumers.
- Exposure: Although use has clearly decreased, there is evidence of the presence of TCEP in imported articles in known concentrations, with potential to harm the general public. This provides a potential basis for a restriction and may allow for estimation of health benefits. *Criteria should therefore take into account evidence of the presence of the substance in articles (both domestic and imported) and potential for consumer exposure.*

Having determined that an Article 68.2 restriction is potentially suitable, there are a number of socio-economic issues arising from this case study that are relevant to deciding whether this simplified route is likely to be suitable:

- Evidence suggests that it is possible, in practical terms, to monitor for the presence of the substance in consumer articles, a factor that would be important in identifying non-compliance and in demonstrating compliance. *Criteria could therefore take into account the availability of techniques to monitor for the presence of a substance in consumer articles.*
- Alternatives: The apparent global availability of a safer, affordable and technically reliable alternative for the majority of the uses of the substance limits substantially the potential economic impacts of substitution while minimizing the number of critical uses. *Criteria should therefore take into account the considerations on availability of suitable alternatives.*
- EU and global trends: The use of TCEP has been declining for more than 20 years, motivated by health concerns and the availability of an affordable substitute. This means

that any restriction would bolster with the current trend, accelerating the transition and while having minimal impacts on domestic manufacture and imports... *Criteria could therefore take into account existing trends in the use of a substance (a restriction may accelerate the move away from a substance and hence reduce health damage sooner, but likewise the potential health benefits directly attributed to the restriction may be less than for other substances that do not show a decreasing trend, if use will shortly cease in any case).*

Table 4.45 Identification of relevant impacts by stakeholder group, impact category and supply chain

✓ - Benefit or positive outcome;
- No or insignificant anticipated impact;
× - Cost or negative outcome (less than 5% change).

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMES	CONSUMERS
PUF	Operating costs and conduct of business	No or insignificant impact is anticipated as TCEP is no longer used in the EU for the manufacture of PUF. -	No or insignificant impact anticipated as evidence suggests that the EU manufacturing sector has moved towards safer alternatives in the manufacture of articles containing PUF. -	A ban would exert pressure to check whether products they supply comply, either through obtaining information from suppliers (declaration or test results) or by undertaking their own testing. However, given the global decline in the use of TCEP in PUF, the impact is expected to be limited. ×	No major cost impacts so no specific issues identified for SMEs. SMEs are likely to face more difficulties to afford the costs resulting from a change in suppliers and from ensuring compliance, although they may be able to pass them on to consumers -	Compliance assurance and certification costs may be passed on to consumers. However, as the vast majority of PUF products are currently free of TCEP, the cost increase is expected to be minimal, if any. -
	Competitiveness, Trade and Investment	No or insignificant impact is anticipated as TCEP is no longer used in the EU for the manufacture of PUF. -	A restriction may close the gap between domestic manufacturers and importers regarding the use of TCEP, ensuring that imported products fulfil the same safety requirements as EU-produced ones. ✓	Importers of articles potentially containing TCEP will potentially lose competitive edge due to potential increased prices of final products and extra costs (testing, change of suppliers), if non-EU firms switch from use of TCEP and wish to continue supplying the EU market. However, the volume of the substance entering the EU is considered to be low due to the global decline of the substance and its total prohibition is unlikely to cause significant impact. In addition article price increases as a result of substitution with TCPP are not expected to be significant. ×	No specific issues for SMEs identified -	No significant impacts expected. -

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMES	CONSUMERS
	Competition and the internal market	No or insignificant impact is anticipated as TCEP is no longer used in the EU for the manufacture of PUF. -	No negative impact anticipated as EU manufacturers do not use TCEP in PUF anymore. In this sense, they could benefit slightly from a competitive advantage. ✓	EU importers of articles will face a competitive disadvantage if their current imports of PUF articles are found to contain ETU. Additional costs will be related to potential tests and changes in suppliers. Even so, the volume of the substance entering the EU is considered to be low due to global decline in its use and its total prohibition is unlikely to cause significant impact on internal competition -	No specific issues for SMEs identified -	No impacts anticipated. -
	Innovation and research	No or insignificant impact is anticipated as TCEP is no longer used in the EU for the manufacture of PUF. -	No or insignificant impact is anticipated as PUF article manufacturers do not use TCEP anymore. -	No significant impact on innovation and research. -	No specific issues for SMEs identified -	No impacts anticipated. -
	Distributive/Equity	No or insignificant impact is anticipated as TCEP is no longer used in the EU for the manufacture of PUF. -	No or insignificant impact is anticipated as PUF article manufacturers no longer use TCEP. -	Larger impact on EU article importers than EU-based manufacturers due to additional costs (testing, supplier change). SMEs are likely to face more difficulties to afford the costs resulting from a change in suppliers and from ensuring compliance, although they may be able to pass them on to consumers ✖	No specific issues for SMEs identified -	No impacts anticipated. -

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMES	CONSUMERS
Painted articles	Operating costs and conduct of business	No additional impacts to those attributable to the authorisation process are anticipated. -	No additional impacts to those attributable to the authorisation process are anticipated. -	Potential impact on costs due to higher article prices and regulatory compliance, possibly driving up prices of imports. Although assumed to be low (if any), the amount of imported articles coated in paints containing TCEP remains unknown. ✗	No major cost impacts so no specific issues identified for SMEs. SMEs may find it hard to exert pressure on suppliers to demonstrate compliance and/or to bear the costs of doing so themselves. -	Compliance and substitution costs may be passed on to consumers. However, the use of paints containing TCEP is expected to be restricted to specialized industrial uses. -
	Competitiveness, Trade and Investment	No additional impacts to those attributable to the authorisation process are anticipated. -	No negative impacts are expected apart from those attributable to the authorisation process. A restriction could provide an economic benefit by levelling the playing field for EU manufacturers. ✓	Importers of articles coated in flame retardant paints containing TCEP will potentially lose competitive edge due to potential increased prices of final products and extra costs (testing, change of suppliers). Although assumed to be low, the amount of imported articles coated in paints containing TCEP remains unknown. ✗	No specific issues for SMEs identified -	No impacts anticipated. -
	Competition and the internal market	No additional impacts to those attributable to the authorisation process are anticipated. -	No negative impacts are expected apart from those attributable to the authorisation process. A restriction could provide an economic benefit by levelling the playing field for EU article producers who would be better able to compete with non-EU firms who may currently supply TCEP-containing articles on the EU market.. ✓	Importers of articles coated in flame retardant paints containing TCEP will potentially lose competitive edge due to potential increased prices of final products and extra costs (testing, change of suppliers). Although assumed to be low, the amount of imported articles coated in paints containing TCEP remains unknown. ✗	No specific issues for SMEs identified -	No impacts anticipated. -

SUPPLY CHAIN	IMPACT CATEGORY/ STAKEHOLDER	EU CHEMICAL PRODUCERS	EU ARTICLE MANUFACTURERS	EU ARTICLE IMPORTERS/ DISTRIBUTORS	SPECIFIC ISSUES FOR SMES	CONSUMERS
	Innovation and research	No additional impacts to those attributable to the authorisation process are anticipated. -	No impacts are expected apart from those attributable to the authorisation process. -	No significant impact on innovation and research. -	No specific issues for SMEs identified -	No significant impacts anticipated. -
	Distributive/Equity	No additional impacts to those attributable to the authorisation process are anticipated. -	EU article manufacturers are expected to be the most positively affected stakeholder. A restriction would aim to address reduced competitiveness arising from an authorisation requirement on EU-use but could not cover articles, so the restriction closes the gap. ✓	Larger (negative) impact on EU firms that import articles than EU manufacturers due to additional costs (testing, supplier change). ×	Small importers are likely to face more difficulties to afford the costs resulting from a change in suppliers and from ensuring compliance, although they may be able to pass them on to consumers × -	No significant impacts identified. -

Source: ICF/AMEC Consultation

4.13 Summary of substance-specific considerations for development of criteria

The preceding chapters present the scoping-level SEAs developed during the course of Task 2 of this project. They provide an indication of the type and level of information that it is possible to achieve within a relatively modest allocation of staff time as compared to the work involved in preparing a full SEA in the context of restrictions (Article 69).

The scoping-level SEAs were selected and prepared in order to consider different types of learning points for the potential application of restrictions under Article 68.2.

At the end of each of the scoping-level SEAs, some conclusions were drawn on the implications of the case study for potential restriction proposals. These were divided into two categories of conclusions:

- Firstly, consideration of issues relevant to the case study substance that are important in determining whether Article 68.2 restriction is potentially most appropriate, compared to other forms of restriction.
- Secondly, the identified socio-economic issues that it would be important to take into account in assessing the merits of a restriction are discussed, again specific to that case study.

The two tables below consolidate some of these learning points, in order to inform the analysis in Section 5, which considers potential criteria for use in deciding whether Article 68.2 restriction may be appropriate.

Table 4.46 draws together some of the common issues that seem to be most relevant in deciding whether Article 68.2 is an appropriate type of restriction. For each 'consideration' identified, an example is provided from amongst the case study substances. Some commentary is provided on the implications of the particular 'consideration' for choice of Article 68.2. Details are provided of some of the case-study substances in which relevant discussion is included within the scoping-level SEAs. Finally, some suggestions are made (based on the case studies) of the types of information that might typically be needed when undertaking analysis to decide upon potential restriction under Article 68.2.

Table 4.47 provides a synthesis of some of the learning points from the case study substances, in particular common themes or issues that it will be important to take into account in deciding on the potential scope of a restriction under Article 68.2 (or other restriction if this is not the most appropriate route for the substance). Many of the issues are equally applicable in the context of a full restriction proposal and we have drawn some conclusions on whether a "scoping-level SEA" of the sort undertaken in the current study might give confidence that the health and socio-economic impacts of an Article 68.2 restriction are sufficiently well understood to make use of this simplified process. The format is largely similar to Table 4.46, with the exception that the contents are not specifically related to deciding on the suitability of the Article 68.2 route. The intention of this table is to help consider whether undertaking similar scoping-level SEAs in the future could avoid the lengthy process of preparing full SEAs / risk assessments under Article 68, while still providing sufficient reassurance that the impacts for EU society are well understood.

Table 4.46 Key considerations in determining whether Article 68.2 could be an appropriate approach to restriction

Consideration	Examples	Implications for choice of Article 68.2	Substances where relevant discussion included	Examples of information needed
Is there evidence of ongoing harm to EU citizens from the substance in consumer articles?	No specific examples from substances from this study but DMF provides an example where urgent action may be necessary to address an immediate health risk	This could be a key use of Article 68.2, allowing restrictions to be introduced without the need for extensive/time-consuming assessment of health and socio-economic implications.	N/A	■ Evidence of high levels of exposure / harm to health from exposure.
Is there potential for exposure of consumers (or can it be ruled out on technical grounds)?	GaAs is used in small quantities and in encapsulated form, leading to negligible potential for exposure	Such a consideration tends to make any form of restriction (Article 68.2 or otherwise) less appropriate.	GaAs	■ Results of exposure/risk assessments or other scientific studies suggesting that exposure cannot be ruled out. ■ Note that it may not be necessary to demonstrate an unacceptable risk to consumers (exposure > DNEL/DMEL) in the context of Article 68.2.
Is there a threshold for effects with the substance? [Note 1]	There is a threshold for effects with DEHP. Moreover, there is a recent opinion from ECHA's RAC that a restriction is not warranted.	A threshold for effects associated with a substance could lead to an Article 68.2 restriction being questioned. Existence of such a thresholds tends to suggest that there is a safe level at which the substance can be used, meaning that it could be more appropriate to undertake further analysis (e.g. Article 69 restriction).	DEHP	■ Toxicological data on the substance.
Is there evidence that the substance is or has been present in consumer articles?	Most substances include consideration of whether there is evidence of presence in consumer articles	Without such evidence, a restriction may be difficult to justify, and benefits may be limited. Whilst this consideration is relevant (to all types of restriction), if the evidence suggests that there may be no consumer article uses, this may be an indication that further analysis is required before deciding on a possible restriction route. The issue relates to both imported and EU-produced articles.	All	■ Confirmation in the literature from test results. Data from article manufacturers, test-houses, etc.
For Annex XIV	DEHP and DBP –	Article 68.2 may provide a rapid means of ensuring a level	DEHP, DBP,	■ Literature / consultation

Consideration	Examples	Implications for choice of Article 68.2	Substances where relevant discussion included	Examples of information needed
substances, are there historical/reported uses for which no authorisation has been granted/applied for? If so, a restriction may be necessary to cover imported articles.	authorisation applications expected for some but not all uses.	playing field for EU article manufacturers (where no authorisation is granted), ensuring equal treatment with non-EU suppliers of articles to the EU market. (Placing articles containing Annex XIV substances on the market is not covered by REACH authorisation).	TCEP	information on historical uses. ■ Comparison with uses applied for under REACH authorisation.
Is EU use negligible (or will it be in certain uses after the sunset date for substances in Annex XIV), meaning that impacts on EU firms are likely to be negligible?	EU firms have substituted ETU in e.g. neoprene garments, but non-EU firms can still potentially sell products containing the substance on the EU market.	If EU use is negligible, it is likely that the economic impacts on EU firms will not be significant. There are some examples where the EU is world-leading in substitution of hazardous substances, meaning that a restriction could protect EU consumers from exposure via imported articles, while avoiding potential negative employment effects of the status quo (with non-EU firms still allowed to place articles containing the substance on the EU market).	DBP (certain applications), Direct Black 38, TCEP, ETU (certain applications)	■ Information from industry and production/consumption statistics on the substance. ■ Indication that the substance has e.g. been phased out of use.
Are some, but not all, article uses already restricted?	Direct Black 38 (rather aromatic amines to which the substance can clear) in textiles and leather are already restricted. There is some evidence of use in other consumer articles.	A restriction under Article 68.2 could help to address gaps in existing restrictions where it seems clear that exposure potential exists for non-restricted article types in which the substance is used, and where the existing restrictions have already demonstrated the need to address risks to consumers.	Direct Black 38, o-anisidine	■ Details of restricted uses (under REACH and other legislation). ■ Evidence of possible/probably use/presence in other consumer article types
Are there critical uses of the substance for which it would be necessary to introduce derogations from any restriction?	GaAs is a crucial enabling substance for many technologies of the EU economy.	If the substance is identified as a critical raw material, it is likely that a simplified restriction procedure will not be suitable and more detailed consideration of the impacts of a restriction is required.	GaAs	■ Data on whether the substance in question is a critical (raw) material in relevant article types.
How much uncertainty is there regarding the extent of current use	For some substances, there remains significant uncertainty on what articles	If there is information to suggest that there is only very partial knowledge of the uses of the substance, this may be an indication that either (a) further data is needed on the uses of	o-anisidine	■ Information on actual current use in the EU or presence in imported articles (decision

Consideration	Examples	Implications for choice of Article 68.2	Substances where relevant discussion included	Examples of information needed
and exposure to the substance and what level of evidence is sufficient to make a decision on restriction?	are relevant. For example, o-anisidine is used widely as an intermediate in dyes/pigments, and can lead to the presence of the substance in articles. However, the range of articles is potentially very large.	the substance, or (b) a restriction could be limited to certain uses only, in order to avoid potential unintended consequences.		will be needed on what level of certainty is needed for a decision). ■ If substance is an intermediate, data on substances manufactured from the substance, decomposition, etc.

Note: Many CMR substances are "non-threshold" substances i.e. it is not possible to define a derived no-effect level, whereas for some (mainly reprotoxic) substances it is possible to define a threshold. For the latter, exposure below the threshold (in principle) means that there is no harm to human health.

Source: ICF/AMEC

Table 4.47 Further socio-economic considerations relevant to the scope of a possible restriction

Consideration	Examples	Implications for deciding on socio-economic impacts of a restriction	Substances where relevant discussion included	Examples of information needed
Are there technically suitable alternatives to EU article producers (in sufficient quantities and affordable)?	For TCEP, there are clearly alternatives available on the EU market and substitution has largely taken place.	The case study substances considered cover a range of different situations with regard to the availability of alternatives. For some, it is clear that alternatives are widely available and being used (e.g. TCEP) whereas for others (e.g. ETU) some further steps are required before alternatives are fully available on the EU market. The socio-economic information collected in the scoping-level SEAs provides indications of the timescales needed for replacement, providing an indication of the level of information that can be developed in such a study (not a full SEA).	ETU, o-anisidine, borax, TCEP, formaldehyde, DHNUP, GaAs	■ Evidence from main article producers; details of research projects ongoing to develop alternatives; indication of likely commercialisation timescales and volumes. ■ Extent to which a restriction could create certainty and encourage innovation for producers/users of alternatives (DHNUP)

Consideration	Examples	Implications for deciding on socio-economic impacts of a restriction	Substances where relevant discussion included	Examples of information needed
Is the supply chain complex, making it difficult to be confident that the key uses and users can be identified and hence there will not be significant adverse effects of a fast-track restriction?	Formaldehyde has a highly complex supply chain with numerous different uses. It was not possible to cover all of these uses in a scoping-level SEA.	Relatively simple supply chains tend to make it more simple to identify the main potential implications of a restriction within the type of scoping-level SEA done for the current study, rather than undertaking a full SEA as is undertaken under Article 69. For example, the supply chain involved for ETU is, in comparison to formaldehyde, much simpler, giving a reasonable degree of confidence that the impacts are well understood.	DBP, o-anisidine, DEHP, Formaldehyde	■ Numbers and types of actors in the supply chain and role in production of different types of articles.
Could a restriction potentially introduce technical barriers to trade?	For DEHP, the ECHA RAC recently concluded that there is no need for a restriction (based on the Danish proposal).	DEHP is one example (amongst several) of where there may be evidence that a restriction may not reduce risks to consumers, potentially leading to a restriction being viewed as protectionism	DEHP	■ For example, evidence that risks to consumers are already adequately controlled.
Is the industry (article producers or importers/suppliers) comprised mainly of SMEs?	For Direct Black 38, there seem to be many smaller companies amongst e.g. importers/retailers of textiles that may contain the substance (or it's degradation products)	If there are many SMEs involved in the supply chain, and a restriction would lead to costs for them, this could be an indication of potential significant adverse effects of a restriction, suggesting that a more detailed analysis (Article 69) might be required. For some of the substances, a restriction would imply companies trying to obtain information from their supply chains on absence/presence of the substance, and/or testing for the substance themselves. The associated costs would be more difficult for SMEs to bear.	Direct Black 38, DHNUP	■ Data on numbers and sizes of industry (trade associations, Eurostat, etc.)
Are the markets that involve use of the substance quickly moving / innovative, meaning potential presence in different types of articles?	Use of borates involves quickly evolving markets and use of innovative products that become part of consumers' lives within rapid timescales (e.g. LCD screens, innovative textiles).	The socio-economic implications of a restriction in such markets is likely to be more difficult to understand and will change rapidly over time. A detailed, long-term analysis of a restriction may be out-of-date before it is complete.	Borates	■ Knowledge on e.g. typical product cycles for articles of interest
Is there potential for co-benefits of a restriction (e.g.	For ETU, there may be an additional benefit of reducing exposure to workers in industrial	Even if use is shown to be 'safe' for consumers, a restriction on use/presence in consumer articles might be warranted on the basis that it will also protect people in	ETU	■ Evidence of worker exposure from literature, REACH registration, etc.

Consideration	Examples	Implications for deciding on socio-economic impacts of a restriction	Substances where relevant discussion included	Examples of information needed
reduced worker exposure to CMRs)?	settings (which may actually be of more significance than any consumer benefit).	other parts of the supply chain.		
Is the substance already phased out in the EU and seems to be undergoing phase-out elsewhere?	There are restrictions on use of Direct Black 38 in key countries that export relevant products (e.g. textiles) for sale on the EU market.	In many cases, companies will already have an incentive to remove CMRs from their products (other regulations, consumer pressure, etc). Where use is minimal / already being phased out, there would be more minimal health benefits from a restriction, for either EU-produced or imported consumer articles. This may suggest that substances in such situations should be a relatively lower priority for restriction. Notwithstanding this, however, a restriction (Article 68.2 or Article 69) could be important in driving remaining, slow-moving, firms to undertake substitution.	Direct Black 38, TCEP, DHNUP,	■ Data on trends in use (and e.g. restrictions) in key non-EU markets where relevant article types may be imported from.
Are there different forms of the chemical which can lead to significant differences in risks (hence potentially leading to derogations)?	o-anisidine is used in production of both dyes and pigments. The potential for consumer exposure is significantly higher for the former.	Where there are different forms of the substance, with associated differences in potential for consumer exposure, there might be a basis for introducing separate restriction approaches. A scoping-level SEA might be sufficient to conclude that Article 68.2 restriction is appropriate for some uses, but others might need to undergo a more rigorous analysis (e.g. restriction dossier under Article 69.	o-anisidine	■ Knowledge of risks associated with different forms of the substance / derivatives.
Can the presence of the substance in articles be measured/monitored?	There are established methods for monitoring certain substances e.g. DEHP, leading to extensive data on concentrations in various consumer products.	This is a key issue relevant to demonstrating compliance with a restriction as well as to enforcement. For some of the substances considered in the scoping-level SEAs it is clearly possible to measure the presence of the substance in relevant articles (as evidenced by standardised tests undertaken by companies specifically set up to test textiles for example). For others, monitoring may be more problematic (e.g. ETU) and it can be difficult to determine remaining concentrations in articles. This is important in the context of deciding upon e.g. concentration limits set in restrictions.	DEHP, DBP, TCEP, Direct Black 38, o-anisidine	■ Information on availability, applicability and costs of relevant analytical test methods.

Consideration	Examples	Implications for deciding on socio-economic impacts of a restriction	Substances where relevant discussion included	Examples of information needed
Can ensuring compliance with restrictions for imported articles be problematic?	As evidenced by information from RAPEX, ensuring compliance with existing restrictions (e.g. DEHP in toys) for imported articles can be problematic. This is just as true for 'standard' restrictions as it is for restrictions under Article 68.2.	If there is information to suggest that ensuring compliance with the restriction may be problematic, this may be an indication that a more detailed investigation is required on whether there are other potential RMOs that could be more effective.	DEHP, DBP	■ Information on compliance and enforcement (e.g. RAPEX database).
Are recycled materials likely to be a significant source of the substance in consumer articles?	Flexible PVC products are widely recycled and there could therefore be important issues related to placing recycled consumer articles containing DEHP and other phthalates on the market. In the case of substances no longer produced in the EU (e.g. DnHP) recycled PVC articles may be the most significant source of exposure.	Recycled materials in the supply chain should be considered when considering a restriction under Article 68.2, particularly where there is evidence showing that this is a significant source of the substance in consumer articles (e.g. DnHP). This is important for the effectiveness of the restriction and may be relevant when deciding upon its wording.	DnHP, DEHP, DBP	■ Knowledge on e.g. typical product cycles and recycling trends for articles of interest.

Source: ICF/AMEC

5 Considerations for development of draft criteria to implement Article 68.2 to CMR 1A and 1B in consumer articles

5.1 Introduction

Article 68.2 of REACH states:

"For a substance on its own, in a preparation or in an article which meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4). Articles 69 to 73 shall not apply".

In short, Article 68.2 permits the Commission to follow a simplified procedure to amend Annex XVII of REACH to address restrictions to consumer use of a substance – on its own, in a preparation or in an article – which meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1A or 1B[141] (CLP criteria).

For the purposes of this study, Article 68.2 can only be considered as a valid restrictions procedure where a CMR substance, category 1A or 1B is present in a consumer article. Article 68.2 restriction are adopted through comitology (regulatory procedure) and does not require a SEA, or for the Commission to substantiate any human health or environmental exposure hazard relating to the uses of the relevant substance found in articles. For clarification, the definition of an article is presented in the box below.

Definition of an article under REACH

"an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition" (Article 3(3))

Additional guidance is provided on substances in articles:

- Is the function of an object determined to a greater degree by shape, surface or design, if so then an article
- Is the function of an object determined to equal or greater degree by its chemical composition, then likely to be substance/preparation in a container/carrier material
- Buildings are not articles in the meaning of Article 3(3) provided they are fixed the land on which they stand.

Source: EC, 2011c.

However, there is no guidance on which substances and uses in articles could fall under this simplified procedure (opposed to adopting a standard restrictions procedure for consumer articles under Article 69 of REACH) and how the developed criteria could be used in the long term to help prioritise CMR substances in articles under this simplified restrictions procedure.

The purpose of this section is to propose a set of possible criteria that the Commission could use to identify whether an Article 68.2 simplified procedure should be considered for restrictions on CMR substances in consumer articles, and is preferable to a standard Article 69 procedure. Further, the criteria considered should determine the most appropriate scope of any restrictions, and should begin to think about how the developed criteria can be used to

[141] CMR category 1A: known to have carcinogenic, mutagenic, toxic for reproduction potential for humans, classification largely based on human evidence. CMR category 1B: presumed to have carcinogenic, mutagenic , toxic for reproduction potential for humans, classification largely based on animal evidence

prioritise action in the future. As far as possible, the decision steps and criteria developed have been aligned with the underlying intervention logic for restrictions under REACH.

Four specific questions are addressed:

- Can the presence of a CMR category 1A or 1B substance in a consumer article be identified which would indicate the possibility of consumer exposure;
- Is the Article 68.2 simplified procedure the most appropriate restrictions procedure for the Commission to adopt;
- What should be the scope of any restrictions (i.e. should they cover all or only specific uses of the substance in consumer articles); and
- How should the Commission consider prioritising the substances selected for the Article 68.2 procedure?

5.2 Decision tree for selection of the Article 68.2 procedure

Addressing the first two bullets, the decision tree presented in Figure 5.1 has been developed based on the findings of the scoping SEAs to determine whether a CMR substance found in articles is should be considered for an Article 68.2 simplified restriction or a standard Article 69 restrictions procedure. In other cases, the decision tree should also help determine whether a restriction should be ruled out altogether.

Acknowledging that, in the absence of an SEA or similar information gathering exercise, information available to the Commission may be limited, the decision tree contains a number of either/or questions to account for different sources of evidence which may be available, with guidance on the type of information required to make a decision provided in the left hand side of the decision tree.

The purpose of the ***first criterion*** presented in the middle column of the decision tree is to establish that the relevant substance is present in consumer articles, based on the use of the substance in the production process, any direct use within the article or the degradation of other substances found within the article. Where this cannot be confirmed or refuted from existing information sources, including chemical dossiers and available literature, then consultation with industry stakeholders (producers, article manufacturers, and importers) may be required. If uncertainty remains, greater evidence gathering and data gathering exercise, through an Article 69 procedure is recommended. If it can be reliably proven that the substance is not used or contained in consumer articles then the restrictions process should be ruled out at this stage.

Having confirmed that the substance is contained in consumer articles, the ***second criterion*** asks whether the presence of the substance in a consumer article presents the possibility for ongoing health concern to EU citizens. In such a case, the Commission could take rapid action to mitigate the harm. An emergency simplified restrictions procedure could then be followed, indicated by the broken line in the figure. By ruling out this emergency procedure, the remaining criteria are focussed on determining whether an Article 68.2 simplified procedure is the most appropriate or whether other restrictions procedures (i.e. Article 69) should be considered.

Once the presence of a substance in an article is confirmed, the ***third criterion*** assesses the likelihood of consumer exposure to the substance based on technical grounds. A substance can be bound within a specific material and unlikely to be released during normal consumer use. This was found to be the case with boron compounds found in borosilicate glass as the boron is chemically bonded within the glass material. In the case of gallium arsenide used in semiconductors, the electronic compounds were found to the encapsulated within the consumer electrical article and therefore exposure to the substance is highly unlikely in normal use. In both cases, consumer exposure can be ruled out on technical grounds. When evaluating the likelihood of consumer exposure from a substance in an

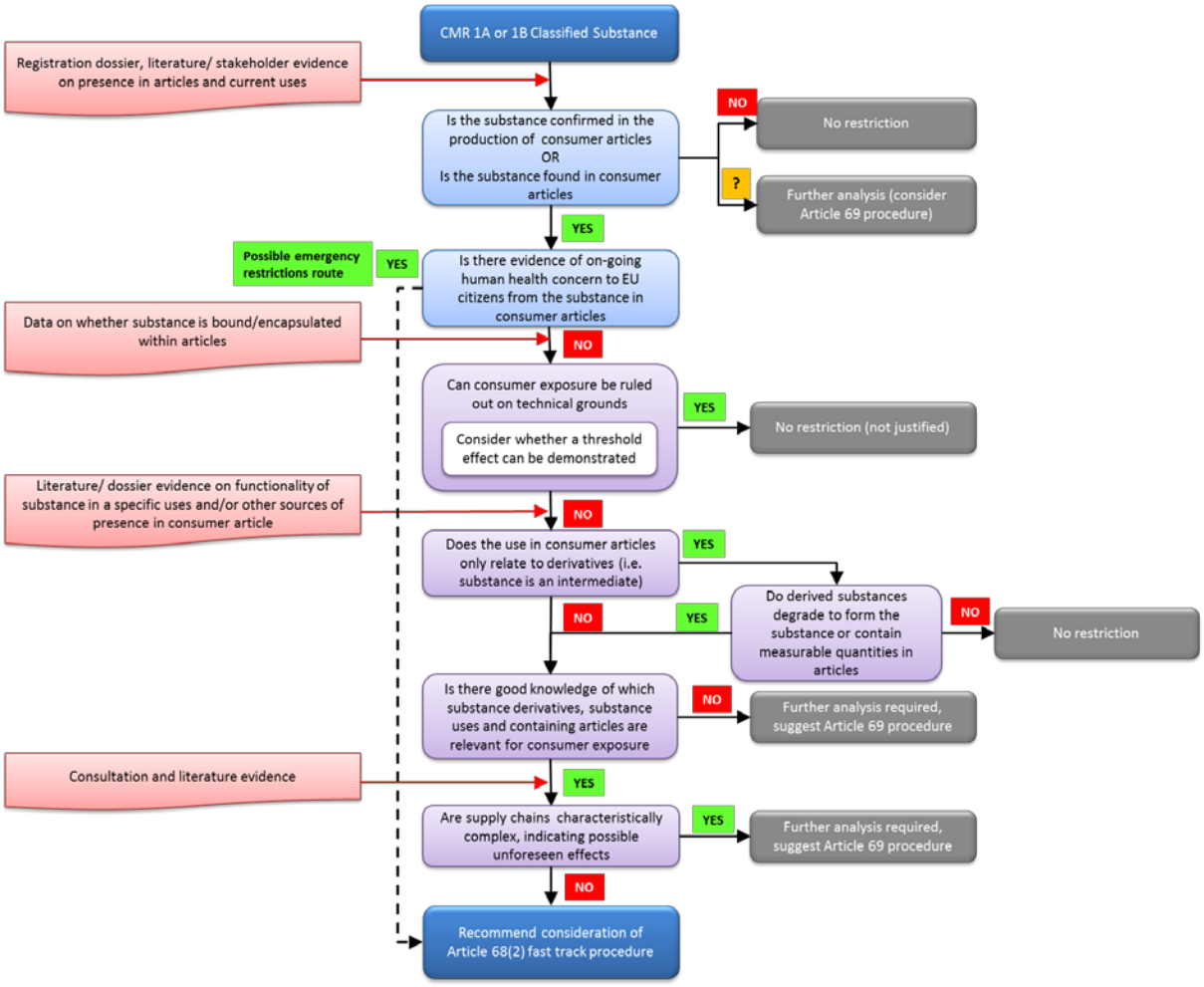
article, consideration should also be given to the existence of threshold effects. The presence of the substance in articles below a threshold could indicate that the dose or concentrations to which a consumer is exposed is insufficient to induce an adverse human health impact. Where this threshold has been determined for a given substance, any proposed restriction should take this into account and could be a reason for not proceeding with a restrictions procedure at this point in the decision tree.

The ***fourth criterion*** is used to exclude those substances from the Article 68.2 route where the CMR of concern is found to be present in the article as an impurity. For this reason, the box to the right asks whether the presence of the substance in articles comes from the use of a derivative of the substance or intermediate in the production process. If this is the case, the presence of the substance in the article as a by-product or from the breaking down of the derivative in the article should be present in quantities greater than an impurity.

If the substance is not an intermediate or is found to be present in the articles in sufficient quantities, then the ***fifth criterion*** in the middle column of the flow chart asks whether there is sufficient knowledge of the identified uses, derivatives of degradation and articles containing them for the Article 68.2 procedure to be confidently considered. If there is insufficient information available to make informed judgments, then an Article 69 restriction should be considered to allow more time to investigate uses and human health impacts more thoroughly. At this stage some knowledge of the potential quantity of the substance contained in articles, whether the main source of use is from EU production or imported articles, as well as some indication of how exposure occurs (inhalation, dermal exposure, etc.) should be known to the decision maker.

The decision tree concludes with the ***sixth criterion*** by considering the complexity of the supply chains within which the substance is present. The more complex the supply chain, the greater the potential for unforeseen effects from a simplified procedure. For example, a simplified procedure might miss particular uses or propagate misunderstandings of the technical nature of how a substance is used in the article. Where the supply chain is relatively straightforward and decision maker is confident the supply chain is complete and understood from the evidence available, then it is recommended that the Article 68.2 simplified procedure is considered. Where the decision maker is still uncertain about the supply chain, Article 69 should be considered.

Figure 5.1 Deciding whether a substance is appropriate for an Article 68.2 restriction

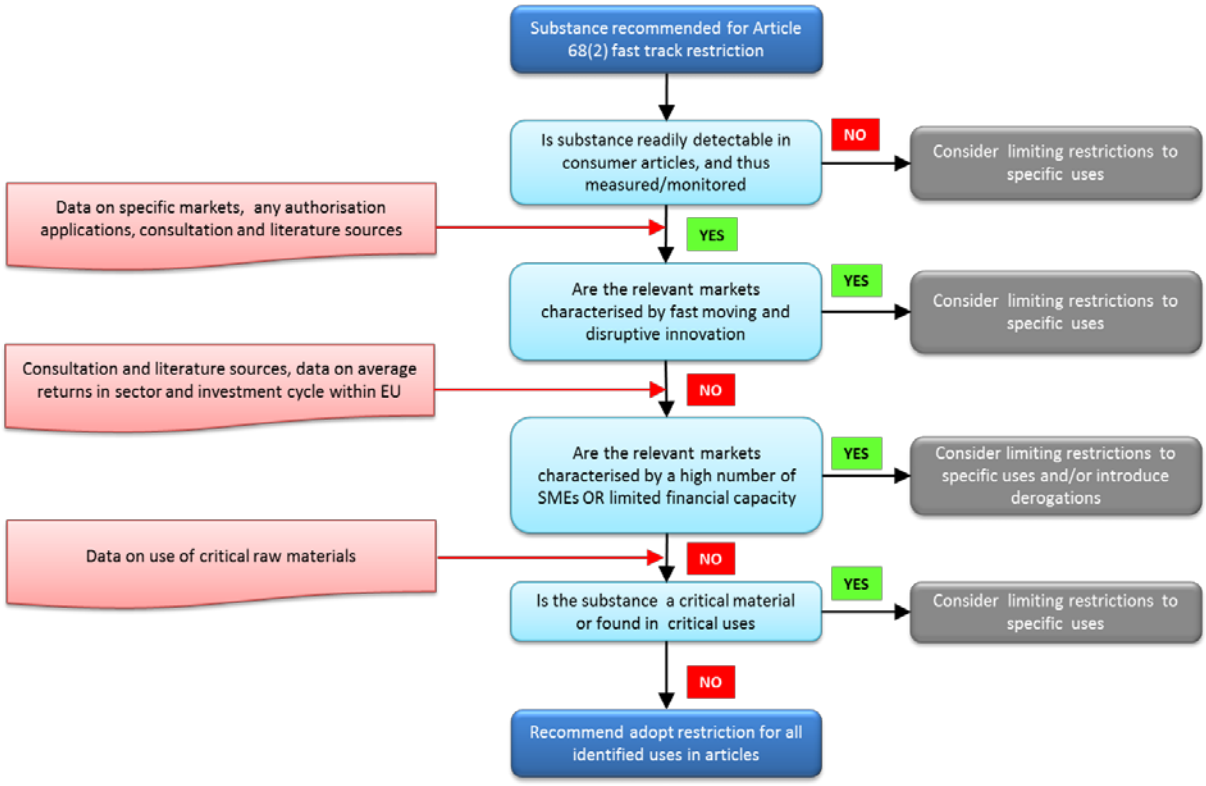


Source: ICF/AMEC

5.3 Decision criteria for determining the scope of any restriction

Once the Article 68.2 route is deemed the most appropriate restrictions procedure, guided by the above criteria, consideration should focus on the scope of any restriction, for example, whether the restriction should apply to all consumer articles containing that substance, a sub-set of articles or whether derogations should apply to specific uses. Figure 5.2 presents a decision tree to assess the scope of an Article 68.2 restriction.

Figure 5.2 Determining the scope of an Article 68.2 restriction



Source: ICF/AMEC

The ***first criterion*** relates to the detectability and traceability of the substance under consideration, necessary if the restriction is to be effective at reducing consumer exposure. Although this criterion does not help the decision maker differentiate between an Article 68.2 or 69 restriction procedure, it could help define the most appropriate scope of the restriction, by eliminating those uses where the presence of the substance would be difficult to measure and monitor in articles.

The ***second criterion*** assesses whether the relevant markets for the article are characterised by fast moving and disruptive innovation. If the market is characterised as such, then a restriction has the potential to slow down or prevent future innovation and product development, which would potentially put EU industry at a disadvantage to non-EU industry.

The ***third criterion*** addresses whether the affected industry has the financial capacity and capability to make the necessary changes to production processes, invest in new machinery and switch to alternatives following the adoption of a restriction. The presence of a high number of SME enterprises, EU manufacturers making low average returns or manufacturer's mid-way through their investment cycle may be indications of limited capacity to adjust to a restriction. However, if a phase out by EU industry has already taken place or is ongoing, this criterion may become obsolete as investments and changes to production have already taken place.

The ***fourth criterion*** assesses whether the substance is a critical material or has critical uses of strategic and/or economic importance to the EU. Criticality in a given use should be considered and critical material lists should be consulted at this stage. If the substance falls in this category, it should be ruled out for an Article 68.2 restriction, but may merit further investigation under an Article 69 procedure.

Annex 5 presents an example of the application of the decision trees in Figure 5.1 and Figure 5.2 to substances. These examples illustrate what information can be used to reach a judgment at each stage and the rationale behind the final outcome.

5.4 Thinking about the future prioritisation of substances

The purpose of this section is to begin to think about how the developed criteria could be used in the long term, to help prioritising CMR substances in articles for an Article 68.2 restrictions procedure.

Prioritisation of substances for a simplified restrictions procedure should logically be based on the net benefits restrictions generated for society. That is, those substances and uses where a restriction is expected to significantly improve human health outcomes at least cost should be prioritised over substances and uses where the costs may be disproportionate and/or the restriction has marginal impacts on improving human health outcomes.

Prioritisation of substances for a simplified restrictions procedure should logically be based on the net benefits restrictions generated for society. That is, those substances and uses where a restriction is expected to improve human health outcomes at least cost should be prioritised over substances and uses where the costs may be disproportionate and/or the restriction has marginal impacts on improving human health outcomes.

In a restrictions procedure under Article 69, SEA is undertaken to gather and analyse available data to quantify this implied trade-off in costs and benefits, informing the decision-making process. Under a simplified procedure, the opportunities for information gathering and analysis are more limited. Hence, alternative approaches should be considered when starting to think about preparing a case for an Article 68.2 simplified restriction. The “net benefit” can be seen as an indicator to support the Commission’s decision, where the route taken to implementing a restriction is chosen on the basis of the previous decision criteria which screen for appropriateness and scope.

This alternative approach is developed in two parts:

- The first identifies from the scoping SEAs the factors found to have an impact on the scale of costs and/or benefits which may be used to indicate the presence of net benefits; and
- The second establishes an evaluation framework, which ex-ante and ex-post allows the decision maker to qualitatively assess the potential of net benefits occurring for a given substance and uses in articles.

5.4.1 Identifying factors which potentially drive the costs and benefits of a restriction

The results of the scoping SEAs showed that there is a wide range of factors which could be considered when thinking about the costs and benefits of a simplified restrictions procedure. A summary of the factors identified by substance-specific scoping SEAs are presented in Figure 5.3 on the next page.

Categories of factors included consideration of availability and economic/technical feasibility of alternatives, the characteristics of relevant supply chains in terms of the types of businesses and their complexity, potential trade implications and critical uses in highly innovative sectors or those of high safety or economic importance.

Regarding human health and environmental factors, whether the substance in the article has potential for consumers exposure in a particular use was found to be important. Another element to be considered is the presence of a threshold (specific concentration limits defined in Annex VI of CLP, or no effect levels agreed by scientific committees). Other elements to be considered are whether the substance is bound within the article, is present in such low quantities that would make monitoring not possible, or compliance with already existing restrictions.

Figure 5.3 Substance-specific considerations identified from the scoping SEAs

Consideration/substance (a shaded block in the substance column denotes a positive response)	DHNUP	Gallium arsenide	Dihexyl phthalate	Formaldehyde	TGIC	o-Anisidine	Boric acid & Borax dehydrate	Ethylene thiourea	Direct Black 38	Bis(2-ethylhexyl) phthalate	Dibutyl phthalate (DBP)	Tris(2-chloroethyl) phosphate
Economic and technical												
Are there technically suitable alternatives to EU article producers (in sufficient quantities and if so, are these alternatives affordable in most cases?)?	■	■		■		■	■	■	■			■
If certain uses are already subject to authorisation, is a restriction on the substance in consumer articles necessary to cover imported articles?			■							■	■	■
Is the supply chain complex, making it difficult to be confident that the key uses and users can be identified and hence to estimate the main socio-economic impacts via a simplified restriction?			■	■		■				■	■	
Is EU use negligible (or will it be in certain uses after the sunset date for substances in Annex XIV), meaning that impacts on EU firms are likely to be negligible?									■	■	■	
Could a restriction potentially introduce technical barriers to trade?			■	■								
Is the industry (article producers or importers/suppliers) comprised mainly of SMEs, potentially indicating disproportionate costs (for substances still used in the EU)	■								■			
Are the markets that involve use of the substance quickly moving / innovative, meaning potential presence in different types of articles?		■					■					
Are there critical uses of the substance for which it would be necessary to introduce derogations from any restriction?		■										■
Health and environmental												
Is there genuinely potential for consumer exposure to the substance in the article (necessary to demonstrate justification for the restriction?)		■		■		■						■

Consideration/substance (a shaded block in the substance column denotes a positive response)	DHNUP	Gallium arsenide	Dihexyl phthalate	Formaldehyde	TGIC	o-Anisidine	Boric acid & Borax dehydrate	Ethylene thiourea	Direct Black 38	Bis(2-ethylhexyl) phthalate	Dibutyl phthalate (DBP)	Tris(2-chloroethyl) phosphate
Is there potential for co-benefits of a restriction on the substance in other than the consumer area (e.g. reduced worker exposure to CMRs, even if use is shown to be 'safe' in CSRs and even if risk to consumers is likely to be small)?								■				
If phased out in the EU or on the way to being phased out, is there the suggestion, that the substance is being replaced elsewhere, hence limiting the health benefits of a restriction?	■								■			■
Are other uses of the substance already restricted and is there a need for additional restriction to close the remaining gaps?						■			■			
How much uncertainty is there regarding the extent of current use and exposure to the substance and what level of evidence is sufficient to make a decision on restriction?									■			
If the substance is an intermediate, is there knowledge of which substances are derived from it, the products in which they are used and the extent to which they can lead to exposure to the substance from articles (e.g. through decomposition)?						■						
Does the substance have a threshold[142] for effects, meaning the scope of a restriction may need to be limited?			■									

Source: ICF/AMEC

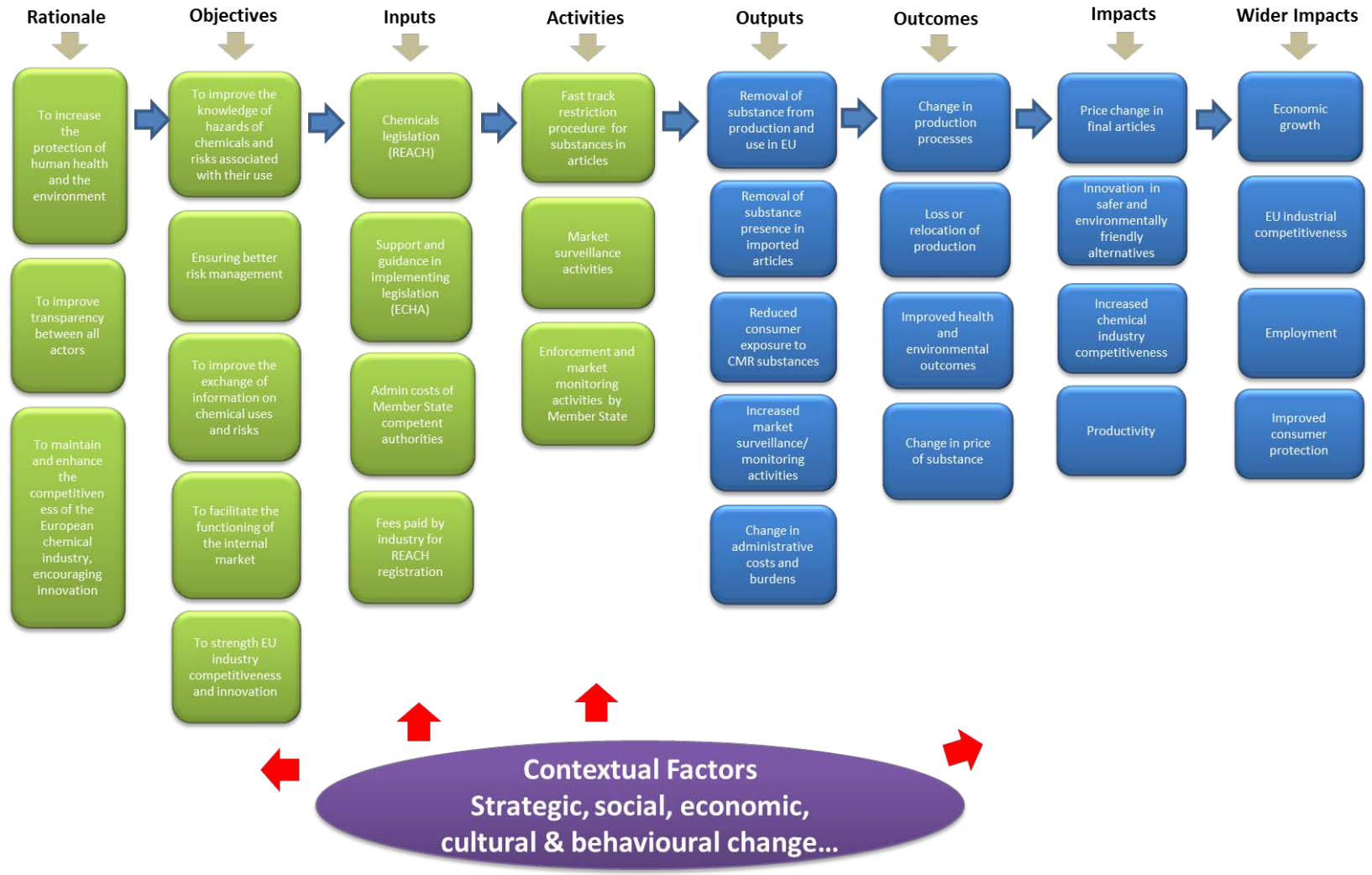
[142] A threshold is the dose or concentration limit of a substance which is likely to induce an adverse human health effect. Presence of a CMR below an established threshold would indicate that human health is not adversely affected.

5.4.2 Framework for ex-ante evaluation of the potential for net benefits

Due to the different characteristics of substances, their uses and socio-economic value in each use, plus the level of uncertainty associated with consumer exposure and health related impacts, quantitative approaches are ruled out due to a lack of available evidence to monetise and therefore compare substances even-handedly. Scoring and ranking of expected impacts can also mislead the decision maker due to differences in the uses and economic value of each substance.

The framework is designed to fit within an intervention logic. Intervention logics bring together the rationale, purpose and intended impacts of policy intervention, aiding the understanding of how a restriction procedure relates to wider policy objectives and the factors which contribute to its achievement. A draft intervention logic for an Article 68.2 restriction is provided on the following page in Figure 5.4. For the purposes of evaluating impacts, interest is focussed on the blue shaded elements of the logic, which indicate outputs, outcomes and impacts that map back to the initial objectives of the action. In this sense we are identifying those factors which influence the outputs and outcomes of the restriction to deliver desired direct and wider impacts (on the right of the intervention logic).

Figure 5.4 Intervention logic for an Article 68.2 Restriction



Source: ICF/AMEC

The developed evaluative framework is qualitative in structure and intended as a first screening of the potential scale and scope of net benefits resulting from a restriction, thus supporting the Commission's decision and helping to identify the data needs when making a case for an Article 68.2 restriction. By identifying those factors which drive the costs and benefits for a substance in a particular use, it can be indicated whether a net benefit is more or less likely compared to other substances and uses under consideration. For example, a restricted substance with many technically and economically feasible substitutes is likely to incur costs towards the lower end of the spectrum when compared to substances with few alternatives in some instances. A net benefit is therefore more likely in such circumstances.

The evaluation framework in Figure 5.5 includes those elements of the intervention logic of concern in the first row. Beneath the first two rows, each row sets out the identified factors from the scoping SEA, the presence of which has been found to affect the probability that positive net benefit impact from a restriction occurs. By considering each factor in turn, it is possible to evaluate the potential of the restriction to achieve net benefits.

The **first** category relates to the current use of the CMR. Where a phase-out by EU industry of the substance has already occurred or is currently underway, it is likely that industry will incur minimal costs from the restriction, as changes to production processes and associated investments would have already been made prior to the implementation of the restriction. This would indicate that a net benefit to EU industry and citizens is more likely.

Figure 5.5 A suggested framework for assessing ex ante the scope of net benefits from a restriction

Core programme intervention logic	Outputs	Outcomes	Sector Impact	Wider impact	Assessment of net impacts
NET BENEFIT POTENTIAL	↓	↓	↓	↓	**NET BENEFIT IF:**
Substance use	Current EU industry use: ■ Completed or undergoing phase out				Indicator: ■ Positive
Market and industry structure	Size and value of sector ■ Size of market is large (by volume/value) ■ Scope of market is global ■ Supply chain is complex (cross-border, multiple uses and end user applications, intermediates) ■ High capital intensity (investment as share of sales) ■ High productivity (GVA per worker) ■ Higher than average profitability of sector(s) ■ High number of SMEs in sector ■ Market has technical barriers to trade (testing requirements, standards, etc.)				Indicator: ■ Negative ■ Negative ■ Negative ■ Negative ■ Negative ■ Positive ■ Negative ■ Positive
Nature of article technology and innovation	Article characteristics: ■ High number of end-user applications ■ Substance is chemically bound in article ■ Substance can be separated from article				Indicator: ■ Negative ■ Negative ■ Positive

	Typology of innovation ■ Disruptive technology a feature of market/sector ■ Innovation in the sector is fast moving ■ Innovation typically occurs upstream ■ Substance is known to be critical for use(s)	Indicator ■ Ambiguous ■ Negative ■ Positive ■ Negative
Substance and article trade	Trade (*Eurostat data*) ■ Competitors located mainly within EU ■ Imports account for a large proportion of EU consumption ■ Substance/article traded worldwide	Indicator ■ Positive ■ Negative ■ Negative
Alternative substances	Alternative substance characteristics (*ECHA dossier*) ■ Technical performance comparable or better ■ Substitutable in production process ■ Affordable in most uses ■ Produced in sufficient quantities ■ Lower hazard (relative to current substance) ■ Reduced hazard potential/migration routes	Indicator: ■ Positive ■ Positive ■ Positive ■ Positive ■ Positive ■ Positive
Consumer factors	Consumer impacts ■ Consumers highly response to article prices ■ Consumer have high willing to pay to remove substance from use	Indicator: ■ Positive ■ Positive
Human health and environmental factors	Benefit indicators ■ Lower hazard (relative to current substance) ■ Reduced hazard potential/migration routes ■ Possible co-benefit from restriction for workers ■ Removal of substance from recycling waste streams	Indicator: ■ Positive ■ Positive ■ Positive ■ Positive

Source: ICF/AMEC

The ***second*** category of factors concerns market and industry structure, from which the following are derived:

- **Size of market/sector** – the larger the market/sector associated with the substance and its uses, the higher the anticipated costs of substitution. This is due to the multiplication of costs over a larger volume of output or number of businesses/uses affected. Critical uses of a substance and the potential for disproportionately are also greater in a larger market/sector as the diversity of firms and end user applications is broader (See Formaldehyde scoping SEA).
- **Complexity of supply chains** – the less complex the supply chain, the more likely complete information is available on the substance and its uses for the decision maker to make more informed judgments as highlighted in decision tree above. Greater traceability in less complex supply chains may also improve enforcement of any restrictions. Global (complex) supply chains may also increase the chance of relocation outside Europe from any restriction (see Borax scoping SEA).
- **Capital intensity** – high intensity industries are characterised by long term investment cycles in plant and machinery. Where a restriction requires changes to the production process during an investment cycle, high fixed costs are more likely. In contrast, low capital intensive industries may find changing production processes less costly, but may still incur high variable costs (e.g., the alternative costs twice as much as the restricted substance as an input). As the location of production often depends on where large scale investments are made, relocation to outside the EU is more likely from a restriction

where high fixed investments are needed. Data on firm/sector investment as share of annual sales could be used as an indicator and is useful when combined with an indication of the scale of the costs incurred.

- **Productivity/value added** – highly productive sectors have more to lose from disruptive changes to production than less productive sectors, hence the costs of a restriction are likely to be higher in high valued added sectors. In less productive sectors the opposite could be true as by instigating substitution and changes to production processes, innovation is facilitated which may lead to businesses identifying cost savings and increasing productivity in the longer term. The Gallium arsenide scoping SEA provides an example where high value added technology sectors could be disrupted by a restriction, resulting in lost EU industry competitiveness.
- **Profit margins** – are an indicator of the financial capacity of a sector to make the investments necessary to switch production from the restricted substance to the alternative. Above average profitability would therefore indicate that the restriction is affordable to businesses, however low margins may indicate situations where the business may struggle and consequently exit the market or relocate in response to a restriction to maintain profitability and the viability of the business. This was noted in the Direct Black 38 scoping SEA where the affordability of alternatives for smaller businesses was questioned.
- **SMEs** – often with limited financial capacity and limited resources to change production, a high presence of SMEs in the relevant sectors/markets is a factor likely to increase the costs of substitution or create disproportionate outcomes as shown in the formaldehyde, DHNUP and Direct Black 38 scoping SEAs. The limited resources of SMEs may also make following the REACH Processes more difficult, in which case there is a greater chance of missing information in the simplified Article 68.2 procedure which could have a negative impact of the net benefits.
- **Technical barriers to trade** – the presence of product testing and certification procedures before new products can be placed on the market or accepted by downstream users increases the costs of substitution. Lower technical barriers are therefore an indicator of lower costs.

The ***third*** category concerns those technology and innovation factors which may determine the scale of costs or benefits from a restriction. The factors identified include:

- **End-user applications** – consistent with the hypothesis that a larger market for a substance contains more uses and therefore generates higher costs, it is consistent to predict that substances with a higher number of end user applications also creates higher costs as shown by the formaldehyde and boron scoping SEAs.
- **Substance within article** – how the substance is found within the article is likely to be a significant determinate of the relevant costs and benefits. For example, substances chemically bound within the article are likely to be much more difficult to substitute (i.e. Gallium Arsenide) due to the uniqueness of its properties and how it reacts with other chemicals to create the final article. This compares to articles where the substance can be more easily separated from the article and replaced by a substitute (i.e. phthalate containing PVC coatings or textile coverings).
- **Disruptive innovation** – where disruptive technology is a feature of the relevant article market, a restriction could in some cases facilitate the introduction of the next innovation through creative destruction of the current substance and market. In other cases, the restriction could prevent the latest innovation reaching market, hence the impact of this factor is judged to be ambiguous and specific to the article in question.

- **Rate of innovation** – in a market with fast moving innovation, a restriction could slow innovation by forcing businesses to prioritise the development of substitute substances or redesign production processes at the expense of other innovation activities. In markets characterised by a much slower rate of innovation, the impact of the restriction is therefore likely to be less pronounced. Gallium Arsenide used in semiconductors is an example from the scoping SEAs where the rate of innovation could be reduced by a restriction (i.e. in miniaturisation of silicon chips) resulting in lost competitiveness for EU industry producing and using these semiconductors. Rapid innovation in the market is therefore associated with negative impact on possible net benefits.
- **Upstream/downstream innovation** – where innovation in an end user market is driven by upstream innovation (i.e. in materials), then a restriction could have positive first mover advantage benefits for EU industry by switching production to better performing and less hazardous articles for which the EU can become a world leader. Where innovation is predominately downstream in a market, then a restriction on the substances used as inputs to production are more likely to be disruptive to innovation and incur greater costs while substitute substances are found, introduced, tested and accepted.
- **Critical materials and critical uses** – described in the scoping criteria for a restrictions procedure above, a restriction which affects critical materials and/or critical uses of a substance is likely to generate much higher socio-economic costs than substance uses which are not so critical, hence a negative impact is associated with the presence of critical uses and materials at the end of the supply chain (e.g. critical uses were found in the Gallium Arsenide and TCP scoping SEAs).

The geographical scope of trade for substances and articles is an important factor in determining the extent to which users can purchase supplies of a substance or article from outside a national or European market and therefore the possibility for manufacturing to relocate outside the EU in response to a restriction. The factors to consider are:

- **Location of competitors** – where the majority of substance and article manufacturers are located within the EU, then competition can be regarded as regional in nature. Should a restriction result in a higher cost for EU producers, then the probability of production relocating outside the EU is less likely as rivals are predominately within the EU and facing the same costs. The more local the market for the substance/article the more likely negative wider socio-economic impacts on employment and investment can be avoided. The direct black scoping SEA provides some evidence for this as rivals are regional in location.
- **Extend of imports** – where imports account for a larger proportion of EU consumption of substances or articles, then the market is likely to be more global in scale. The opportunity to relocate or shift production to outside the EU is therefore greater. The phthalate scoping SEAs highlights that in a market with a high level of imports; increased manufacturing outside the EU is likely from a restriction.
- **Trade in substance/article** – consistent with the above assessment, where trade is global and competitors are located worldwide, the impacts of any cost increase on EU industry is likely to have a negative impact on the generation of net benefits from a restriction.

The ***fifth*** category of factors refers to the characteristics of the alternative substances which are substituted in the production process:

- **Comparable or better technical performance** – alternatives with superior technical or at least comparable performance (assuming they are less hazardous) implies that the benefits of a restriction are likely to be higher; hence the presence of this factor is likely to indicate net benefits are more likely to occur.

- **Substitutability in production process** – High levels of substitutability in production processes in the sense that drop-in substitutes are possible, opposed to product or production redesign should increase the likelihood of net benefits by reducing costs, hence a positive relationship is indicated in the framework.
- **Affordability** – it is rational to assume that the more affordable an alternative in a production process or article, the more likely net benefits are likely to exist.
- **Produced in sufficient quantities** – lowest cost and effective substitution requires that the alternative is supplied in quantities sufficient to meet demand in the relevant use of the substance. If the substitute is produced in limited volumes, then this is a good indicator that the costs of substitution (at least in the short term) are high, therefore having a negative impact on net benefits.
- **Lower hazard** – assessed relative to the current restricted substance, a lower hazard profile for the alternatives is indicative of higher net benefits potential, as the human health and environment benefits are anticipated to be of a higher magnitude.
- **Reduced hazard potential/migration routes** – where the alternative is characterised by fewer migration routes or hazard potential compared to the current substance, then a positive net socio-economic outcome is logically more likely, through reduced exposure from the article.

A leading determinant of the affordability of a restriction and therefore its costs and benefits relates to consumers as follows:

- **Consumer responsiveness to prices** – the more elastic and responsive demand is to price, the more likely costs incurred by the restriction are likely to be absorbed by manufacturers, distributors and retailers in the supply chain, as the losses in revenue from consumers responding to the price change are greater than the costs. Where demand is more inelastic, then cost pass through is likely to be greater as costs can be passed on to consumers with only marginal changes in demand occurring. As a result, the more responsive the consumer the greater the cost impact for businesses, which could make the alternative unaffordable to introduce. In a given market.
- **Consumer willingness to pay for human health and environmental improvements** – higher willingness should be associated with more inelastic demand, therefore if consumers are willing to pay more for articles which are more human health and environmentally friendly (gauged from consumer surveys), then it is more likely the substitute is affordable for businesses and net benefits are possible.

The final group of factors relate to the human health and environmental benefits, including:

- **Possible co-benefits from restrictions for workers** – where it can be identified that substitution of the current substance removes hazards from intermediate use by workers, additional human health benefits are likely, ensuring net benefits are more likely to occur.
- **Removal of substance from recycling waste streams** – as above, the removal of the current substance from present and future supply chains (specifically in recycling waste streams) is likely to generate higher benefits and make net benefits more likely.

The number of positives and negatives can be summed up and compared across substances to give some indication of which substance restrictions are more likely to generate the highest net benefits. This process should assist in prioritise data gathering to support a case for a chosen restrictions procedure.

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Annex 2 List of stakeholders contacted during Task 1

A2.1 Stakeholders within the European Union

Stakeholder Groups	Stakeholders Contacted	
Public authorities and regulators		
National Competent Authorities	*Did not participate in the consultation*	*Participated in the consultation*
	■ Austria Ministry of Life ■ Austria Ministry of Labour, Social Affairs and Consumer Protection ■ Austria BMASK (Ministry of social affairs) ■ Austria BMWFJ (Ministry for Economy) ■ Belgium Federal Public Service Health, Food chain Security and Environment, Risk management Unit ■ Belgium Federal Public Service Economy, SMEs, Self-employed and Energy - DG Quality & Safety, Division Regulation & Enforcement Policy, Consumer Safety Service ■ Bulgaria Ministry of Economy, Energy and Tourism ■ Bulgaria Ministry of Health ■ Bulgaria Commission for Consumer Protection ■ Cyprus Ministry of Commerce, Industry and Tourism, Competition and Consumers Protection Service ■ Cyprus Ministry Of Labour And Social Insurance, Department Of Labour Inspection ■ Czech Republic Ministry of the Environment ■ Czech Republic Ministry of Industry and Trade ■ Danish Safety Technology Authority ■ Estonian Health Board ■ Estonian Consumer Protection Board ■ France Ministry of Sustainable Development ■ France Ministry of Economy and Finances, DG de la Concurrence, de la Consommation et de la Répression des Fraudes ■ Germany Federal Environment Agency	■ Austria Environment Agency ■ Danish EPA ■ Finnish Safety and Chemicals Agency, TUKES ■ Hungarian Authority for Consumer Protection ■ Hungary National Institute of Chemical Safety ■ Iceland Environment Agency ■ Irish Health and Safety Authority ■ Lithuania Environmental Protection Agency ■ Luxembourg Administration de l'environnement ■ Malta Competition and Consumer Affairs Authority ■ Republic of Slovenia National Chemicals Office ■ Slovakia Centre for Chemical Substances and Preparations ■ Spain Ministry of Health, Social services and Equality ■ Swedish Chemicals Agency ■ Swedish Consumer Agency

Stakeholder Groups	Stakeholders Contacted
	■ Germany Federal Institute for Occupational Safety and Health ■ Germany Federal Ministry for the Environment, Nature Conservation and Nuclear Safety ■ Greek Ministry of Labour and Social Security, General Secretariat for Consumer Affairs, Directorate of Technical Control ■ Iceland Consumer Agency ■ Irish National Consumer Agency ■ Italy Ministry of Health ■ Italy Istituto Superiore di Sanità ■ Italian Institute for Environmental Protection and Research ■ Italian Ministry of Economic Development ■ Latvian Environment, Geology and Meteorology Centre (LEGMC) ■ Lithuania State Consumer Rights Protection Authority ■ Institut luxembourgeois de la normalisation, de l'accréditation, de la sécurité et qualité des produits et services ■ Malta Standards Authority ■ Netherlands RIVM Bureau REACH (especially concerning NMP restriction dossier) ■ Netherlands Ministry of Health, Welfare and Sport ■ Netherlands Ministry of Infrastructure & Environment, REACH Bureau ■ Nederlandse Voedsel en Waren Autoriteit ■ Poland Bureau for Chemical Substances ■ Poland Office of Competition and Consumer Protection, Market Surveillance Department ■ Poland Innovation and Industry Department, Chemistry and Pharmacy Unit ■ Portuguese Environment Agency ■ Portuguese Directorate General for Consumers ■ Romanian National Authority for Consumers Protection ■ Slovakia Centre for Chemical Substances and Preparations ■ Slovak Republic Ministry of

Stakeholder Groups	Stakeholders Contacted
	Economy ■ Republic of Slovenia National Chemicals Office ■ Republic of Slovenia Market Inspectorate ■ UK Health & Safety Executive ■ UK Department for Environment, Food & Rural Affairs (DEFRA) ■ UK Department for Business, Innovation and Skills (BiS)
EU Level	■ EEB – European Environmental Bureau ■ EFTA Surveillance Authority
Representative Bodies of CMR Substance Manufacturers and Importers	
Manufacturers of CMR substances	■ CEFIC –European Chemical Industry Council ■ EUPC – European Plastics Converters ■ EFMA – European Fertilizer Manufacturers Association ■ EIGA – European Industrial Gases Association ■ EPCA – European Petrochemical Association ■ EUROCHLOR – European Association of the Chlor-Alkali Industry ■ FEICA – Association of European Adhesives Manufacturers ■ ISOPA – European Diisocyanate and Polyol Producers Association ■ Plastics Europe
Importers of CMR substances	■ FECC – European Association of Chemical Distributors
Representative Bodies of Downstream Users	
Manufacturers of Fabrics, Textiles and Apparel	■ AEDT – European Associations of Fashion Retailers ■ CEC – European Confederation of Footwear industry ■ Centexbel - Centre Technique et Scientifique de l'Industrie Textile Belge ■ CIRFS – International Rayon and Synthetic Fibres Committee ■ COTANCE – Confédération des associations nationales des tanneurs et des mégissiers de la Communauté européenne ■ EUROCOTON – Committee of the Cotton and Allied Textile Industries of the EU ■ EURATEX – European Apparel and Textile Organisation ■ EDANA – international association for the nonwovens and related industries ■ UEA - Furniture industry
Manufacturers of Chemicals, Rubber and Plastics (incl. Paints)	■ AFERA – Association of European Self-Adhesive Industry ■ AISE – Association of the Soap, Detergent and Maintenance Products Industry ■ APME – Association of plastic manufacturers Europe ■ BCCI – Bulgarian Chamber of Chemical Industry ■ CEPE - Association of Paints, Printing Inks and Artists' colours in Europe ■ COLIPA – European cosmetic, toiletry and perfumery association ■ DUCC – Downstream Users of Chemicals Coordination Group ■ EBA – European Borates Association ■ ECPA – European Crop Protection Association ■ ECPI – European Council for Plasticisers and Intermediates ■ EFFA – European Flavour and Fragrance Association ■ ETRMA – European Tyre and Rubber Manufacturers' Association

Stakeholder Groups	Stakeholders Contacted
	■ Estonian Plastics Associations ■ FINAT – Self-adhesive labels industry ■ Safe Rubber Project : for research on alternatives to ethylene thiourea (FP7) ■ TIE – Toy industry ■ The Federation of Estonian Chemical Industries
Manufacturers of Batteries	■ AVERE – European Association for Battery, Hybrid and Fuel Cell Electric Vehicles ■ EUROBAT – Association of European Automotive and Industrial Battery Manufacturers
Construction Industry	■ CEETB - European Technical Contractors Committee for the Construction Industry ■ CEI Bois - Woodworking industry ■ Cembureau – The European Cement Association ■ CERAME UNIE – The European Ceramic Industries ■ CPIV – Standing Committee of the European Glass Industries ■ EBC – European Builders Confederation ■ EDRA – European DIY Retail Association ■ EETL – Association of Construction Material Producers of Estonia ■ EFFC - European Federation of Foundation Contractors ■ EFPI – European Federation of Parquet Importers ■ ELCA – European Lift Components Association ■ EPSA - European Platform Stair-lift Association ■ EUPAVE - The European Concrete Paving Association ■ FIEC - European Construction Industry Federation ■ FEVE - European Container Glass Federation ■ Glass for Europe
Machinery, mechanical appliances, electronic articles	■ EACEM - European Association of Consumer Electronics Manufacturers ■ CIMAC – International Council on Combustion engines ■ ORGALIME - European Engineering Industries Association ■ SEMI – global industry association serving the manufacturing supply chain for the micro- and nano-electronics industries
Manufacturers of Metal articles	■ CAEF - European Foundry Association ■ EUROFER - European Confederation of Iron and Steel Industries ■ Eurometal ■ EMPAC – Light metal packaging ■ REACH Alliance c/o Eurometaux
Vehicle Manufacturers	■ ACEA - European Automobile Manufacturers Association ■ ACEM - European Association of Motorcycle Industry ■ ASD STAN – Aerospace and Defence Industries Association of Europe ■ CESA - Committee of European Union Shipbuilders' Associations ■ CLEPA - European Association of Automotive Suppliers ■ EUCAR - Automotive Manufacturers' Association for Research and Development in Europe
Importers of major articles	■ EPDA – European Plastics Distributors Association
Paper, paper-based articles and packaging industry	■ CITPA - Paper and board converting industry ■ ECMA - Carton makers industry ■ FEFCO - European Federation of Corrugated Board Manufacturers ■ FPE - Flexible packaging industry ■ INTERGRAF - Printing industry

Stakeholder Groups	Stakeholders Contacted
Other stakeholder groups	
General industry representations	■ BDI – Federation of German Industries ■ BusinessEurope ■ EDMA - European Diagnostic Manufacturers Association ■ Eurocommerce ■ Foreign Trade Association ■ UEAPME – Union Européenne de l'Artisanat et des PME
Trade union and consumer representation	■ ClientEarth ■ Consumer Rights Protection Centre ■ European Trade Union Institute ■ ETUC – European Trade Union Confederation ■ The Humane Society International ■ IndustriALL – IG BCE
Environmental groups	■ Greenpeace ■ Eurogroup for Animals ■ Health and Environment Alliance
Individual companies	■ 19 individual companies were contacted directly and as agreed with them their names will not be communicated.

A2.2 Stakeholders outside of the European Union

Stakeholder Groups	Stakeholders Contacted
National Competent Authorities	■ Permanent Representation of Canada to the EU ■ Croatia Ministry of Health, Department of Chemicals ■ India Ministry of Environment and Forests, International Cooperation Division ■ Liechtenstein Office of Environmental Affairs ■ Liechtenstein Office of Economic Affairs, Division Technology, Innovation and Energy ■ Norway Climate and Pollution Agency ■ Norway Directorate for Civil Protection and Emergency Planning ■ Serbia Ministry Of Energy, Development And Environmental Protection ■ Swiss Federal Office of Public Health ■ Turkey Ministry of Economy, Department of Harmonisation to the EU Legislation ■ Turkey Ministry of Environment and Urbanization ■ US Environmental Protection Agency ■ US Mission to the European Union
Global Level	■ United Nations Environment Programme (UNEP), Chemicals in Products Project ■ World Trade Organisation (WTO), Committee on Trade and Environment
Representative Bodies of CMR Substance Manufacturers and Exporters	■ AAEI – American Association of Exporters and Importers ■ IKMIB – Istanbul Chemicals and Chemical Products Exporters' Association ■ ITKIB – Istanbul Textile and Apparel Exporter Associations ■ TCMA – Turkish Clothing Manufacturers' Association ■ CAPEXIL – Chemical and Allied Export Promotion Council of India ■ The Association of Thai Textile Bleaching Dyeing Printing and Finishing Industries ■ The Thai Textile Manufacturing Association ■ Thai Textile Merchants Association ■ Vietnam textile and garment association (VITAS) ■ Carpet Institute of Australia Limited ■ Garment Manufacturers Association in Cambodia
Chinese organisations wishing to stay anonymous	■ 1 Environmental group ■ 3 Trade associations ■ 2 Research Institutes ■ 1 Individual company

Annex 3 List of stakeholders contacted during Task 2

A3.1 Stakeholders within the EU

Stakeholder Groups	Stakeholders Contacted
Public authorities and regulators	
National Competent Authorities	■ Environmental Protection Agency (EPA) – Lithuania ■ Environmental Agency - Austria
EU Level	■ None
Industry Representations	
Manufacturers of CMR substances	■ European Chemical Industry Council (CEFIC) ■ European Council for Plasticisers and Intermediates (ECPI) ■ European Borates Association (EBA) ■ European Federation for Construction Chemicals (EFCC) ■ European confederation of woodworking industries (CEI-Bois) ■ European Panel Federation (EPF) ■ European Flame Retardants Association (EFRA) ■ Formacare ■ IMAT – VDMA ■ SEMI Europe
Downstream users	■ AeroSpace and Defence Industries Association of Europe (ASD) ■ Association of the European Adhesive & Sealant Industry (FEICA) ■ Association of Paints, Printing Inks and Artists' colours in Europe (CEPE) ■ Bundesverband Glasindustrie e.V. ■ Confederation of National Associations of Tanners and Dressers of the European Community (COTANCE) ■ Confederation of European Paper Industries (CEPI) ■ Corrugated Board Manufacturers in Europe (FEFCO) ■ European Apparel and Textile Confederation (EURATEX) ■ European Diagnostic Manufacturers Association (EDMA) ■ European Tyre & Rubber Manufacturers' Association (ETRMA) ■ European Organization of the Sawmill Industry (EOS) ■ European confederation of woodworking industries (CEI-Bois) ■ European Panel Federation (EPF) ■ European Plastics Converters (EUPC) ■ European Furniture Industries Confederation (EFIC) ■ European Confederation of Linen and Hemp (CELC) ■ European Aluminium Foil Association (EAFA) ■ European Confederation of the Footwear Industry ■ European Outdoor Group (EOG) ■ European Producers of Laminate Flooring ■ European Association of Flexible Polyurethane Foam Blocks (EUROPUR) ■ European Diisocyanate and Polyol Producers Association (ISOPA) ■ European Council of Vinyl Manufacturers (ECVM) ■ European Polyvinyl Film Manufacturers' Association (EPFMA) ■ European PVC Floors Manufacturers (EPFLOOR) ■ European Resilient Flooring Manufacturers' Institute (ERFMI) ■ Federation of the European Sporting Goods Industry ■ Federation of European Furniture manufacturers (UEA) ■ Flexible packaging association ■ International Confederation of Paper and Board Converters in Europe (CITPA) ■ Lighting Europe ■ Metal packaging Europe

Stakeholder Groups	Stakeholders Contacted
	■ Orgalime ■ PU-Europe ■ Toy Industries of Europe (TIE) ■ Tattoo ink manufacturers of Europe (TIME)
Individual companies	
Manufacturer / formulator / importer of CMR substances	■ 26 manufacturers / formulators / importers of CMR substances have been contacted during the consultation exercise
Downstream users	■ 46 downstream user companies have been contacted during the consultation exercise
Chemical suppliers / distributors	■ 6 chemical suppliers / distributors have been contacted during the consultation exercise
Other stakeholder groups	
Trade union and consumer representation	■ European Trade Union Institute (ETUI)
Testing bodies	■ Centexbel

A3.2 Stakeholders contacted outside the EU

Stakeholder Group	Stakeholders Contacted
Public authorities and regulators	
National Competent Authorities	■ United States Environmental Protection Agency
Industry Representations	
Manufacturers of CMR substances	■ Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD) ■ Dyestuffs Manufacturers' Association of India
Downstream manufacturers	■ Apparel Export Promotion Council (AEPC) of India ■ Istanbul Textile and Apparel Exporter Associations
Individual companies	
Manufacturer of CMR substances	■ 2 manufacturers / formulators / importers of CMR substances have been contacted during the consultation exercise
Downstream manufacturers	■ 7 downstream user companies have been contacted during the consultation exercise
Other stakeholder groups	
Trade union and consumer representation	■ None
Environmental groups	■ None

Annex 4 Detailed summary tables for the 13 substances that were selected for Task 2

Important notice: These summary tables are based on the information which was collected and available at the conclusion of Task 1 and updated with information that was collected during Task 2.

A4.1 Summary information on 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters

1B-02	**Substance**	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters		
	CAS Number	68515-42-4	**EC Number**	271-084-6
	Common name	DHNUP		
Information available				
Amount of information available	**AVERAGE**	Available Info: uses, presence in articles, tonnages, substitutes Limited Info: quantity of articles imported into EU, quantity of substance in articles, exposure to customers		
Key literature sources	Annex XV Report (2011) [1] SPIN database (2013) [2]			
Consultation	MS responses: 0	Industry responses: 5	Testing body/research institute: 2	
Summary information on uses				
Identified uses	Reported in the EU as used in the plasticization of electrical and communication wire insulation. Reported use in Nordic countries for the following product categories: - Adhesive and binding agents. - Paint, lacquers and varnishes. - Construction materials (probably covering sealants or adhesives). - Softener In Canada is mainly used as plasticisers of PVC. Used in the electrical industry for the manufacture of cable sealants. [1] Used in "Construction", "Specialized construction activities", "Civil engineering" and "Construction of buildings". [2] An industry associated indicated use as a plasticiser.			
Use in consumer articles	**LIKELY**	Not reported - only preparations [mixtures] are mentioned, with no consumer preparations mentioned (latest data refer to 2010). [2] 1 company respondent answered that there is no use in articles, 5 consultation responses (1 company, 2 industry associations, 1 testing body and 1 research institute) indicate use in articles: textile prints, plastisol prints, domestic plastics, tank linings and in inspection procedures for turbine components.		
Consumers' exposure to the substance				
Can risk of exposure to consumers be excluded?	**NO**	Annex XV dossier indicates not enough data exist to define exposure to consumers. [1] The registered uses do not indicate direct exposure to customers. A very probable occupational exposure has been reported. [2] 3 consultation responses (1 industry association, 1 testing body and 1 research institute) indicate exposures does/can occur does/can occur due to the function of the substance. One research institute response indicates exposure via skin and/or by inhalation. One industry association and one company suggest that direct exposure does not occur as the substance is sealed in polymers/ paint matrices.		

Market-based information	
Route into the EU	Published sources indicate import. All but one (who did not answer) of the consultation responses indicate import and manufacture of articles containing the substance in the EU.
Manufacture sites and supply chain	DHNUP does not seem to be manufactured in the EU anymore. However, there is a discrepancy of records. One EU based producer of cables reported the use of this substance, being supplied by three producers of plasticizers. The suppliers reported no manufacture of DHNUP. [1] Consultation responses indicate that articles containing DHNUP are manufactured in the EU.
Quantities used per annum of the substance (tonnes)	100-700 tonnes/year by one EU producer. No data about imports but it is known to be used in other countries (Canada) in relatively large quantities. Import of DHNUP to the EU market in final products should not be excluded. [1]
Concentration of the substance in articles	No information was identified in the published sources analysed. 1 testing body and 1 industry association indicate concentrations of 1 – 10% and 1 company and 1 industry association indicate concentrations of less than 0.1%.
Quantity of articles imported/produced in the EU	No information was identified in the sources analysed.
Alternatives available	No specific information provided by the data sources. However, the author of the Annex XV dossier points out DIDP and DINP as potential feasible and affordable alternatives. Other non-ortho-phthalate alternatives are indicated such as, TOTM, DEHT and COMGHA. [1]

References:

[1] Annex XV Dossier: Proposal for Identification of a Substance as a CMR Category 1A or 1B, PBT, vPvB or a Substance of an Equivalent Level of Concern, http://echa.europa.eu/documents/10162/248dd51f-b218-455f-bb00-fbe34d500a5c
[2] SPIN database, http://90.184.2.100/DotNetNuke/default.aspx, accessed 6 March 2013

A4.2 Summary information on Gallium Arsenide

1D-02	**Substance**	Gallium arsenide		
	CAS Number	1303-00-0	**EC Number**	215-114-8
	Common name	GaAs		
Information available				
Amount of information available	**MORE THAN AVERAGE**	Available Info (limited in published sources, more than average in consultation responses): uses, quantity of articles imported into EU, quantity of substance in articles, exposure to customers, presence in articles, tonnages, substitutes.		
Key literature sources	ECHA Registration Data [1] Annex XV Report for C&L (2009) [2] OECD Emissions Scenario Document [3]			
Consultation (1st and 2nd phase)	MS responses: 0 (1st phase); 0 (2nd phase)	Industry responses: 14 (1st phase); 10 (2nd phase)	Testing body/research institute: 2 (1st phase); 0 (2nd phase)	
Summary information on uses				
Identified uses	Literature and consultation responses indicated among others the following uses (industry or company responses unless otherwise indicated): • Used in the manufacture of GaAs wafers for the electronics industry; • Used as substrate in the manufacture of semiconductors within the micro-electronics and photonics industry; • Functional semiconductor used as a base material for electronic and optoelectronic devices and applications; • Multi-junction solar cells for space and terrestrial concentrator (sealed into concentrator assembly) applications (research institute – 1st phase); • Used in the manufacturing process of LED and Diodes. These are then used for energy-efficient lighting purpose or for other purposes such as laser devises or sensors for solar panels and presence detection; • Radiofrequency/wireless communication (consumer devices: smartphones, handsets, PCs and tablets, etc.; infrastructure: base stations, satellites); • Photonics application: red and IR diodes emitters and photo-detectors (consumer devices: DVD/CD/Blue Ray players, remote controls, device interface, gesture recognition, etc.; infrastructure: fiber-optic communication, optical interconnects, etc.); • Radars, IR night vision; • Medical lasers for surgery and dermatology; • Smart metering; • Energy harvesting (e.g., high efficiency cells for concentrated PV; multi-junction cells, etc.).			
Use in consumer articles	**YES**	Depending on its functionality during the manufacturing process, GaAs is either present as residue or as component of the final products. In the majority of the products it is present at a very low concentration.		
Consumers' exposure to the substance				
Can risk of exposure to consumers be excluded?	**LIKELY**	Annex XV C&L report mentions only worker exposure. [2] Consultation responses vary, however only 3 responses indicate that exposure does/can occur while 12 responses indicate that exposure does not/cannot occur (1st phase). This was confirmed by the second phase of consultation. Responses include (all from industry associations or companies unless otherwise indicated): • Processed in clean room environment and finally embedded into a polymer matrix. Exposition is excluded for end user. • The substance is handled in clean rooms during manufacturing excluding the contamination of the environment and the employees. In the final application GaAs is packaged to maintain its properties and to protect it from the environment (moisture, etc.). • Exposure very unlikely, however, breakage, dust can be inhaled (research		

		institute). • Substance in solid covalent form and components fully encapsulated in plastic or metallic packages, themselves embedded in the final electronic devices (e.g. : mobile phone). • Fully encapsulated in metallic, ceramic or plastic housing. Stable during product life time. • Inorganic crystal in the form of a microchip, typically mg quantities, encapsulated and embedded inside a component/module within the article - subject to WEEE directive for disposal • There is no exposure to consumers as regards the articles. The substances in the final product are in crystalline form and are encapsulated. GaAs chips in this crystalline form are inert, and pose no risk whilst completely encapsulated. Both during the manufacturing stage and at end of life, there are standards in place to avoid exposure, in line with existing regulations (e.g. WEEE). • Article 68.2 of REACH is not applicable on III-V semiconductors like GaAs. There is no exposition possible for private end-user. • The substance is totally encased in potting compound in the final article. One research institute claimed exposure possible via skin exposure or inhalation without providing data or details.
Market-based information		
Route into the EU	GaAs is both manufactured within the EU and imported to the EU. It undergoes a series of manipulation before its integration in final consumer articles. The above products and their components are both manufactured and imported in Europe – the micro-nano-electronics and photonics industries consist of a global value chain that is closely interlinked and with a high prevalence of SMEs specialized in various parts of the manufacturing process.	
Manufacture sites and supply chain	Four companies share the vast majority of the global GaAs ingot production. One of these is based in the EU and is a market leader in the manufacturing of both semi-conducting and semi-insulating GaAs. GaAs wafers are then developed based on GaAs ingots. This process is undertaken either by the companies developing the ingots or by specialised companies. GaAs wafers developed in Europe do not only use raw materials produced in Europe - raw materials are also imported from third countries (e.g. US, China, Japan). The GaAs wafers produced in Europe are then sold not only in Europe but also in the US and different Asian countries. GaAs based compounds are then developed through epitaxy. Manufacturers of GaAs substrates and epiwafers based in Europe import GaAs wafers from different part of the world (EU, US and Asia) and export their encapsulated GaAs compounds to consumers worldwide. These GaAs compounds are then integrated in consumer articles or in consumer articles' components.	
Quantities used per annum of the substance (tonnes)	ECHA's report indicates the annual use of GaAs in Europe to be between 10 and 100 tonnes [1]. During the 2nd phase of consultation, we identified the manufacturing of approximately 70 tonnes of GaAs ingots within the EU every year. These ingots are then sold within the EU or exported to consumer worldwide. GaAs ingots undergo then a series of manipulation to prepare GaAs wafers. The quantity of GaAs wafers manufactured in the EU is estimated to be around 40 tonnes per year and based on GaAs ingots produced within the EU and imported to the EU. The GaAs wafers produced in Europe are then sold not only in Europe but also in the US and different Asian countries. During the two phases of consultation, individual organisations indicated their annual use of GaAs to be below 1 tonnes.	
Concentration of the substance in articles	Consultation responses vary, depending on the level of article considered: • An electronic device based on GaAs is already an article and therefore contains more than 10% of GaAs. This electronic device is than integrated in applications (handsets, smartphones, cars) representing than much less than 0.1% of the weight. • In case of demonstration/prototype concentrator modules < 0.1%; in case of test structures/prototype cells up to 90% • Concentration is 100% for epitaxial wafer articles - concentration is from 0.1% to maximum a few % for packaged components. • In some cases, GaAs is used as process materials and therefore not present in the final article.	

Quantity of articles imported/produced in the EU	GaAs and InP are essential for many applications, the yearly volume of these key components are in the range of 10-12 Billion per year: • Mobile communications: without GaAs no high speed communication (3G, 4G, Wi-Fi,…) • Infrastructure communication systems: no high speed internet or optical communication without InP optical amplifiers or diodes • Mass market and Computer: DVD, Blu-ray, hard drive memory, LC D TV screen use laser diode of GaAs • Industry and medical: diode lasers are based on GaAs or InP • Defence, security and space: radar or IR sensors based on InP, GaAS • Transport & Mobility: GaAs based devices are key components of the electronics used in cars and become even more essential for Hybrid and e-Cars; • IR Emitters: the world market of remote controlled electronic equipment (TV, DVD, Radio, Zircon etc.) with a volume of about 800 – 1.000 Million depends on GaAs-based IR Emitter. • Power supplies: chargers for mobile devices as well as many other electronic devices contain Opt Coupler based on GaAs technology. Our consultation enabled us to develop the following estimates: • Every year almost 600 kg of GaAs enter the EU market through the sales of smartphones and tablets; • 5 tonnes enter the EU market every year through the import of LED lamps.
Alternatives available	There are no known alternative materials or technologies matching the performance of GaAs based Semiconductors for most applications where GaAs is being used today. A ban of GaAs would consequently eliminate most of these products and applications from the market. Furthermore the industry would be forced to shut down current wafer production in Europe and would lose our worldwide competitiveness completely. GaN and Si represent the two main substances which could potentially substitute GaAs for certain applications, but they are associated with high costs and limited capacities.

References:

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[2] Annex XV report for harmonized Classification and Labelling: http://echa.europa.eu/documents/10162/51644019-868a-42c8-b41c-d76c208e6a12, accessed 12/03/2013.

[3] Emission Scenario Document On Photoresist Use In Semiconductor Manufacturing, http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2004)14/rev1&doclanguage=en, accessed 12/03/2013.

A4.3 Summary information on dihexyl phthalate

1D-03	**Substance**	dihexyl phthalate		
	CAS Number	84-75-3	**EC Number**	201-559-5
	Common name	DnHP		
Information available				
Amount of information available	LIMITED	Available Info: uses Limited Info: quantity of articles imported into EU, quantity of substance in articles, exposure to customers, presence in articles, tonnages, substitutes		
Key literature sources	Annex I Background Document C&L (2011) [1] SPIN database [2] US Department of Health and Human Services, Monograph on the Potential Human Reproductive and Developmental Effects of DnHP (2003) [3] Chinese online retail website (2013) [4]			
Consultation	MS responses: 1	Industry responses: 1	Testing body/research institute: 2	
Summary information on uses				
Identified uses	DnHP is a plasticizer used in the manufacture of PVC and other plastics to add flexibility. [1, 3] No usage information. Registered in Sweden for a very narrow range of applications. [2]			
Use in consumer articles	LIKELY	Recent data is confidential but between 1999 and 2003 the substance was recorded as present in consumer preparations. [2] DnHP is used in the making of plastisols that are subsequently used in the manufacture of automobile parts (air filters, battery covers) and dip-moulded products (tool handles, dishwasher baskets). Commercial phthalate substances containing DnHP may be added to the PVC utilized in the manufacture of flooring, canvas tarps, and notebook covers. Substances containing DnHP may also be used in traffic cones, toys, vinyl gloves, weather stripping, flea collars, shoes, and conveyor belts used in food packaging operations. [3] 4 consultation response indicate use in articles: • toys (Hungarian MSA) • textile prints (testing body) • plastisol prints (industry association) • domestic plastics (research institute) Uses include as an emollient in toys and a plasticiser. Potentially used in China. [4]	
Consumers' exposure to the substance				
Can risk of exposure to consumers be excluded?	UNLIKELY	One or several uses indicate a potential exposure to consumers. [2] Unlike other phthalates, DnHP is not bound to plastics so it can be released during the use or disposal of the product and taken up by crops. The general population is exposed to phthalates primarily through the oral and dermal routes. Based on data for other phthalates, the most likely source of human exposure to DnHP is dietary intake. Dermal contact with products containing DnHP is possible, but absorption through skin is unlikely. Although information about exposure is limited, the chemical properties of the substance (unbound to the matrix) and its presence in articles suggests that risk of exposure cannot be excluded. DnHP may be found in food as a result of environmental uptake during cultivation		

		or as a result of migration from processing equipment or packaging materials. DHP (isomer not specified) was below limit of detection (0.01 mg/kg) in samples of household dust and textiles. A level of 0.03 mg/kg was detected in flooring tile.[3] The Hungarian MSA indicated that exposure does not/cannot occur. An industry association and testing body indicates that exposure does/can occur due to function and a research institute specified via skin and/or inhalation (giving no data or additional information).
Market-based information		
Route into the EU	Consultation responses indicate that the substance is no longer used in the EU. Many alternatives are available and have substituted for the substance in production lines. However, the extent to which the substance may still be used in third countries is uncertain. Imports would therefore constitute a primary route via which DnHP enters the EU market.	
Manufacture sites and supply chain	Usually added to DIHP (up to 25%). It's also found in small concentrations in other phthalate mixtures. [3]	
Quantities used per annum of the substance (tonnes)	Recent data on quantity is confidential. From 1999 to 2002, 1 to 2 tonnes of this substance where used in Sweden. [2] There is currently no information available on production volumes of DnHP, but production is stated to be "small" compared to other phthalates Extrapolating from other phthalates, a maximum of 500 tonnes per year for the plastic industry are suggested for Europe. [3]	
Concentration of the substance in articles	Consultation responses vary: • 1- 10% • Less than 0.1%	
Quantity of articles imported/produced in the EU	No information available from any of the sources analysed.	
Alternatives available	. • Alternative plasticisers such as citrates, sebacates, adipates, and phosphates [5] • Some indication that DnHP may have been replaced by other phthalates such as DEHP and DINP in some applications [6]	

References:
[1] ANNEX 1 – Background Document to the Opinion proposing harmonised classification and labelling at Community level of Di-n-hexyl phthalate (DnHP) : http://echa.europa.eu/documents/10162/0fc1bf32-1cd4-4294-a7fc-7ba778f78f13
[2] SPIN database, http://90.184.2.100/DotNetNuke/default.aspx, accessed 12 March 2013
[3] US Department of Health and Human Services, NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Di-n -Hexyl Phthalate (DnHP), National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction. May 2003. http://ntp.niehs.nih.gov/ntp/ohat/phthalates/dnhp/DnHP_Monograph_Final.pdf, accessed 13/03/2013.
[4] Online retail website: http://www.alibaba.com/
[5] Lowell Centre for Sustainable Production (2011): *Phthalates and their Alternatives: Health and their Environmental Concerns* http://www.sustainableproduction.org/downloads/PhthalateAlternatives-January2011.pdf
[6] ICF consultation (DHNUP)

A4.4 Summary information on Formaldehyde

1D-07	**Substance**	formaldehyde		
	CAS Number	50-00-0	**EC Number**	200-001-8
	Common name			
Information available				
Amount of information available	**MORE THAN AVERAGE**	Available Info: uses, exposure to consumers, presence in articles, tonnages, substitutes, quantity of substance in articles Limited Info: supply chain, quantity of articles imported into and produced in EU		
Key literature sources	ECHA registration data [1] ECHA CLH Report (2010) [2] RAPEX database (2013) [3] SPIN database (2013) [4] OECD Emissions Scenario Documents [5] TURI Factsheet (2013) [6] US EPA Technology Transfer Network, Air Toxics Website (2013) [7] Chinese online retail website (2013) [8]			
Consultation	MS responses: 3	Industry responses: 42	Testing body/research institute: 2	
Summary information on uses				
Identified uses	Used in a wide range of activities including: Production of wood based materials (panels, bricks, etc.), Production of impregnated paper, Production of bonded fibres or fibre mats, Production of bonded particulates (abrasive, casting, moulding), Use of adhesives and coatings, Production of rubber, Impregnation of textiles, Production of leather, Production of foams, Production of paper, Production of firelighters and Manufacturing of chemicals / resins / polymers. [1] Industrial/occupational : starting material in chemical synthesis, intermediate in the chemical industry for the production of condensed resins for the wood, paper and textile processing industry, reagent used for tissue preservation and in embalming fluids in autopsy rooms and pathology departments, disinfectant in operating rooms [2] Reported to be used in a very wide range of applications, including use in "Manufacture of chemicals and chemical products" and "Manufacture of rubber and plastic products". [4] Used in chemical synthesis of many other chemicals and in adhesives for PW and chipboard. Also used in pretty large quantities as an active ingredient in various biocidal products. [5] Used mainly as a chemical intermediate and in the production of resins used in PB products. Minor uses in agriculture, as an analytical reagent. [7] Consultation responses indicated the following uses and functions (industry responses unless otherwise indicated): • Crosslinker of resin, giving adhesion in the polymerised state, no free formaldehyde in our articles • Gives adhesion between reinforcing cords and rubber matrix (e.g. tires). • Polymerisation reaction product in plastic film • Wood glue; provides colour to textile (Lithuanian MSA) • The dressing (softened, fleshed) of furs • It is one of the main components of the dip used to increase the adhesion between cord/fabric and rubber • Formaldehyde is used in preparation of Resin formulation for coating on Rayon cord for imparting necessary adhesion properties. • For analyses in chemical laboratory • Component in mixture which is used as raw material in manufacturing. It reacts during the process and not present in finished product.			

		• No CMR substance is used in our articles. We use only formaldehyde in laboratory purposes in small quantities. • Used in resistors, capacitors, diodes • Provides a finish • [Used in] acid curing technology, biocides, UV-curable resins • Impregnation of textiles
Use in consumer articles	**YES**	Preservative in cosmetics. [2] Since 2005, 58 products have been reported under RAPEX because of their high content in formaldehyde. Most of them are cosmetics and textiles. [3] Many products contain formaldehyde, including resins and adhesives, permanent press fabric treatments, tissue preservatives, lawn fertilizers, cosmetics and disinfectants. [6] Minor uses in concrete and plaster additives, cosmetics, and photography. Pressed wood products (hardwood PW wall panelling, PB, fibreboard) and furniture made with these pressed wood products are the main current concern for EPA. [7] Also appears to be used in China. [8] 27 consultation responses indicated no use in articles, specific comments included: • It is a raw material for an organic polymer (purchased resin then mixed in our manufacturing sites with other raw materials to make a binder. During manufacture this binder is heated (cured) to high temperatures to form solid, inert bonds which hold the products in mat or board form. This process virtually eliminates the release of formaldehyde from the finished product. In the cured binder, formaldehyde does NOT exist anymore and one added that these substances are monomers in the supply chain • They are not used directly by us, only incorporated into polymers 20 consultation response indicated formaldehyde in used in articles, with the following examples (industry response unless otherwise indicated): • Textile reinforcements for the rubber industry (tires, hoses, belts, air springs etc.) giving the adhesion from textile reinforcement to the rubber • Reinforcing cords for rubber applications. Formaldehyde reacts during manufacturing and is incorporated in a polymer giving adhesion between cord and rubber. • Primary Food Packaging Material • Is used in adhesives for bonding wood; in formaldehyde resin for furniture, for PW; for tanning hides; as textile auxiliary materials; for tanning hides (furs)-leathering (Lithuanian MSA) • Treated cords/fabrics used in tire production process • Construction products • Dipped Rayon Fabric is used as reinforcement material for tyres. • Used in the wood market industry (industry and research institute) • Used as a monomer in polymers, it gives ink its desirable properties – such as hardness, solubility and setting properties for e.g. allows ink to dry quickly and to be hydrophobic. In the final end-product, formaldehyde is likely to be contained as an unreacted impurity • Used in the polymerisation process required for the production of insulation and energy-saving products • Used in the production of melamine resins that are used in coatings/lacquers/varnishes (typically in the automotive/aircraft/construction) sectors • Used as a disinfectant in various applications (e.g. medical sector)
Consumers' exposure to the substance		

Can risk of exposure to consumers be excluded?	NO	One or several uses indicate a very probable exposure to both workers (occupational) and consumers. [4] Unreacted formaldehyde may off-gas into the air and be inhaled. Tobacco smoke also contains formaldehyde. Air pollution and cosmetics are also sources of this gas. NOTE: Exposure to formaldehyde from articles should be differentiated to exposure from non-article sources (e.g. cigarette smoke, use as a preservative in laboratory, combustion, etc.). Consumers are exposed in their everyday lives to small concentrations of this substance [6] Consumers are clearly exposed to this substance. Pressed wood furniture is an example of article that may contain formaldehyde and is in direct contact with consumers. Studies have found concentrations of formaldehyde in indoor air in houses and schools. [7] 12 consultation responses indicated that exposure does not/cannot occur with the following comments (industry response unless otherwise indicated): • The substance is covalently bonded into polymer matrix. • One company indicated that they have done tests to verify possible exposure due to formaldehyde from their finished products. • Residual monomer is <0.1%. • Most of the substance evaporates before reaching the consumer. • Not contained in the finished products/contained only as an unreacted impurity. • Investigations have proven that the free formaldehyde content after manufacturing the products is zero as all is incorporated into the polymer matrix. • Ample technical safeguards are taken to ensure complete conversion of Formaldehyde into the resin by the following mandatory steps: 1. Necessary ageing of the resin formulation. 2. Processing of the resin coated fabric at 130-150 deg. C ensuring removal of volatile matter. 3. Curing of the fabric ensuring complete curing of resin. • The manufacture of thermoset polymers using UF or melamine-formaldehyde condensation cannot entirely and practicably exclude all traces of residual monomer. • When minimized in process hydrolysis can lead to its regeneration. 9 consultation responses indicated that is does/can occur, with the following explanations: • Migration possible into food but subject to a SML of 15 mg/ kg food • Release due to chemical equilibrium reaction. • Uptake can occur via food transfer of chemical • Skin and/or inhalation • While formaldehyde is covalently bonded into the matrix of the polymers used to make articles, it can be present as an unintended impurity at extremely low levels. It is also possible that formaldehyde can be released at extremely low levels by hydrolysis.
Market-based information		
Route into the EU	Consultation responses indicate both manufacture and import to the EU of articles containing the substance.	
Manufacture sites and supply chain	• Location of manufacture of formaldehyde, formaldehyde-based products, articles containing formaldehyde: Austria, Belgium, Germany, Turkey, Lithuania, Norway [9] [10] • Location of sales: EU-wide, including Turkey; third countries (e.g. Argentina) [9] [10]	

Quantities used per annum of the substance (tonnes)	• Registered under REACH for a tonnage of 1,000,000 + tonnes per annum. [1] • In 2010, Norway reported 32300.3 tonnes Finland 21373.2, Denmark 14206.5 and Sweden 3865 tonnes. [4] • Considered a HPVC and "bulk chemical". [5] • One consultee indicated the following quantities of formaldehyde/formalin manufactured/sold by member state companies: *Formaldehyde* - From 0,036 t/y to 2,3 t/y (2012) [10] *Formalin* - Manufactured: 46, 297 t/year; sold: 896 t/year [10] • Other consultation responses indicated the following quantities of the substance used in articles per year: - 10 to 50 tonnes (2 responses) - Less than 1t (6 responses) - 5 to 10 tonnes (1 response) - 1t to 5t (1 response)
Concentration of the substance in articles	• 12 consultation responses indicate <0.1%, 2 others indicate 0.1% - 1% and 1 other indicates 1% - 10%. • One consultation response indicates the formaldehyde content in PB to be between 0,004 and 0,008 % w/w [10]
Quantity of articles imported/produced in the EU	• One consultee indicated that about 38 t/y of formaldehyde and boric acid/articles containing these substances are imported into the EU by member state companies (ref: Lithuania) and about 64 t/y are exported to non-EU countries [10]
Alternatives available	Several alternative processes and substances are mentioned in the TURI factsheet. [6] Consultation responses include: • To our best knowledge there is no other chemical available which could provide the same performance in the rfl-recipes for bonding rubber to textile reinforcements, the whole rubber industry is dependent on textile reforments made with rfl adhesives. Measurements show, that there is not more than 100 ppm formaldehyde being evaporated from the textile at 200°C or below. The formaldehyde is polymerised in our process into the adhesive and is not available to the human being after our process. • Melamine (and phenolic) resins with 0.4 to 2 % free formaldehyde content are relevant raw materials for industrial and professional coatings; some applications might be replaced by 2-component coatings with isocyanate hardeners (which are known for their sensitizing properties). • Alternative polymer systems such as epoxy or urethane bring other converns such as bisphenol A or isocyanate. Specific industries have the option of switching to alternatives: in the automotive sector one consultee suggested that 2-component coatings (2K) with isocyanate hardeners; partially powder coatings; or UV cured coatings could substitute for formaldehyde-based coatings [9] An EU furniture industry representative suggested low formaldehyde-emitting panels can be used in the production of furniture. Consultee also evoked the possible use of PU-bound panels and formaldehyde-free glues [9]

References:

[1] ECHA Registration data, apps.echa.europa.eu/registered/data/dossiers/DISS-9daa7594-c409-0ed0-e044-00144f67d249.html, accessed 18/03/2013.
[2] CLH Report, PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING: http://echa.europa.eu/documents/10162/33be542e-7f27-4982-8078-d468f94310e4, accessed 25/03/2013.
[3] Rapex database, http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm
[4] SPIN database, http://90.184.2.100/DotNetNuke/default.aspx, accessed 14/03/2013
[5] OECD Emission scenario document on the chemical industry, http://www.oecd.org/env/ehs/risk-assessment/emissionscenariodocuments.htm, accessed 25/03/2013.
[6] TURI, 2013, Formaldehyde Chemical Factsheet. Available at:

http://www.turi.org/content/download/180/1433/file/Formaldehyde%20fact%20sheet%20-%202013.pdf
[7] EPA Technology Transfer Network - Air Toxics Web Site, http://www.epa.gov/ttnatw01/hlthef/formalde.html#ref1 accessed 27/03/2013.
[8] Online retail website: http://www.alibaba.com/
[9] Based on ICF consultation with EU industry representatives and businesses in relevant sectors
[10] Based on ICF consultation. Location of manufacturing site/raw material production: Turkey; sale of raw material to: EU MS

A4.5 Summary information on 1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione

2A-01	**Substance**	1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione		
	CAS Number	2451-62-9	**EC Number**	219-514-3
	Common name	TGIC		
Information available				
Amount of information available	**AVERAGE**	Available Info: uses, presence in articles, exposure to customers, tonnages, quantity of substance in articles, substitutes Limited Info: quantity of articles imported into EU		
Key literature sources	Annex XV Dossier (2011) [1] Comments an Annex XV Dossier and Responses to These Comments (2012) [2] Powder Coatings Center (2013) [3] UK Health and Safety Executive Information Sheet [4]			
Consultation (1st and 2nd phase)	MS responses: 0 (1st phase); 0 (2nd phase)	Industry responses: 5 (1st phase); 6 (2nd phase)	Testing body/research institute: 1 (1st phase); 0 (2nd phase)	
Summary information on uses				
Identified uses	In Europe, TGIC is principally used in various polyester powder coatings applications (e.g., weather resistant powder coating articles such as steel garden furniture, car parts, metal fencing, window and door frames, electrical equipment, refrigerators, washing machines and ovens). The main use is in polyester powder coatings for metal finishing and such coatings typically contain between 4 and 10% TGIC. [1] TGIC is also used in the European semiconductor manufacturing as component of solder mask ink. It is then used in the manufacturing of computer, electronic and optical product, and electrical equipment [2] The literature identified the following additional uses of TGIC in articles. However we were unable to confirm whether use in Europe has ceased or whether articles produced outside Europe continue to contain TGIC which are then imported in to the EU. ■ Electrical insulation materials; ■ Resin-moulding systems; ■ Laminated sheeting; ■ Silk-screen printing coatings; ■ Adhesives; ■ Lining materials; and ■ Stabilisers for plastics. It is suspected that given the findings of the Annex XV dossier on TGIC that use in Europe is limited to powder coatings and semiconductor applications that the above additional uses have ceased. Imports in articles are therefore likely to be the main sources of TGIC in this context.			
Use in consumer articles	**YES**	TGIC is used in the manufacturing process of the different articles identified above. However, TGIC is a cross-linking agent used during the manufacturing process and at the end of this process TGIC is fully cross-linked and bound into a solid matrix and therefore not present as free substance any more.		
Consumers' exposure to the substance				
Can risk of exposure to consumers be excluded?	**UNLIKELY**	The TGIC used in the manufacturing of powder coated articles and printed circuit boards is fully cross-links with the polyester resins during the manufacturing process. It is not present as free substance in the final products and it poses therefore no health risk for the consumers. However, despite this statement, ECHA argues that: "without measurements (leaching data) it is not possible to say		

	that consumer exposure is negligible, although this seems likely". [1].
Market-based information	
Route into the EU	TGIC is imported to Europe from different production sites located in Switzerland, Japan and China. For current data on production and use of TGIC see confidential Annex 2 of Annex XV dossier. Global production volume is not known. The total current EU use is estimated by ECHA to be at the lower end 100-1,000 tonnes per year range. The current use of TGIC in the EU is estimated at approximately 20% of the total import for solder mask ink and 80% for powder coating applications. The following amounts are by far outdated and current manufacture and use has been declined considerably: • Worldwide production of triglycidyl isocyanurate in the past was approximately 7000–8000 tonnes per year. • UK imported approximately 400 tonnes of triglycidyl isocyanurate per year for use in powder coatings. • In UK, approximately 30 tonnes of solder "mask" inks containing triglycidyl isocyanurate were manufactured per year by four or five companies (CICAD 1998). [1]. TGIC is being phased out in Europe for the majority of its application in the powder coating industry. There are already several alternatives known and largely used. Considering the different regulatory initiatives to limit the use of TGIC and the availability of more alternatives, this downward trend in use is expected to continue in Europe for the foreseeable future. In the rest of the world and in particular in Asian countries, TGIC is still largely used.
Manufacture sites and supply chain	Imported into EU for use in manufacture of coatings and semiconductor devices. [1] The consultation enabled us to identify production sites in Switzerland, Japan and China. TGIC is imported to the EU and distributed by a variety of suppliers located in Europe and abroad. Powder coating manufacturer use then TGIC to produce powder coating which is either sold directly to product manufacturers or to coating enterprises. Consultation responses indicated both import and manufacture in the EU of articles containing TGIC, although there is a clear phasing-out process underway in Europe.
Quantities used per annum of the substance (tonnes)	The total current EU use is estimated at the lower end 100-1,000 tonnes per year range. [1] Our consultation enabled us to estimate the total EU import of TGIC in 2012 to be between 90 and 100 tonnes. Forecast from the industry for the year 2013 are considerably lower: below 50 tonnes. One facility reported importing a quantity of 84 kg of resin containing TGIC @ 15% (in 2011) for manufacturing of semiconductor devices. [2]
Concentration of the substance in articles	Powder coating containing TGIC usually contains between 4 and 10% of TGIC. The TGIC in powder coatings after application to metal particles is fully cross-linked and is bound in a solid matrix and therefore not present as free substance [1] [4] Based on its resistance to heat and to corrosion, TGIC is used as part of the hardener for solder mask inks. The two-part inks can contain up to 60% of TGIC in the hardener component, resulting in a very low level of TGIC in the final inks. During the manufacturing process TGIC is immobilised through cross-linking in an insoluble matrix. Maximum nominal concentration in finished semiconductor devices being used in Europe or exported from Europe is 6 % of TGIC. [2]
Quantity of articles imported/produced in the EU	No information was identified in the sources analysed. The data collected during the consultation did not permit to evaluate the quantities of articles imported/produced in the EU.
Alternatives available	There are already several alternatives known and used for TGIC in powder coating. Further R&D activities are ongoing in direction of further search for new alternatives. There is also information that TGIC is already banned in many countries and replaced by -hydroxy-alkylamides (HAA). In recent years more than 90% of the TGIC powders coating formulations have successfully been replaced in Europe using beta-HAA or glycidylester alternative cross linkers. A few TGIC based powder coatings are however still being used. It is considered that for some applications the current alternative cross linkers do not completely satisfy the most demanding technical profiles or that the switch to an alternative technology may be shifted or hindered because the volume in use at some powder users is too small to justify for economic reason any development work, parameter

	adjustment. Replacement of TGIC with alternatives in solder mask inks is possible for low performance electronics, but not possible for high performance electronics. [1] DuPont Powder Coatings announces the transition of the DuPont™ Alesta® RAL product line from the standard triglycidyl isocyanurate (TGIC) to hydroxyalkylamide (HAA), TGIC-free chemistry. DuPont Powder has over 20 years of experience in formulating HAAs and believes the trend in North America will reflect the transition from TGIC to HAA polyesters already occurring in other regions around the world. [3]

References:

[1] Annex XV Dossier: Proposal for Identification of a Substance as a CMR Category 1A Or 1B, PBT, vPvB or a Substance of an Equivalent Level of Concern, http://echa.europa.eu/documents/10162/13638/svhc_axvrep_tgic_combinationisomers_en.pdf
[2] Comments on Annex XV Dossier For Identification of a Substance as SVHC And Responses to these Comments, https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&ved=0CDEQFjAA&url=http%3A%2F%2Fecha.europa.eu%2Fdocuments%2F10162%2F9f61c3f4-8caa-4efc-a854-0b248815be1e&ei=yhdoUZnqDIfXsgbz54DYDA&usg=AFQjCNHTH2X5fI6vPVitj5A_0s9VVgImCA&sig2=KTJ-JbuVHnGe7i5GB8iAaA 8 May 2012
[3] Powder Coatings Center, http://www.specialchem4coatings.com/tc/powder-coatings/index.aspx, Accessed 02/04/2013.
[4] UK Health and Safety Executive Information Sheet, http://www.hse.gov.uk/pubns/eis15.pdf, accessed 02/04/2013

A4.6 Summary information on 2-Methoxyaniline; o-Anisidine

2A-06	**Substance**	2-Methoxyaniline		
	CAS Number	90-04-0	**EC Number**	201-963-1
	Common name	o-Anisidine		
Information available				
Amount of information available	**AVERAGE**	Available Info: uses, presence in articles, exposure to customers Limited Info: quantity of articles, tonnage, alternatives		
Key literature sources	Annex XV report (2011) [1];			
Consultation	MS responses: 2	Industry responses: 2	Testing body/research institute: 2	
Summary information on uses				
Identified uses	Used for manufacture of dyes and as a processing aid, particularly for azo pigments. These are mainly used in printing inks for packing materials like paper, cardboard, polymer and aluminium foil. Also used to process other dyes for textile, leather and paper [1]. In recent years, azo pigments have been used in tattooing and permanent make-up [2]. Six consultation responses acknowledge the use of the substance.			
Use in consumer articles	**LIKELY**	It seems it is not intentionally used in articles but may occur as a residue or metabolite. Particularly it is indicated that o-Anisidine may be present in pigments or dyes and as a component in printed polymers and metal articles, especially in printed aluminium foils [1], [4]. Consultation responses are mixed: two Member State Authorities (Hungary and Denmark) and one research institute suggest the use in articles (clothes, bed linen, electronic components, and textiles) but the two respondents from industry declare the substance is not used in articles.		
Consumers' exposure to the substance				
Can risk of exposure to consumers be excluded?	**NO**	According to RAPEX, it has been found in tattoo inks as recently as 2013, which poses a serious exposure risk [3]. It has also been found in mixtures such as crayons, toner ink and colorant for do-it-yourself candles (although these may not strictly be articles). May also be present as a residue in textile or leather articles. O-anisidine was detected in the blood and urine of general population [1]. The Annex XV report also indicates that releases from o-Anisidine based tattoo pigments may result in a considerable risk for consumers, although this risk has not been fully evaluated due to limited information. Note that direct use of the substance (or mixtures) by consumers is covered by the generic restriction under REACH Annex XVII Entry 28, which prohibits its use in consumer products. This restriction does not apply to the use of the substance in articles. Its use is also restricted in leather and textile products by REACH Annex XVII Entry 43 and prohibited in cosmetics under Annex II of Regulation (EC) No 1223/2009.		
Market-based information				
Route into the EU	Manufacture and imports are the routes of the substance into the EU. There is no information on volumes of o-Anisidine incorporated into imported articles [1]. Responses from the Hungarian Authority for Consumer Protection and one research institute suggest that articles containing the substance are manufactured and imported into the EU.			
Manufacture sites	Used in the EU as an intermediate only. The Annex XV report indicates that most of manufactured and			

and supply chain	imported o-Anisidine in the EU was processed to azo pigments.[1].
Quantities used per annum of the substance (tonnes)	Between 1000 and 10 000 tonnes per year [1].
Concentration of the substance in articles	Regarding printed packing and aluminium foil, the German Printing Industry estimated an amount of o-Anisidine between 1.5 and 15 µg per m² foil [1]. Responses from the Hungarian Authority for Consumer Protection suggest less than 0.1%.
Quantity of articles imported/produced in the EU	No information was identified in the sources analysed or received from consultation.
Alternatives available	Several EU MS have issued national laws on substitution of o-Anisidine based colorants in tattoo inks according to resolutions of the European Council (ResAP (2003) 2 and ResAP (2008) 1). In addition, o-Anisidine releasing colorants have been included in a voluntary exclusion list for printing inks and related products adopted by the EUPIA. It has been indicated that there are suitable alternatives to the substance in printing and tattoo inks [2].

References:

[1] ECHA Annex XV report, http://echa.europa.eu/documents/10162/8679db03-ce69-47a7-b57b-b39cfc2237a6
[3] RAPEX Database http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm, accessed 19/03/2013.
[4] Swedish Chemical Agency (2013): Hazardous chemicals in textiles – report of a government assignment. Stockholm, April 2013

A4.7 Summary information on boric acid

2A-09	**Substance**	Boric acid		
	CAS Number	10043-35-3	**EC Number**	233-139-2
	Common name	Boric acid		
Information available				
Amount of information available	**MORE THAN AVERAGE**	Available Info: uses, tonnage, concentration in articles, quantity of articles Limited Info: alternatives		
Key literature sources	ECHA risk assessment (2007) [1] RPA (2008) [2] Chinese online retail website (2013) [3]			
Consultation (1st and 2nd phase)	MS responses: 2 (1st phase); 1 (2nd phase)	Industry responses: 33 (1st phase); 16 (2nd phase)	Testing body/research institute: 2 (1st phase); 0 (2nd phase)	
Summary information on uses				
Identified uses	Used in a wide range of substances including cosmetics; toiletries; pharmaceuticals; insulation and textile fibre glass; borosilicate glass; ceramics; steel and non-ferrous metals; welding, blazing and soldering fluxes; plating; metal working fluids; water treatment chemicals; fuel additives; adhesives; flame retardants; biocides; and fertilisers [1]. Highly versatile – 140 different types of end-use applications [1] Used in industrial fluids such as antifreezes, lubricants, brake fluids, metalworking fluids, water treatment chemicals and fuel additives [2]. Potentially used in China. [3]			
Use in consumer articles	**YES**	Boric acid is used in technical textiles, primary food packaging material, wood preservative (antiseptics), epoxy, construction products, lubrication of espresso machine gaskets, plastic (ethylene vinyl alcohol) based packaging materials, cellulose insulation for insulating buildings, plasterboard for building construction (walls, ceilings), paper/board articles containing an adhesive (variety of uses of the paper/board), flame retardants (as a synergist), special glass types, electronic components.		
Consumers' exposure to the substance				
Can risk of exposure to consumers be excluded?	**NO**	The risk is low but exposure can occur through inhalation or through ingestion by way of material transfers (e.g. fertilisers, detergents etc.) [2]. Consultation inputs are mixed: Companies: 9 agree, 2 disagree as exposure may occur 'during uncontrolled handling of articles and breathing of weld fumes' or through 'human contact with product' (C67) Industry associations: 3 agree, 5 disagree as exposure may occur: 'linked to function' 'Migration possible into food but subject to a SML of 6 mg/ kg food' , exposure expected but low , 'most frequently used in enclosed environments or removed by rinsing prior to article being used' A testing body disagrees and a research institute disagrees as exposure could occur through the skin or through inhalation.		
Market-based information				
Route into the EU	Imports for use in manufactured articles [1]. Consultation inputs suggest that boric acid is used in articles manufactured in as well as imported into			

	the EU.
Manufacture sites and supply chain	Consultation indicates that approximately 100% of boric acid is imported into the EU [1].
Quantities used per annum of the substance (tonnes)	Global production of borates: 5 million tonnes per annum [2]; supply of boric acid to EU: 45,445 tonnes in 2012, as reported by consulted importers
Concentration of the substance in articles	The concentration-response curve for boron is likely to be U-shaped for many species, with adverse effects observed at very high and very low concentrations, while no adverse effects are observed at the intermediate concentrations [1]. A number of boron compounds have recently been classified as mutagenic and/or toxic for reproduction, in the latter case with specific concentration limits. These specific concentration limits set for the boron compounds indicate that thresholds for the reproductive toxicity could be established. Boric acid, borates and tetraborates are regulated in the Cosmetics Directive 76/768/EEC with maximum use concentrations. The SCCS is asked to review the safety of use of the classified boron compounds as cosmetic ingredients. (European Commission information) Consultation responses were mixed, with 4 company respondents indicating that boric acid concentration levels in articles were less than 0.1%, one company suggesting that the level was between 0.1% and 1%, 2 industry association and a testing body suggesting that it was between 1% and 10% and one company suggesting that it exceeded 10%.
Quantity of articles imported/produced in the EU	45,445 tonnes of boric acid imported by the EU in 2012, as reported by consulted importers Consultation inputs suggested that the quantity of boric acid used in articles may vary widely: it was reported to be less than 1t (4 responses), between 1t and 5t (1 response), between 10t and 50t (2 responses) and in excess of 100t (2 responses).
Alternatives available	As reported by consulted companies, borates do not have viable substitutes in the context of several uses (e.g. borosilicate ceramic and glass, adhesives for corrugated paperboard, manufacture of precious metals). Potential alternatives may exist for some uses, although at considerably higher prices and/or with a negative impact in terms of quality and safety (e.g. flame retardants in textiles).

References:

[1] ECHA risk assessment report (2007), http://echa.europa.eu/documents/10162/6434698/orats_final_rar_disodiumtetraborate_anhydrous_en.pdf
[2] RPA (2008) – Assessment of the Risk to Consumers from Borates and the Impact of Potential Restrictions on their Marketing and Use: Final Report, http://ec.europa.eu/enterprise/sectors/chemicals/files/docs_studies/final_report_borates_en.pdf
[3] Online retail website: http://www.alibaba.com/

A4.8 Summary information on disodium tetraborate decahydrate (borax decahydrate)

2A-10	**Substance**	Disodium tetraborate decahydrate (Borax decahydrate)		
	CAS Number	1330-43-4	**EC Number**	215-540-4
	Common name	Borax decahydrate		
Information available				
Amount of information available	**AVERAGE**	Available Info: uses, tonnage, quantity of articles Limited Info: concentration in articles, alternatives		
Key literature sources	ECHA risk assessment (2007) [1] European Commission (2008) [2] Chinese online retail website (2013) [3]			
Consultation	MS responses: 0	Industry responses: 18	Testing body/research institute: 2	
Summary information on uses				
Identified uses	Used in a range of substances including Powder hand soap; detergents; cosmetics; toiletries; pharmaceuticals; refractories; steel and non-ferrous metals; lubricants; water treatment chemicals; adhesives; cellulose insulation; and fertilisers [1]. Highly versatile – 140 different types of end-use applications [1]			
Use in consumer articles	**YES**	Used in industrial fluids such as antifreezes, lubricants, brake fluids, metalworking fluids, water treatment chemicals and fuel additives [2]. Potentially used in China. [3] Industry consultation responses suggest that borax decahydrate is used in technical textiles, shipping containers, construction products, cellulose insulation for insulating buildings, plasterboard for building construction (walls, ceilings), refractory bricks for lining kilns/furnaces, paper/board articles containing an adhesive (variety of uses of the paper/board), special glass types		
Consumers' exposure to the substance				
Can risk of exposure to consumers be excluded?	**NO**	The risk is low but exposure can occur through inhalation or through ingestion by way of material transfers (e.g. fertilisers, detergents etc.) [2]. Consultation inputs are mixed, with 5 industry respondents suggesting that exposure does not/cannot occur and 4 other industry respondents, plus a testing body and research institute, suggesting that it does/can.		
Market-based information				
Route into the EU	Imports for use in manufactured articles [1]. Consultation inputs suggest that borax decahydrate is in articles that are manufactured in as well as imported into the EU.			
Manufacture sites and supply chain	Does not seem to be manufactured in the EU. Importers will be relevant. May also be imported in manufactured articles. [1].			
Quantities used per annum of the substance (tonnes)	Global production of borates: 5 million tonnes per annum; supply to EU: 60,000 tonnes per annum [2]			
Concentration of the substance in articles	The concentration-response curve for boron is likely to be U-shaped for many species, with adverse effects observed at very high and very low concentrations, while no adverse effects are observed at the intermediate concentrations [1]. Consultation responses were mixed, with 3 respondents indicating that borax decahydrate			

	concentration levels in articles were between 1% and 10% and one other suggesting that the level was between 0.1% and 1%.
Quantity of articles imported/produced in the EU	60,000 tonnes of borates are imported by the EU per annum [2] Consultation inputs suggested that the quantity of borax decahydrate used in articles may vary widely: it was reported to be less than 1t (2 responses) and more than 100t (2 responses).
Alternatives available	There appears to be little information on substitutes of borax decahydrate per se but in general borates do not appear to have viable substitutes in the context of several substances (e.g. detergents, borosilicates etc.) [2].

References: [1] ECHA risk assessment report (2007), http://echa.europa.eu/documents/10162/6434698/orats_final_rar_disodiumtetraborate_anhydrous_en.pdf
[2] European Commission (2008) – Assessment of the Risk to Consumers from Borates and the Impact of Potential Restrictions on their Marketing and Use: Final Report, http://ec.europa.eu/enterprise/sectors/chemicals/files/docs_studies/final_report_borates_en.pdf
[3] Online retail website: http://www.alibaba.com/

A4.9 Summary information on Ethylene thiourea; imidazolidine-2-thione; 2-imidazoline-2-thiol

2B-01	**Substance**	Imidazolidine-2-thione; 2-imidazoline-2-thiol		
	CAS Number	96-45-7	**EC Number**	202-506-9
	Common name	Ethylene thiourea (ETU);		
Information available				
Amount of information available	**LIMITED**	The Danish EPA assessment [3] offers formation on uses and concentrations in formulations for use in the apparel industry but information on exposure is inconclusive.		
Key literature sources	ECHA Registration data [1];; Danish EPA [3]; Dupont 2004 [4].			
Consultation	MS responses: 0	Industry responses: 7	Testing body/research institute: 1	
Summary information on uses				
Identified uses	Literature indicates that it is mainly used as a vulcanization agent or accelerator in the manufacture of chloroprene rubber (neoprene) products [2], [3]. The main applications of neoprene are water sports and other outdoor activities, including products such as wetsuits, trunks, hoods, gloves, waders and boots [3]. Chloroprene rubber is also used in the manufacture of industrial products (e.g. conveyor belts, car parts, tank lining) [4].Additionally, use of ETU as an intermediate for antioxidants, in pesticides, dyes, pharmaceuticals, electroplating baths or synthetic resins are mentioned in the literature [2]. Eight consultation responses acknowledge the use of the substance in Task 1.			
Use in consumer articles	**YES**	Reportedly used in the manufacture of articles available to consumers (e.g. neoprene footwear and wetsuits). Three consultation responses (two from industry and one from a research institute) suggest the use in general rubber goods, construction chemicals and flooring articles.		
Consumers' exposure to the substance				
Can risk of exposure to consumers be excluded?	**UNLIKELY**	There may be a potential for consumer exposure (dermal and inhalation) through contact with articles containing the substance (e.g. wetsuits, footwear). However, the Danish EPA [3] conducted a survey on chloroprene rubber apparel and could not detect ETU in any of them, suggesting that the substance either was not used in the specific products tested or that it reacts completely during vulcanisation. No information is provided on exposure of consumers to industrial chloroprene products. Note that direct use of the substance (or mixtures) by consumers is covered by the generic restriction under REACH Annex XVII Entry 28, which prohibits placing on the market of the substance or related mixtures for sale to the general public. This restriction does not apply to the use of the substance in articles. Its use is also prohibited in cosmetics under Annex II of EU Regulation 1223/2009. A research institute suggests that it cannot be excluded, industry suggests that the exposure can be excluded because it chemically reacts during vulcanisation of the rubber article and is bonded into matrix, making it difficult for the substance to leach out.		
Market-based information				
Route into the EU	Substance is registered under REACH and manufactured within the EU. One company and one industrial association suggest articles containing the substance are manufactured and imported to the EU.			
Manufacture sites and supply chain	There is one EU manufacturer of ETU. The substance may also be imported. Chloroprene rubber is manufactured within the EU and imported.			
Quantities used per	Between 100 and 1000 tonnes per annum [1]. One industry response suggests 10 to 50 tonnes per year are			

annum of the substance (tonnes)	used in articles
Concentration of the substance in articles	No information was identified in the sources analysed, but consultation suggests less than 0.1%. ETU is added to the formulation in concentrations in the range 0.2-1% [3].
Quantity of articles imported/produced in the EU	No information was identified in the sources analysed or from consultation.
Alternatives available	Limited information appears to be available on alternatives to replace Ethylene thiourea as an accelerator in rubber manufacturing. The RIVM report mentions the SafeRubber project which aims to develop potential substitutes for the substance in the rubber industry by 2013. Additionally, industry has indicated that viable alternatives, with similar properties, are already available or in the process of being developed [2]. Other thiourea-based accelerators are known to be used in the manufacture of neoprene [3] [4].

References: [1] ECHA Registration data: http://echa.europa.eu.
[3] Danish EPA (2012) Survey and health assessment of thiourea compounds in chloroprene rubber.
[4] Dupont (2004) A Guide to Grades, Compounding and Processing of Neoprene Rubber, Rev. 3.

A4.10 Summary information on Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate

2C-01	**Substance**	Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate		
	CAS Number	1937-37-7	**EC Number**	217-710-3
	Common name	CI Direct Black 38		
Information available				
Amount of information available	**LIMITED**	There is an Annex XV SVHC dossier but overall there is limited information on risk exposure and current usage.		
Key literature sources	Annex XV SVHC dossier (2013) [2]			
Consultation	MS responses: 2	Industry responses: 3	Testing body/research institute:2	
Summary information on uses				
Identified uses	Direct Black 38 is a benzidine-based dye that has reportedly been used for the dyeing of textiles (i.e. cotton, silk, wool and jute), leather and paper. Use in plastics, inks, wood, biological materials, and hair dyes is also mentioned in the literature [1, 2]. The substance has been primarily used in the textile industry [3]. Six consultation responses, including one company and one industrial association, acknowledge the use of the substance.			
Use in consumer articles	**YES**	Direct Black 38 can be used to dye articles available to consumers (e.g. textiles), mainly textiles, leather and paper [1]. Therefore there is potential for consumer exposure through dermal or oral contact with such dyed articles.. The extent to which it is currently used or imported in articles is unknown, although it is likely to be low [1, 2]. 5 consultation responses (for Task 1), including one industry association, a testing body, a research institute and the Swedish Chemical Agency, declare that the substance is present in articles such as textiles, paper, leather, plastics and adhesives. However, the company reporting use of the substance indicates that it is not contained in articles.		
Consumers' exposure to the substance				
Can risk of exposure to consumers be excluded?	**NO**	Consumers may be exposed through dermal and oral contact with articles dyed with the substance [1, 2]. More information on exposure risk is available in the the Annex XV report. In addition, no consultation respondents consider that consumer exposure can be excluded. Note that direct use of the substance (or mixtures) by consumers is covered by the generic restriction under REACH Annex XVII Entry 28, which prohibits placing on the market of the substance or related mixtures for sale to the general public. This restriction does not apply to the use of the substance in articles. Its use is also prohibited in cosmetics under Annex II of EU Regulation 1223/2009 as well as restricted in leather and textile articles through REACH Annex XVII Entry 43 which restricts the use of azo dyes that could led to the presence of benzidine in final articles under certain conditions		
Market-based information				
Route into the EU	The substance is not registered under REACH and therefore it is assumed that the primary route relates to potential import in articles [1]. The Annex XV report indicates that the substance appears not to be manufactured in the EU but imported into the EU in small quantities. One company, one industry association and one testing body/research institute indicate that articles containing the substance are imported into the EU. One company and one research institute also reports manufacture of these articles.			

Manufacture sites and supply chain	Relevant supply chain stage seems to relate to imported articles due to the substance not being registered under REACH.
Quantities used per annum of the substance (tonnes)	The usage of the substance was estimated to be about 10-1000t per year in EU (ESIS 2008 as cited in the Annex XV SVHC dossier) but it is indicated that there has been a recent move away from use of the substance in the EU. According to a consultation carried within the Annex XV report, only small quantities of Direct Black 38 are imported into the EU, with the total amount less than 500 kg The SPIN database reports use in Denmark up to 2005 but data on use are confidential.
Concentration of the substance in articles	There are no substance-specific data. One Agency has indicated through consultation estimates that the typical concentration of Direct Black 38 in articles is estimated to be below 0.1%.
Quantity of articles imported/produced in the EU	There is no quantitative information in the sources analysed.. The consultation has revealed that although the substance is used and supplied in China (at least 36 suppliers); its use has been prohibited in the Chinese textile industry. The use of the substance in textiles and leather has been also restricted in other jurisdictions such as India [3].
Alternatives available	There is relatively little information on specific alternatives. OECD (2005) (as cited in the Annex XV SVHC dossier) mentions that Direct Black 22, which does not contain benzidine, is more expensive than Direct Black38.

References:

[2] Annex XV SVHC dossier Direct Black 38, 2013. Prepared by the Netherlands. http://www.echa.europa.eu/documents/10162/bd7d4cbe-2b14-4066-bbfc-6b7ec7422b92

[3] Environment Canada, 2009, - Screening Assessment for the Challenge: 2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt (Direct Black 38)

A4.11 Summary information on Bis(2-ethylhexyl) phthalate

3A-02	**Substance**	Bis(2-ethylhexyl) phthalate		
	CAS Number	117-81-7	**EC Number**	204-211-0
	Common name	DEHP		
Information available				
Amount of information available	**MORE THAN AVERAGE**	Available Info: uses, exposure to costumers, presence in articles, tonnage, alternatives. Limited Info: supply chain, quantity of articles.		
Key literature sources	Annex XV report (2008) [1] COWI, IOM and Entec, 2009 - Report on production, uses, releases and alternatives of DEHP [2]			
Consultation	MS responses: 0	Industry responses: 0	Testing body/research institute: 1	
Summary information on uses				
Identified uses	In Europe, 97% of the DEHP consumption is used as a plasticiser in polymers, mainly flexible PVC. The remaining 3% is used in non-polymer applications such as adhesives and sealants, paints and lacquers, printing inks and capacitors. It is also used in advanced ceramic materials for electronic and structural applications [1]. Following the inclusion of DEHP in Annex XIV Authorization list of REACH, use of this substance is expected to further decline. DEHP is will be phased out in 2015 unless users of the substance apply and are granted an authorisation. The use of this substance in a concentration over 0.1% in toys and childcare products is banned under Annex XVII of REACH. Its use is also banned in cosmetics (EU Regulation 1223/2009.).			
Use in consumer articles	**YES**	The substance is used in the production of a wide range of plastic and rubber articles available to consumers [1] [3] [5]. Its presence is frequently reported in plastic toys [4]. A Danish database of chemicals in consumer products offered 98 records including clothing, sandals, toys, bath mats, shower curtains, rubber clogs, bags, swimming equipment, packaging material, wallpaper, flooring, furniture, etc. [6]. A testing body declared that this substance may be present in a wide range of PVC articles including plastics prints on garments, toilet bags, weather proof clothing, tents and tarpaulins.		
Consumers' exposure to the substance				
Can risk of exposure to consumers be excluded?	**NO**	Given the widespread use and availability of the substance, it is clear that consumers are exposed. The exposure of adults was estimated via analysis of DEHP-metabolites in urine. Although uncertain, a 95-percentile exposure level of 17µg/kg/day was agreed for the general population. This value may be higher for children [1].		
Market-based information				
Route into the EU	Manufactured in the EU [1] [2]. According to consultation for Task 1, this substance is found in imported articles (confirmed in Task 2).			
Manufacture sites and supply chain	Inconclusive			
Quantities used per annum of the substance (tonnes)	The total manufactured volume in 2007 within the EU was 341,000 tonnes, of which 187,000 tonnes was manufactured in Western Europe. 54,522 tonnes were exported and 4,479 tonnes imported [2].			

Concentration of the substance in articles	The content of DEHP in flexible polymer materials varies (e.g. 12 to 300,000 mg/kg [5]), but is often around 30% [1]. A typical concentration of 30% was also indicated during the consultation. In toys, it has been recently reported in concentrations ranging 0.5% and 41.2% by weight (first 12 weeks of 2013) [4]. Concentration records in a Danish database in consumer products ranged from traces up to 46% in weight in a pair of sandals [6].
Quantity of articles imported/produced in the EU	Unclear. It is estimated that 285,000 tonnes of this substance are used in EU end-products [2].
Alternatives available	There are several alternatives depending on the product. The alternatives are in general more expensive than DEHP with DINP being the least expensive feasible alternative at an incremental cost of about 10%. Non-phthalate alternatives are being applied for PVC products of particular concern like toys, medical equipment, packaging for food, etc. Alternative materials to PVC are another option. More details can be found on the Annex XV [1] and COWI, IOM and Entec report on DEHP (2009)[2].

References: [1] Annex XV report, July 2008, http://echa.europa.eu/documents/10162/e0a2db43-7a7f-4f18-92f9-2eaa3e4aff92
[2] COWI, IOM and Entec, 2009, Data on manufacture, import, export, uses and releases of Bis(2-ethylhexyl) phthalate (DEHP) as well as information on potential alternatives to its use. http://echa.europa.eu/documents/10162/13640/tech_rep_dehp_en.pdf
[3] ECHA Data on Candidate List Substances in Articles http://echa.europa.eu/documents/10162/24e96360-d320-4b26-b7a4-0172ef9f4913
[4] Rapex database, http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm.
[5] Swedish Chemical Agency (2013): Hazardous chemicals in textiles – report of a government assignment. Stockholm, April 2013
[6] Danish EPA - Database of chemical substances in consumer products. http://www.mst.dk/Virksomhed_og_myndighed/Kemikalier/Fokus+paa+saerlige+produkter/Database_forbrugerprodukter/Vidensbank.htm

A4.12 Summary information on Dibutyl phthalate (DBP)

3A-04	**Substance**	Dibutyl phthalate		
	CAS Number	84-74-2	**EC Number**	201-557-4
	Common name	DBP		
Information available				
Amount of information available	**MORE THAN AVERAGE**	Available Info: uses, tonnage, exposure and alternatives Limited Info: concentration in articles, quantity of articles		
Key literature sources	ECHA Annex XV report (2008)[1] COWI, IOM and Entec, 2009 - Report on production, uses, releases and alternatives of DBP [2]			
Consultation	MS responses: 0	Industry responses: 0	Testing body/research institute: 1	
Summary information on uses				
Identified uses	DBP is a specialist, fast fusing plasticiser. It is primarily used in PVC as a gelling aid in combination with other plasticisers [2]. It also has minor applications in the manufacture of printing inks, adhesives, sealants, nitrocellulose paints, film coatings, propellants for ammunition and glass fibres [1]. DBP is included on the REACH Annex XIV Authorisation List and will be phased out in 2015 unless users of the substance apply and are granted an authorisation. The use of this substance in a concentration over 0.1% in toys and childcare products is banned under Annex XVII of REACH. Its use is also banned in cosmetics (EU Regulation 1223/2009.).			
Use in consumer articles	**YES**	The presence of DBP has been notified to ECHA in a wide variety of plastic consumer articles, from rainwear to microwave dishes [3]. Its presence in plastic toys has often been reported in RAPEX [4]. A Danish database of chemicals in consumer products offered 62 records including sandals, toys, shower curtains, hair dryers, rubber clogs, bags, vinyl wallpaper, flooring and furniture [5].A testing body declared that this substance may be present in a wide range of PVC articles including plastics prints on garments, toilet bags, weather proof clothing, tents and tarpaulins.		
Consumers' exposure to the substance				
Can risk of exposure to consumers be excluded?	**NO**	Consumers are exposed to this substance. Several studies have detected the presence of DBP in humans. Although diminishing, intakes of DBP over the recommended TDI have been reported. Oral is the main exposure route. Inhalation and environmental exposure are also relevant [1].		
Market-based information				
Route into the EU	Manufactured and imported into the EU [2]. According to consultation for Task 1, DBP is found in imported articles.			
Manufacture sites and supply chain	In 2005 DBP was manufactured by 3 companies: Proviron (Belgium), Zak (Zakłady Azotowe Kedzierzyn SA, Poland) and DEZA a.s. (Czech Republic). By 2007 only two of these were still manufacturing DBP. After production, this substance was further used for formulation and processing by major users at 50-100 sites in the EU; in addition, an unknown number of minor users existed. The supply chains of DBP involve several levels and many different types of industries and activities with a large number of actors throughout EU [2]. Following the inclusion of DBP on the REACH Authorization list, the use of this substance and the number of actors involved in the supply chain is expected to be much lower,			

Quantities used per annum of the substance (tonnes)	Less than 10,000 tonnes of DBP were produced in the EU in 2007. Nearly 2,000 tonnes were exported. The market for DBP has reduced considerably during the last 20 years [2].
Concentration of the substance in articles	Information about the concentration of DBP in articles is limited. Concentrations in toys are available; During the first 12 weeks of 2013 Rapex reported 10 toys containing DBP in concentrations ranging 0.2% - 24.6% by weight. Most of reported toys had concentrations below 5%. Concentration records in a Danish database in consumer products ranged from traces up to 345,000 mg/kg in weight (in a pair of adult sandals) [5]. The consultation revealed a concentration of up to 10% by weight, usually used in combination with DEHP.
Quantity of articles imported/produced in the EU	It was estimated that 8,250 tonnes of DBP are used annually in end-product uses [2]. The quantity of DBP present in articles is expected to be lower. No information was found about the quantity of articles imported or produced.
Alternatives available	There is no universal alternative for DBP. Other phthalates are closest in terms of functionality. Depending on the use, DBP may be replaced by other substances including DIBP, DINP, DINCH, GTA, DGD. Some of these substitutes may also be of concern regarding human health. Another alternative consists of the use of different plasticizing techniques avoiding the need for DBP in the production of PVC. Finally, another approach is the substitution of PVC for other materials avoiding the use of phthalates as plasticisers [1] [2].

References: [1] ECHA Annex XV report (2008), http://echa.europa.eu/documents/10162/d9d7265f-b7c9-4dcf-8554-f92ae6170d66.
[2] COWI, IOM and Entec, 2009, Data on manufacture, import, export, uses and releases of Dibutyl phthalate (DBP) as well as information on potential alternatives to its use. http://echa.europa.eu/documents/10162/13640/tech_rep_dbp_en.pdf.
[3] ECHA data on Candidate List Substances In Articles, http://echa.europa.eu/documents/10162/ee4b5cc6-facb-4686-9d17-c69350c2e138, accessed 25/03/2013.
[4] Rapex database, http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm, accessed 25/02/2013.
[5] Danish EPA - Database of chemical substances in consumer products. http://www.mst.dk/Virksomhed_og_myndighed/Kemikalier/Fokus+paa+saerlige+produkter/Database_forbrugerprodukter/Vidensbank.htm

A4.13 Summary information on Tris(2-chloroethyl) phosphate

3A-05	**Substance**	Tris(2-chloroethyl) phosphate		
	CAS Number	115-96-8	**EC Number**	204-118-5
	Common name	TCEP		
Information available				
Amount of information available	**MORE THAN AVERAGE**	Available Info: uses, presence in articles, exposure and alternatives Limited Info: concentration in articles, quantity of articles, exact tonnage		
Key literature sources	Annex XV report (2009) [1] ;EU RAR (2009) [2]			
Consultation	MS responses: 0	Industry responses: 1	Testing body/research institute: 1	
Summary information on uses				
Identified uses	TCEP is mainly used in the manufacture of unsaturated polyester resins (~ 80 %), particularly in polyurethane foam. Also in acrylic resins, adhesives and coatings [1]. However, ECHA Registration data only indicates its use in coatings, particularly in the offshore and construction industry [6]. Similarly, ECHA's Substance in Article information (SiA) only includes records of the use of TCEP in coatings [3]. Thanks to its flame retardant properties, the main industrial fields where the substance is used are in the furniture, textile and construction industry. Although it is assumed that no TCEP is formulated into consumer paints, it can be found in some industrial paints (10 t/a) [2]. TCEP is included on REACH Annex XIV Authorisation List and will be phased out in 2015 unless users of the substance apply and are granted an authorisation. Its use is also banned in cosmetics (EU Regulation 1223/2009. Consultation suggests that the substance is used and supplied in China (at least 56 suppliers).			
Use in consumer articles	**YES**	TCEP may be present in articles treated with flame retardants such as timber, foam rubber, carpets and plastic materials [2]. Use of TCEP as a coating for the categories of "metal articles" and "stone, plaster, cement, glass and ceramic articles" have been notified to ECHA, although this use is limited (in the EU) to the offshore and construction industry, which may imply limited exposure to average consumers [3]. A Danish database of chemicals in consumer products offered 9 records of TCEP in articles although 7 of them were below the detection limit [4]. A testing body declared that TCEP may be present in technical textiles, personal protective clothing and flame laminated foam articles.		
Consumers' exposure to the substance				
Can risk of exposure to consumers be excluded?	**UNLIKELY**	In the SPIN Database, only Denmark reports a potential exposure to customers and none of the Scandinavian countries report this substance to be used in consumer preparations [5]. However, TCEP has been found in house dust in schools and houses of Germany and Austria in 2008. Exposure to dust containing TCEP (through inhalation, ingestion or direct dermal contact) is deemed to be the main exposure risk. Environmental exposure may also be relevant [1].		
Market-based information				
Route into the EU	Currently manufactured in the EU. According to consultation, TCEP is found in imported articles.			
Manufacture sites and supply chain	As of 2002, it was imported by three companies into the EU-15, mainly from Russia and Poland [2].			

Quantities used per annum of the substance (tonnes)	The EU RAR report estimated the import of this substance as 1150 tonnes into the EU-15 in 2002. After exports of around 150t the total EU-15 tonnage was estimated as around 1000 t/a. This means a significant drop from 1991/1992 when 10,500 tonnes were being used annually in the European market [2]. The Annex XV report calculates from pre-registration data a minimum amount of 7,500 t/a which, although highly uncertain, is far over the EU RAR estimates [1]. In any case, both reports agree that the use of this substance has decreased substantially. This trend is supported by the SPIN database information which reported a total use of 219.2 tonnes for the four Scandinavian countries in 2010 against 1609.3 tonnes in 2001 [5]. Currently registered under REACH in the tonnage band of 10 - 100 tonnes per annum [6].
Concentration of the substance in articles	TCEP was found in an article (a cube) in a concentration of 4900-6500 mg/kg [4]. One testing body indicated concentrations between 2% and 10% (by weight).
Quantity of articles imported/produced in the EU	No information was identified in the sources analysed.
Alternatives available	TCPP (Tris(2-chlorpropyl)phosphate) is the main substitute for TCEP as a flame retardant. At the time that the Annex XV report was produced (2009) it was being produced at four sites within the EU in volumes above 30,000 tonnes/year. Industry has already substituted TCEP for TCPP in many applications [1].

References: [1] Annex XV report, August 2009, http://echa.europa.eu/documents/10162/47b10d27-024d-47c1-9ad3-c3a6004daaa5, accessed 25/03/2013.
[2] European Union Risk Assessment Report, July 2009, http://echa.europa.eu/documents/10162/2663989d-1795-44a1-8f50-153a81133258, accessed 25/03/2013.
[3] ECHA data on Candidate List Substances In Articles, http://echa.europa.eu/documents/10162/a71c7c9b-7c52-44f6-bda6-9524d32d36cc, accessed 25/03/2013.
[4] Danish EPA - Database of chemical substances in consumer products. http://www.mst.dk/Virksomhed_og_myndighed/Kemikalier/Fokus+paa+saerlige+produkter/Database_forbrugerprodukter/Vidensbank.htm
[5] SPIN database, http://90.184.2.100/DotNetNuke/default.aspx, accessed 25/02/2013.
[6] ECHA Registration data, http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d851c42-6bc0-6ee4-e044-00144f67d249/DISS-9d851c42-6bc0-6ee4-e044-00144f67d249_DISS-9d851c42-6bc0-6ee4-e044-00144f67d249.html

Annex 5 Application of the decision tree - Worked Example: Polycyclic Aromatic Hydrocarbons (PAH)

Whilst not one of the substances considered in this study, the Commission has proposed adopting a Regulation which will restrict the presence of eight polycyclic aromatic hydrocarbons (so-called "PAHs") in consumer articles[143]. In support of this initiative, the German authorities prepared a restriction dossier based on the requirements of Annex XV of REACH, with a recommendation that the simplified Article 68(2) restrictions procedure should be considered in this case.

The proposed restrictions on PAHs therefore provide a unique opportunity to test the decision criteria developed in Section 5 of this study. Each decision tree and criterion is discussed in turn below.

Deciding whether a substance is appropriate for an Article 68(2) restrictions procedure

Criterion 1: Is the substances confirmed in the production of consumer articles OR is the substance found in consumer articles

PAHs can be found in the plastic and rubber parts of a wide range of consumer articles including toys, clothing, footwear, gloves and sportswear, sports equipment, household utensils and tools as outlined in the submitted restrictions dossier.

YES

Criterion 2: Is there evidence of on-going human health concern to EU citizens from the substance in consumer articles

REACH Annex XVII already restricts the presence of PAHs in other products, i.e. extender oils used for the manufacture of tyres. There is therefore an established link between use and human health concern. However within articles there is some uncertainty whether where PAH use in article presents an on-going human health concern, given that the containing article must be in contact with human or oral cavity for consumer exposure to occur.

NO

Criterion 3: Can consumer exposure be ruled out on technical grounds

While a specific concentration limit for PAHs in toys under the CLP regulation exists, there is no evidence to suggest that threshold effects are present or consumer exposure can be ruled out given their ubiquitous use in the surface of articles in contact with humans. Use within articles not exposed to humans in normal use should however be considered for omitting from scope of restrictions, as expose might be ruled out.

NO

Criterion 4: Does the use in consumer articles only relate to derivatives. If so, do derived substances degrade to form the substance or contain significant traces in articles

PAHs are present as impurities in some of the raw materials used in the production of consumer articles, in particular in extender oils and in carbon black. They are not added intentionally to the articles and do not perform any specific function as constituents of the plastic or rubber parts.

[143] http://register.consilium.europa.eu/pdf/en/13/st12/st12338.en13.pdf

YES

Criterion 5: Do derived substances degrade to form the substance or contain significant measured quantities in articles

Sufficient concentrations of PAHs have been found in consumer articles, specifically in those articles used by children who are seen as particularly vulnerable to carcinogenic agents.

YES

Criterion 6: Is there good knowledge of which substance derivatives, substance uses and containing articles are relevant for consumer exposure

Information submitted by German authorities to the Commission indicates that articles containing PAHs may pose a risk to consumers' health by ingestion, dermal adsorption and, in some cases, by inhalation, therefore migration routes are clearly known. It is also indicated that a restriction would limit the risk of consumer exposure and would therefore be effective. Presence in consumer articles is well documented.

YES

Criterion 7: Are supply chains characteristically complex, indicating possible unforeseen effects

Supply chains are judged to be complex, but are well understood it terms of where in the production process PAHs become present in articles and traceability to end user applications. Concerns as they relate to imported articles are also well known.

NO

Recommendation: An Article 68(2) restriction procedure should be considered

Socio-economic factors that could help in defining the scope of Article 68(2)

Criterion 1: Is the substance readily detectable in consumer articles, and thus measured /monitored

PAHs in articles are detectable and measurable to the extent that a restriction could be implemented and enforced.

YES

Criterion 2: Are the relevant markets characterised by fast moving and disruptive innovation

The presence of PAHs in most consumer articles can be characterised by continued innovation, but not of the rapid and disruptive type, such that a restriction would be a significant brake of product development (i.e. toys change in colour, packaging and design but innovation is rarely “game changing”, same applies to household utensils, gloves, etc.).

NO

Criterion 3: Are the relevant markets characterised by a high number of SMEs OR limited financial capacity

Many producers of consumer articles containing PAHs, such as footwear, glove and clothing are SMEs, a possibility therefore exists for cost disproportionality particularly when wholesale changes to all product lines are required. Consideration of derogations where consumer exposure is more limited or in specific articles should be considered.

YES

Criterion 4: Is the substance a critical material or found in critical uses

As PAHs are not added intentionally to the articles and do not perform any specific function as constituents of the plastic or rubber parts, critical materials and critical uses are not relevant.

NO

Recommendation: Scope of restrictions should be limited to the presence of PAHs in consumer articles where consumer exposure is a concern, to avoid disproportionate cost implications for SMEs.

Evaluation of Net Benefit Potential

An example of the evaluation framework applied to PAHs s provided in the Figure below, the use of which is best served by comparing the sum of ticks and crosses with other substances considered for an Article 68(2) simplified procedure.

Table A5.1 Ex ante evaluation of the scope of net benefits from a restriction - PAHs

Core programme intervention logic	Outputs	Outcomes	Sector Impact	Wider impact	Assessment of net impacts	Assessment for PAHs
NET BENEFIT POTENTIAL	↓	↓	↓	↓	NET BENEFIT IF:	
Substance use	Current EU industry use: ■ Completed or undergoing phase out				Indicator: ■ Positive	✓
Market and industry structure	Size and value of sector ■ Size of market is large (by volume/value) ■ Scope of market is global ■ Supply chain is complex (cross-border, multiple uses and end user applications, intermediates) ■ High capital intensity (investment as share of sales) ■ High productivity (GVA per worker) ■ Higher than average profitability of sector(s) ■ High number of SMEs in sector ■ Market has technical barriers to trade (testing requirements, standards, etc.)				Indicator: ■ Negative ■ Negative ■ Negative ■ Negative ■ Negative ■ Positive ■ Negative ■ Positive	✓ × × ✓ N/A N/A × ✓
Nature of article technology and innovation	Article characteristics: ■ High number of end-user applications ■ Substance is chemically bound in article ■ Substance can be separated from article Typology of innovation ■ Disruptive technology a feature of market/sector ■ Innovation in the sector is fast moving ■ Innovation typically occurs upstream ■ Substance is known to be critical for use(s)				Indicator: ■ Negative ■ Negative ■ Positive Indicator ■ Ambiguous ■ Negative ■ Positive ■ Negative	× ✓ × ✓ ✓ × ✓

Substance and article trade	Trade (*Eurostat data*) ■ Competitors located mainly within EU ■ Imports account for a large proportion of EU consumption ■ Substance/article traded worldwide	Indicator ■ Positive ■ Negative ■ Negative	 × × ×
Alternative substances	Alternative substance characteristics (*ECHA dossier*) ■ Technical performance comparable or better ■ Substitutable in production process ■ Affordable in most uses ■ Produced in sufficient quantities ■ Lower hazard (relative to current substance) ■ Reduced hazard potential/migration routes	Indicator: ■ Positive ■ Positive ■ Positive ■ Positive ■ Positive ■ Positive	 ✓ ✓ ✓ ✓ ✓ ✓
Consumer factors	Consumer impacts ■ Consumers highly response to article prices ■ Consumer have high willing to pay to remove substance from use	Indicator: ■ Positive ■ Positive	 ✓ N/A