Guidance on requirements for substances in articles

…. 2009 (DRAFT Version 2.0)

Guidance for the implementation of REACH

LEGAL NOTICE

This document contains guidance on REACH explaining the REACH obligations and how to fulfill them. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

PREFACE

This guidance document is part of a series of guidance documents that are aimed at helping all stakeholders prepare for fulfilling their obligations under the REACH Regulation. These documents cover detailed guidance on a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The first version of this guidance document was drafted and discussed within a REACH Implementation Project (RIP) led by the European Commission services, involving all stakeholders: Member States, industry and non-governmental organisations. The European Chemicals Agency (ECHA) updates this and other guidance documents following the Consultation procedure on guidance. These guidance documents can be obtained via the website of ECHA. Further guidance documents will be published on this website when they are finalised or updated.

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the European Council of 18 December 2006[1].

[1] Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006); amended by: Council Regulation (EC) No 1354/2007 of 15 November 2007 adapting Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), by reason of the accession of Bulgaria and Romania, Commission Regulation (EC) No 987/2008 of 8 October 2008 as regards Annexes IV and V; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures; Commission Regulation (EC) No 134/2009 of 16 February 2009 as regards Annex XI and Commission Regulation (EC) No 552/2009 of 22 June 2009 as regards Annex XVII.

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ABBREVIATIONS

CAS	Chemical Abstract Service
CMR	Carcinogenic, mutagenic and toxic for reproduction
EEA	European Economic Area
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ELV	End of Life Vehicle
GC-MS	Gas Chromatography – Mass Spectrometry
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RoHS	Restriction of Hazardous Substances Directive
SDS	Safety Data Sheet
SIEF	Substance Information Exchange Forum
SVHC	Substance of Very High Concern
vPvB	very Persistent and very Bioaccumulative
WEEE	Waste Electrical and Electronic Equipment
w/w	Weight by weight

1 GENERAL INTRODUCTION

This guidance interacts with several other REACH guidance documents. As a general principle, the current document will not repeat what is in other guidance documents, unless found absolutely necessary for the purpose of this guidance. Consequently, there are several references to other guidance documents and tools, which can be found on the website of ECHA.

1.1 What is this guidance about and who is it for?

This guidance document explains and illustrates the provisions of Regulation (EC) No 1907/2006 (REACH Regulation) that apply to substances in articles. It is aimed at:

- Persons responsible for REACH compliance at companies producing, importing and/or supplying articles in the European Economic Area (EEA), in particular purchasing, production and sales managers.
- Only Representatives[2] of non-EEA companies producing and exporting articles to the EEA.
- Experts from industry associations and other stakeholder organisations informing companies about the requirements for substances in articles under REACH.

The guidance particularly assists companies in deciding if they have to fulfil registration, notification and/or communication requirements related to substances in articles (these obligations are compared in table 1). This might be the case for companies producing, importing and/or supplying articles.

In this context, a company is an **article producer**[3] if it produces articles within the EEA, regardless of how the articles are produced and where they are placed on the market. An **article importer**[4] is any company located inside the EEA that imports articles from countries that are located outside the EEA. Article producers and importers, but also other actors in the supply chain such as retailers, are also **article suppliers**[5], if they place articles on the market in the EEA. Thus, the role of article supplier is irrespective of whether the supplier produces the articles himself or whether he purchases them (inside or outside of the EEA).

Please note that companies may have also other roles than those mentioned above and thus have further obligations than those described in the present guidance. If an article producer, for example, purchases substances inside the EEA for use in the production process of his articles, he also has to fulfil downstream user requirements. If the substances are instead purchased outside of the EEA, the article producer has the role of importer of substances along with the related obliga-

[2] Non-EEA producers of articles may appoint 'Only Representatives' to fulfil all REACH obligations of the importers of their articles in the EEA. The role and obligations of an Only Representative are explained in detail in section 1.5.3.4 of the Guidance on registration.

[3] producer of an article: means any natural or legal person who makes or assembles an article within the Community (Article 3(4)).

[4] importer: means any natural or legal person established within the Community who is responsible for import (Article 3(11)); import: means the physical introduction into the customs territory of the Community (Article 3(10)).

[5] supplier of an article: means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market (Article 3(33)).

tions, such as registration. Therefore, in general, companies are advised to identify their obligations by running the Navigator on the ECHA website. The Navigator helps industry to determine its obligations under REACH and find the appropriate guidance on how to fulfil these obligations.

Table 1 Obligations described in the present guidance

Obligation:	**Registration of substances in articles**	**Notification of substances in articles**	**Communication of information on substances in articles**
legal basis in REACH Regulation	Article 7(1)	Article 7(2)	Article 33
actors concerned	article producers and article importers	article producers and article importers	article suppliers
substances concerned	substances intended to be released from articles	substances included in candidate list of substances for authorisation	substances included in candidate list of substances for authorisation
tonnage threshold	1 tonne per year	1 tonne per year	-
concentration in article threshold	-	0.1% (w/w)	0.1% (w/w)
exemption from obligation possible on the basis of:			
substance already registered for that use	yes	yes	no
exposure can be excluded	no	yes	no

1.2 Structure of the guidance

The present document is structured along the following questions, whereas each chapter provides guidance for answering one of the questions.

1. Do I need this guidance? (see chapter 1)
2. Do I have an article? (see chapter 2)
3. Is there an intended release of substances from my article, and what are the consequences of this (i.e. my obligations)? (see chapter 3)
4. Does the composition of my article lead to particular obligations? (see chapter 4)
5. How can I obtain further information on the substances in my article? (see chapter 5)
6. Can I benefit from any exemption from an obligation concerning substances in articles? (see chapter 6)

The flowchart below gives an overview of the major steps involved in identifying one's obligations for substances in articles and directs the reader of the guidance to the corresponding chapters.

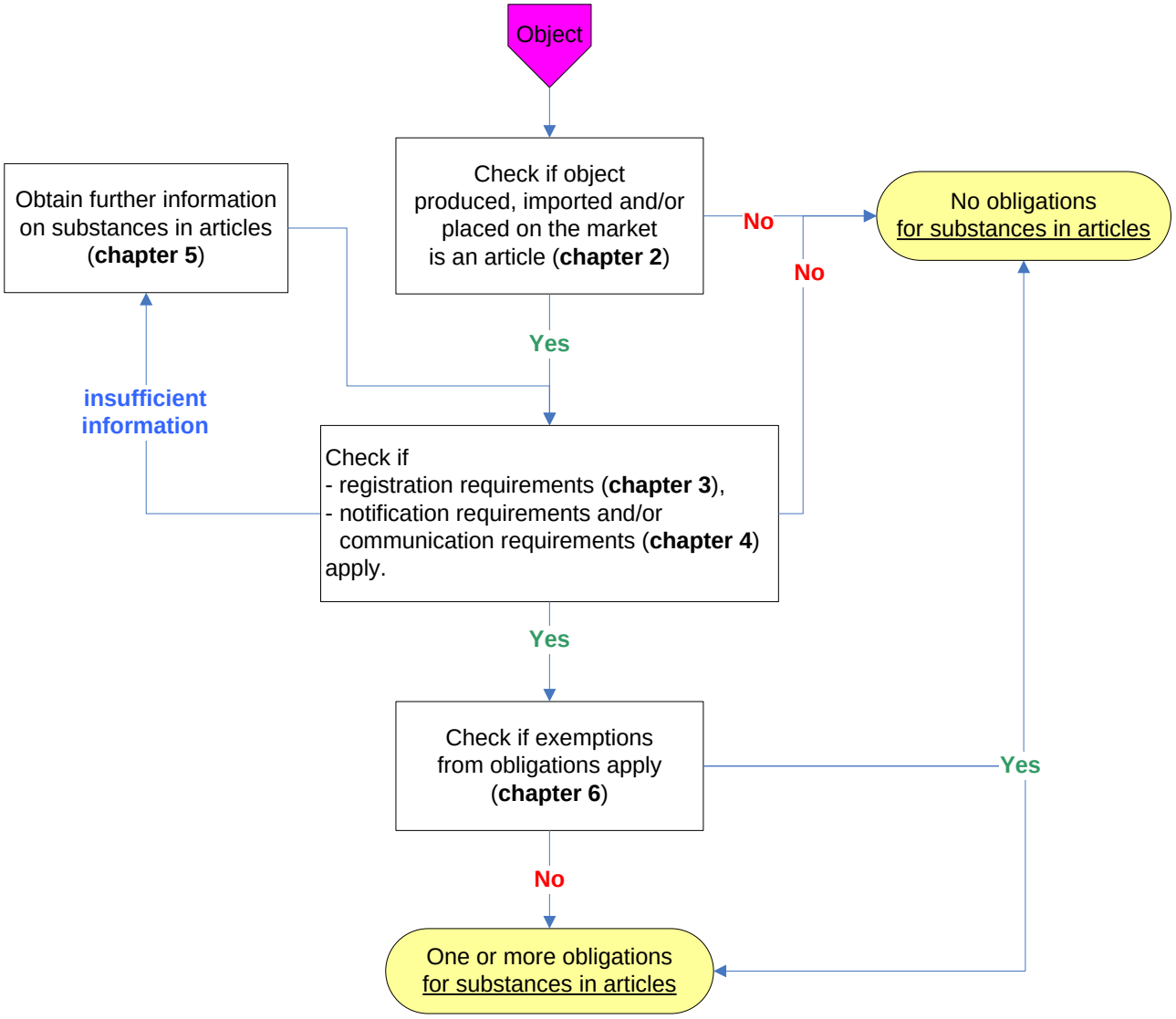

Figure 1 General process of identifying obligations for substances in articles

1.3 Topics covered by other guidance documents

Authorisation and restriction requirements do not affect companies using substances for the production of articles in particular, but downstream users in general. Therefore, detailed guidance on these procedures is given in other guidance documents as outlined below.

Substances being (an integral) part of imported articles cannot be subject to **authorisation**. However, if an EEA-based producer of articles incorporates a substance as such or in a mixture[6] into these articles, that use of the substance may have to be authorised (if the substance is listed in REACH Annex XIV). If such a substance is acquired from the EEA market, the supplier has to give this information in Section 16 of the safety data sheet or via information according to Article 32. If the article producer imports such substances himself, he has to apply for authorisation in order to continue his use(s) of the substances. According to article 3(24) of the REACH Regulation, the production of an article is considered as a use. Details on the authorisation procedure and notifying the use of authorised substances can be found in chapter 12 of the Guidance for downstream users and in the Guidance on authorisation application.

Furthermore, the content of substances in articles can be restricted or banned under the **restrictions** procedure. Therefore, article producers and importers have to follow the conditions outlined in Annex XVII of the REACH Regulation. Details on compliance with restrictions under REACH are given in chapter 13 of the Guidance for downstream users. Please note that other legislation concerning restrictions limiting the use of hazardous substances in articles still apply separately from REACH. Examples are the General Products Safety Directive 2001/95/EEC and product specific legislation such as Directive 2002/95/EC on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS), Directive 88/378/EEC on toys or Directive 2000/53/EC on End of Life Vehicles (ELVs). A list of relevant legislation is provided in Appendix 6 of this guidance.

[6] Following the recent entry into force of the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, the term "preparation" within the meaning of Article 3(2) of REACH was replaced by the term "mixture". Thus, the word "mixture" in this guidance document has the same meaning as the word "preparation" in other (older) guidance documents.

2 DECIDING WHAT IS AN ARTICLE UNDER REACH

When determining if and which requirements apply, the first step is to check whether the objects produced, imported and/or placed on the market are considered to be articles under REACH or not.

An article is generally understood to be an object composed of one or more substances or mixtures given a specific shape, surface or design. It may be produced from natural materials, such as wood or wool, or from synthetic ones, such as polyvinyl chloride (PVC). It may be very simple, like a wooden chair but can also be very complex, like a computer, consisting of many parts. Most of the commonly used objects in private households and industries are articles, e.g. furniture, clothes, vehicles, books, toys, kitchen equipment and electronic equipment.

Article 3(3) of the REACH Regulation defines an article as *"an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition"*. In order to determine whether or not an object fulfils the definition of an article under REACH, the object's function and its characteristics need to be assessed.

Please note that the definition of the status of objects under REACH does not affect legislation which is not based on the REACH definition of articles.

2.1 The function of an object

The term "function" in the article definition should be interpreted as meaning the **basic principle determining the use of the object** rather than the degree of technical sophistication determining the quality of the result. In this sense, it may be helpful to look at the result of using an object and pay less attention to the quality of the result. For example, the basic principle behind a printer cartridge is to bring ink onto paper. A higher degree of technical sophistication of the object "printer cartridge" may improve the functioning and the quality of the result but it does not change the function as such.

2.2 The shape, surface and design of an object

The shape, surface and design of an object represent its physical appearance and can be understood as other than chemical characteristics. **Shape** means the three-dimensional form of an object, like depth, width and height. **Surface** means the outermost layer of an object. **Design** means the arrangement of the "elements of design" in such a way as to best accomplish a particular purpose. For example, the design of a textile may be determined by the twist of fibres in the yarn, the weave of threads in a fabric and the treatment of the surface of the textile.

2.3 Deciding if an object is an article or not

The workflow below provides guidance on deciding if an object is an article or not.

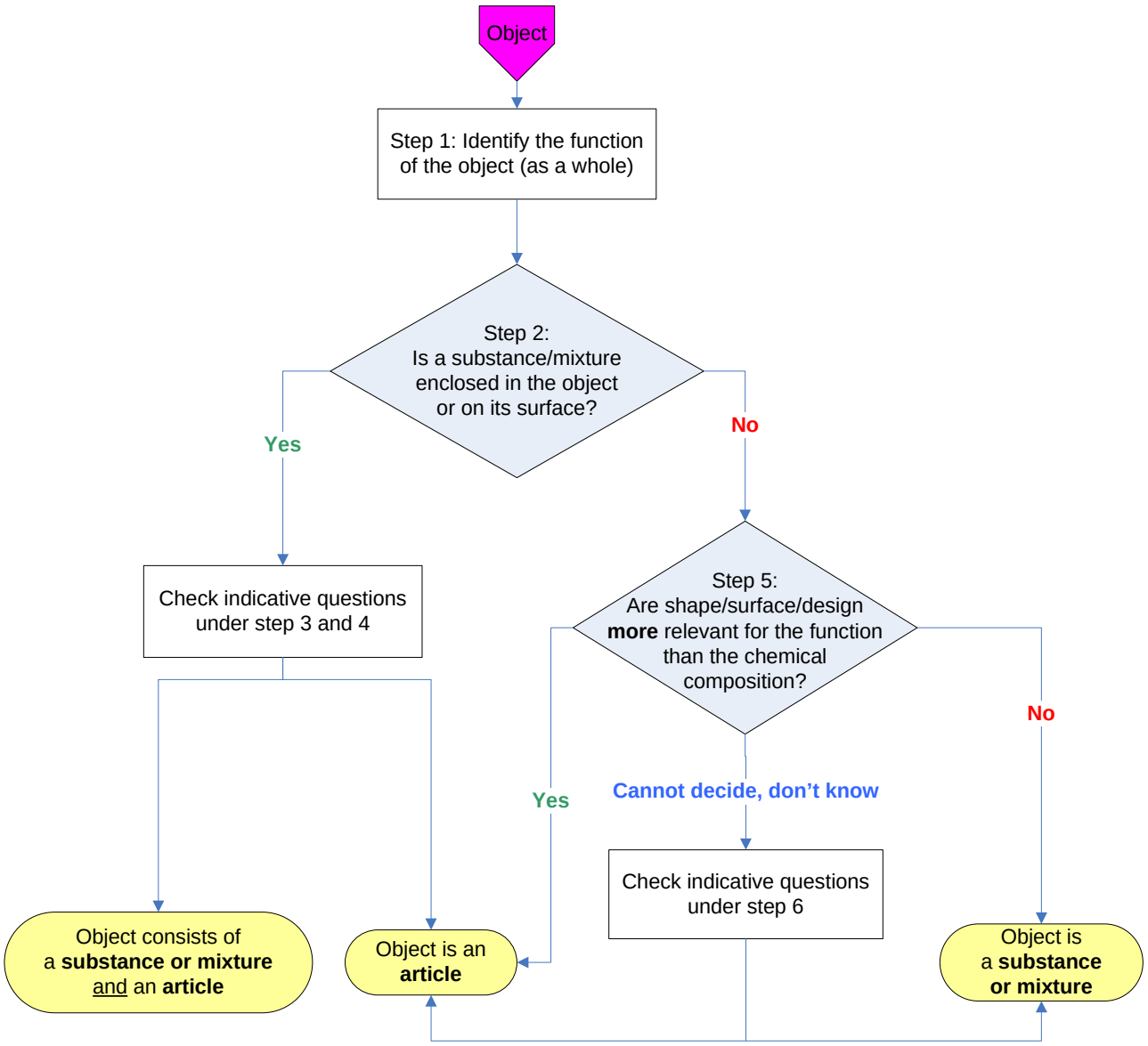

Figure 2 Flowchart illustrating decision-making on whether an object is an article or not

Step 1: Define the function of the object in line with section 2.1.

Step 2: Determine if the object, which may be constructed in a very simple or highly sophisticated manner, meets any of the following two criteria:

- a substance or mixture, which can be solid, liquid or gaseous, is enclosed in the object (like e.g. the liquid in a thermometer)
- the object carries a substance or mixture on its surface (like e.g. an adhesive tape)

If any of these criteria apply, proceed with step 3, otherwise proceed with step 5.

Step 3: For determining whether the chemical content of the object is an integral part thereof (and therefore the object as a whole is an article as defined under REACH) or if it is a substance/mixture for which the rest of the object functions as a container or carrier material, the following indicative questions should be answered:

Question 3a: If the substance/mixture were to be removed or separated from the object and used independently from it or changed from the object to a similar type of object, would the substance/mixture still be capable in principle (though perhaps without convenience or sophistication) of carrying out the function defined under step 1?

Question 3b: Does the object act mainly (i.e. according to the function defined under step 1) as a container or carrier for release or controlled delivery of the substance/mixture or its reaction products?

Question 3c: Is the substance/mixture predominantly consumed or eliminated during the use phase of the object, so that at the end of the useful life of the object the substance/mixture is not anymore in the object as it was in the beginning?

If you can answer these questions with *yes* rather than *no*, then the object should be regarded as an article (functioning as container or carrier material) with a substance/mixture contained within. Importing such an object would mean that the importer might not only have the obligations of importers of articles described in this guidance document, but also the obligations of importers of substances/mixtures (these are explained in detail in the Guidance on registration).

Example 1 Toner cartridge

Answering the above indicative questions: 3a) if the toner was moved from the cartridge, it would still be possible to bring it to paper, although with a loss of quality and convenience; 3b) the function of the cartridge is to hold the toner in place inside a printer and it controls the speed and mode of release; 3c) the cartridge is disposed of without the toner, which is consumed during the useful life of the cartridge. The answers to the questions allow the conclusion that a toner cartridge is an article (functioning as container) containing a substance/mixture.

Step 4: If the answers to the indicative questions above are predominantly no, you should use the following questions to cross-check whether the object as a whole should indeed be considered as an article and not as an article with a substance/mixture contained within.

Question 4a: If the substance/mixture were to be removed or separated from the object or exchanged for a similar type of substance/mixture, would the object be unable to fulfil its intended purpose?

Question 4b: Is the main purpose of the object other than to deliver the substance/mixture or its reaction products?

Question 4c: Is the object normally discarded with the substance/mixture at the end of its useful life, i.e. at disposal?

If you can answer these questions with *yes* rather than *no*, then the object is regarded as an article and the substance/mixture as an integral part thereof.

Example 2 Thermometer

Answering the above questions: 4a) the empty thermometer would fail to show the temperature; thus the object would no longer be useful; 4b) the main function of the thermometer is to show the temperature, this is not a delivery of a substance or mixture; 4c) the thermometer is normally disposed of together with its chemical content. So answering these questions leads to the conclusion that a thermometer (including the liquid it contains) is an article.

Appendix 1 provides further examples of borderline cases of substances/mixtures in containers or carrier materials.

Step 5: The object neither carries a substance/mixture on its surface, nor is a substance/mixture enclosed in it. Thus, the decision on whether the object is an article or not should be directly made by comparing the importance of physical and chemical characteristics for achieving the object's function. **If you can unambiguously conclude that the shape/surface/design of the object are <u>more</u> relevant for the function than its chemical composition, the object is an article.** If the shape, surface or design is of equal or less importance than the chemical composition, it is a substance or mixture. **If you are in doubt, proceed with step 6.**

Step 6: Making a decision might be difficult for certain objects, such as raw materials and semi-finished products that are further processed to final articles. In these cases, you may use the following indicative questions in order to better determine whether or not the object is an article. These questions can only be used to support the evaluation of the importance of the chemical composition versus the shape/surface/design in relation to the function and thus facilitate the application of the article definition.

Question 6a: Does the object have a function other than being further processed?
If the object predominantly has other functions (i.e. end-use functions), then this may be an indication that it is an article according to the definition of REACH.

Question 6b: Does the seller place the object on the market and/or is the customer mainly interested in acquiring the object because of its shape/surface/design (and less because of its chemical composition)?
If the object is mainly put on the market or acquired because of its shape/surface/design, this is an indication that the object is an article.

Question 6c: When further processed, does the object only undergo only "light processing", i.e. no forming processes?
Examples of forming processes and processes regarded as "light processing" are presented in table 2 below. "Light processing" may improve or modify an object's shape, surface or design for carrying out a function and is thus frequently applied to objects which are already articles. Thus, if only "light processing" is applied, this is an indication that the object is an article.

Question 6d: When further processed, does the chemical composition of the object remain similar?
A change of the chemical composition in the next processing steps may indicate the object being a mixture. However, some treatments of an object which is an article may result in a change in its overall chemical composition, but not in the status of the object being an article. Examples are printing onto the surface, painting, applying coatings, dyeing etc.

Not all questions may apply to all objects and the weight of evidence of the answers to the questions may vary from case to case. However, in concluding whether the object is an article or not, the an-

swer to various of the relevant indicative questions should be considered and not only the answer to one of them. **Predominantly answering with *yes* to the questions indicates that the object is an article.** Appendix 2 illustrates how to apply these indicative questions and gives examples from four different industry sectors.

Table 2 Examples of forming processes and processes regarded as "light processing"

Forming processes	Processes regarded as "light processing"
Casting	Coating
Drawing	Cutting
Extrusion	Drilling
Forging	Grinding
Rolling	Milling
Sintering	Soldering
	Turning
	Welding

When deciding whether objects can be regarded as articles or not, difficulties may come up particularly when dealing with sets of objects (e.g. a cookware set consisting of different casseroles and pans; see section 2.3.1) or with especially small and "simple"[7] objects (see section 2.3.2). Furthermore it needs to be taken into consideration whether the objects are contained inside of packaging (see section 2.3.3). Specific guidance on how to decide in these particular cases is provided in the following sections.

2.3.1 Sets of objects

According to Article 3(3) of the REACH Regulation an article is an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition. This implies that the shape, surface or design must be deliberately determined and given during a production step. In this sense, the "production step" of an article can also be understood to include the assembly of the components (which can themselves be articles) of a complex article (e.g. a car). A set of objects that are merely put (or "collected") together to be supplied does not have a particular production step during which a specific shape, surface or design is given to the set. Therefore **a set of objects** (e.g. a cookware set consisting of different casseroles and pans) **cannot be regarded as one article, but has to be regarded as many articles.**

2.3.2 Small and "simple" objects

Media for sandblasting, milling media, toner beads and other products can consist of relatively small and "simple"[3] objects. These small and "simple" objects have in common that they are not used individually (i.e. as one object) but in larger numbers to fulfil their function. A counterexample would be a microchip or a miniature screw which are used as single objects to fulfil their respective function.

[7] To be understood as the opposite of complex/composite like a computer or a car.

The REACH Regulation defines an article as an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition. Hence the definition stipulates that **to be considered as an article an object needs to have a particular function that it can fulfil as a single object**. Furthermore it can be concluded that the article definition is not based on a size limit or minimum degree of complexity below which an object could no longer be regarded as an article.

2.3.3 Packaging

Substances, mixtures and articles can be contained inside of packaging, such as a carton, a plastic wrapping or a tin can. **The packaging does not belong to the substance, mixture or article being packaged and is therefore to be considered as a separate article under REACH**. Producers, importers and suppliers of packaging or of packaged substances, mixtures or articles have to fulfil the same requirements for that packaging as for any other article. Packaging with different functions needs to be considered separately (e.g. if an article is directly wrapped in plastic and then packed in a cardboard box, the plastic and the cardboard box should be considered separate articles).

2.4 Documentation

There are no specific record keeping requirements concerning the identification of obligations for substances in articles. However, companies should consider documenting the results of their compliance checking, even when it has been identified that no obligations under REACH exist. This includes documenting the decision-making on whether certain products are articles, substances or mixtures as well as and the checking if specific requirements apply for these. Documenting this facilitates demonstrating REACH compliance towards customers and (inspecting/enforcing) authorities.

3 SUBSTANCES INTENDED TO BE RELEASED FROM ARTICLES

3.1 Intended release of substances from articles

Substances and mixtures may be released from articles under different circumstances. However, such a release of substances (whether the substance is released as such or as part of a mixture) is to be regarded as an intended release only in specific cases.

A release of substances from articles is intended if it fulfils an **accessory function** (to be differentiated from the main function according to section 2.1) which is deliberately planned and would not be achieved if the substance were not released. In the case of scented articles, for example, the fragrance substances need to be released in order for the article to be smelled. Consequently, substances that are released because of ageing of articles, because of wear and tear or as an unavoidable side-effect of the functioning of the article, are generally not intended releases, as the release as such does not provide a function in itself.

An intended release of a substance from an article has furthermore to occur under (normal or reasonably foreseeable) **conditions of use**. This means that the substance release has to occur during the service life of the article. Hence, a substance release during the production or disposal phase of the article's life cycle is not an intended release.

Furthermore, the conditions of use during which the intended release occurs have to be "normal or reasonably foreseeable". **Normal conditions of use** means the conditions associated with the main function of an article. They are frequently documented in the form of user manuals or instructions for use. Normal conditions of use for articles used by industrial or professional users may differ significantly from conditions that are "normal" for consumers. This may particularly be true for the frequency and duration of normal use as well as temperature, air exchange rates or conditions related to water contact. It is explicitly not a "normal condition of use" if the user of an article uses an article in a situation or manner that the supplier of the article has clearly recommended to avoid in writing, e.g. in the instructions or on the label of the article[8]. **Reasonably foreseeable conditions of use** mean conditions of use that can be anticipated as likely to occur because of the function and appearance of the article (even though they are not normal conditions of use). For example when a small child does not know the function of an article but uses it for any purpose he associates with it, such as biting or licking it. In conclusion, a release which does not occur under normal or reasonably foreseeable conditions of use is not considered to be an intended release.

Example 3 Intended release of substances from articles

In the case of a panty hose with lotion, the main function is to provide clothing. This main function is clearly unrelated to the lotion. The function of the lotion (skincare) is only an accessory function, which would not be achieved if the lotion were not released. As a consequence, the panty hose with lotion should be regarded as an article with an intended release.

[8] Examples of the exclusion of specific conditions of use are care labels in textiles "do not wash above 30°C" and warning statements such as "keep out of children's reach" or "do not expose to high temperatures".

The following cases exemplify when a release of substances from an article is not considered to be an intended release:

- A release occurs during processing of a semi-finished article, i.e. before marketing as a finished article.

  Example: a size is added to a fabric to improve its processability, whereas the size is released again during further wet processing of the textile.

- A release occurs during use or maintenance of the article, but the released substances do not contribute to any function of the article.

  Example: washing of clothes by the consumer where remnants of different chemicals (dye, softener, starch, etc.) from processing are removed over some washing cycles.

- A release of substances is an unavoidable side effect of the functioning of the article. Without the release the article would not work, but the release is not directly intended.

  Example: wear and tear of materials under conditions of high friction, e.g. break linings, tyres.

- A release of substances formed during chemical reactions of any kind.

  Example: ozone released from copy machines, or release of combustion products from articles catching fire.

- A release in an accident.

  Example: release of substances from a thermometer that drops and breaks.

- A release caused by a long-term, extremely intensive use of an article.

  Example: release from a tool, which a consumer uses in disregard of the recommendations on operating time provided in the instructions of use.

3.2 Checking requirements for substances intended to be released from articles

According to Article 7(1) of the REACH Regulation, a substance intended to be released from articles (this can be established by applying the criteria in section 3.1), that are produced and/or imported by one actor, has to be registered, if the total amount of the substance present in those articles (i.e. including the amounts that are not intended to be released) exceeds 1 tonne per year. Hence, **in order to identify a possible obligation to register a substance in articles it needs to be checked if the 1 tonne per year threshold is exceeded**. For this the identity and the tonnage of the actual substance does not always have to be known, as the 1 tonne per year threshold can initially be compared to:

1. the total tonnage of *all articles with intended release* produced and/or imported, and to
2. the total tonnage of *all substances and mixtures intended to be released* incorporated in these articles.

If any of these tonnage values is equal to or remains under 1 tonne per year, the *volume of individual substances intended to be released* incorporated in these articles will definitely also be below 1 tonne per year. Thus, registration of substances in these articles will clearly not be required. However, if the need to register cannot be excluded on the basis of these checks, the *individual substances intended to be released* will have to be identified, and (unless you can benefit from an ex-

emption from registration; see chapter 6) also their respective tonnage.

The tonnage of a *substance intended to be released* contained in articles can be calculated using the following equation:

$$Vol_{subs.} = Weight_{article} \cdot Number_{articles} \cdot Conc_{\max\, mixture\ in\ article} \cdot Conc_{\max\, subs.\ in\ mixture} = Vol_{articles} \cdot Conc_{\max\, subs.\ in\ article}$$

$Vol_{subs.}$: volume of a *substance intended to be released* contained in articles [t/a].

$Weight_{article}$: weight of one article [t/article].

$Number_{articles}$: number of articles produced and/or imported per year [articles/a].

$Conc_{max\ mixture\ in\ article}$: maximum weight percentage of the *mixture intended to be released* in the article; as a value between 0 and 1 (50% = 0.5, 25% = 0.25, 20% = 0.2, etc.).

$Conc_{max\ subs.\ in\ mixture}$: maximum weight percentage of the substance in the *mixture intended to be released*; as a value between 0 and 1 (50% = 0.5, 25% = 0.25, 20% = 0.2, etc.).

$Vol_{articles}$: volume of articles produced and/or imported per year [t/a].

$Conc_{max\ subs.\ in\ article}$: maximum weight percentage of the *substance intended to be released* in the aticle; as a value between 0 and 1 (50% = 0.5, 25% = 0.25, 20% = 0.2, etc.).

Example 4 Calculation of tonnage of a *substance intended to be released*

A T-shirt contains a fragrance substance intended to be released.

Assumption: The fragrance substance constitutes a maximum of 5% by weight of the T-shirt, which is produced in an amount of 100 t/a. The fragrance substance is not contained in other articles of the same producer.

$$Vol_{subs.} = Vol_{articles} \cdot Conc_{\max\, subs.\ in\ article} = 100\,t/a \cdot 0.05 = 5\,t/a$$

Conclusion: The threshold of 1 t/a is exceeded; the producer of the T-shirt must register the fragrance substance.

When calculating the tonnage of a *substance intended to be released* contained in articles, the following points should be taken into account:

- Not only the amounts intended to be released but the total amount in the articles needs to be considered. Thus, if the substance is also part of the article matrix, these amounts have to be considered as well.
- Only the amount of the substance that is actually in the final articles has to be considered, i.e. any amount that is incorporated in the articles and then lost during further production steps (e.g. through evaporation or wash out) does not have to be considered.
- If the same substance is intended to be released from different articles of one producer/importer, the volumes of this substance in all those articles have to be summed up[9].

Please note that according to Article 7(5), ECHA may decide that an article producer or importer must submit a registration for a substance contained in articles (unless already done under Article 7(1)), if the amount of the substance exceeds 1 tonne per year and there is a suspicion that the substance is released from the articles resulting in risk to human health or the environment. This may apply also if the release of the substance from articles is not an intended release.

[9] Example: Company X imports three articles A, B, and C with 60 tonnes of a substance present in each. In article A the substance is not intended to be released, in article B 40 out of 60 tonnes are released under normal conditions and in article C 10 out of 60 tonnes are released under normal conditions. Thus company X will need to register the total volume of the substance in articles B and C, i.e. 120 tonnes, which is in the 100 to 1000 t/a band.

3.3 Registration of substances in articles

For a substance in articles that has to be registered, the producer/importer of the articles shall submit a registration dossier to ECHA. The requirements for the registration dossier are in general the same as for manufacturers and importers of the substance. However, if a chemical safety report is required as part of the registration dossier (volume > 10 t/a) and the substance is classified as dangerous or PBT/vPvB, the article producer/importer must cover in his exposure assessment and risk characterisation only the articles' service life and the disposal of the articles. Apart from this, the same distinction between phase-in substances and non-phase-in substances, the same registration deadlines as well as the same data sharing requirements apply to substances in articles as to substances as such or in mixtures. Detailed guidance on registration and data sharing is provided in the Guidance on registration and the Guidance on data sharing.

4 CHECKING IF ARTICLE 33 AND ARTICLE 7(2) APPLY

#This chapter is not part of the present consultation, it will be revised and submitted for consultation at a later stage.#

The legal obligations of Article 33 and Article 7(2) are explained in Section **Error! Reference source not found.** and **Error! Reference source not found.** of this guidance.

4.1 Obtaining information about substances of very high concern on the candidate list

Communication with suppliers is the best way for any article supplier to find out whether or not substances of very high concern on the candidate list for authorisation are contained in the articles. Communication can be targeted, as the identity of substances is available from the candidate list. Furthermore, for many substances the article supplier can exclude their presence based on knowledge on the substance itself, as well as information on the article (see also Section **Error! Reference source not found.**). In communicating, the complexity of supply chains needs to be taken into account, as well as confidentiality related to concentrations of substances in preparations and articles. Principles of supply chain communication and what information can be obtained from which actors are explained in Chapter **Error! Reference source not found.**. Chemical analysis should only be applied as a last resort (see also Section **Error! Reference source not found.**).

In many cases substances of very high concern can be traced in the documentation of substances and preparations used to produce the article. Producers of articles receive information on SVHCs from their EU suppliers of substances/preparations as the identity, the classification and the concentration ranges of SVHCs in preparations have to be communicated either in safety data sheets or with information according to Article 32 (if contained in concentrations above the cut off limits in REACH article 14). In addition, safety data sheets of substances or preparations imported from non-EU Member States will often specify classified substances.

EU suppliers of articles containing SVHCs in concentrations exceeding 0.1% (w/w) must deliver information available to them, sufficiently to enable safe use of the articles, as a minimum the name of the substance according to Article 33(1) of REACH.

To identify communication obligations under Article 33 only the identity and concentration of an SVHC on the candidate list need to be known.

To notify substances in articles according to Article 7(2), the total amount in the produced/imported articles needs to be known in addition to the information required for Article 33 communication, although exemptions apply if:

- The SVHC has already been registered for that use(s)
- Exposure of humans or the environment during normal and reasonable conditions of use including disposal can be excluded[10]

4.2 Determining whether the article contains substances of very high concern

[10] See Section 2.4 in relation to documentation of such a conclusion.

Article 7.2 and 33 do not apply if the concentration of a substance of very high concern on the candidate list is either not present or does not exceed 0.1% (w/w) in his articles. In investigating this he could use the strategies outlined in Section **Error! Reference source not found.**, including the likelihood of the presence or absence of certain substances in the articles or parts of the articles, as well as considering other legislation restricting or banning the use of certain substances in articles (see also a list of relevant legislation in Appendix 7).

Article suppliers should consider how to document their compliance checking (see Section 2.4) and could include for example statements of their suppliers that substances of very high concern on the candidate list for authorisation are not used, calculations proving that the concentrations in articles remain equal to or under 0.1% (w/w), safety data sheets of input materials, supply contracts and documentation of their implementation and auditing etc.

If the content of SVHCs cannot be excluded, initially, it is only necessary to know whether or not the article contains an SVHC on the candidate list. The information may be obtained via safety data sheets, Article 32 information[11], supply chain requests etc. (see Chapter 5 and 5.1.2.1)

When no safety data sheet or other standardised information is available for the substances and/or preparations in the article or the presence of an SVHC cannot be excluded, the following actions should be taken:

Article producers

- Request the supplier of substances/preparations included in the article to provide the registration number, when available, the identity and concentration range of any SVHC on the candidate list and contained therein. For article components, ask the supplier to either confirm that no SVHCs on the candidate list are contained in concentrations > 0.1% (w/w) in the article or to specify the identity and concentration of the SVHC in the article.

Article importers and only representatives

- Request the supplier to confirm whether or not an article contains any SVHC on the candidate list in concentrations > 0.1% (w/w). If the supplier cannot confirm this, ask for the identity and the amount (or concentration) of these substances in the article. If he is not willing or able to provide these, ask him to forward your request to the next actor up his supply chain or to provide you with the contact details of his suppliers.

All article suppliers

- Collect information from studies and surveys, if available, on the specific article made by e.g. EU Member States (e.g., www.mst.dk 'Survey and migration of chemical agents in toothbrushes', Survey No. 42, 2004) and branch knowledge to confirm information from supply chain communication or to find information on the likelihood of an SVHC being contained in the article.

- Check if the article conforms to any specific requirements such as standards, labels or other legislation that ensures that the content of some SVHCs is below a certain threshold level, e.g. the TOXPROOF label/certificate of cars (Appendix 6).

If no or insufficient information to comply with Articles 33 and 7(2) is made available through supply chain communication and branch knowledge for a specific article as a last resort, a chemical analysis may be conducted. For this, knowledge about which parts and materials of the article may

[11] Note that SDS and Art. 32 information can only confirm the presence of a SVHC, not exclude it.

contain an SVHC is an advantage. For more information see Section **Error! Reference source not found.**

4.3 Workflow for checking whether forwarding information and notification are required

If SVHC(s) have been identified in the article, you may use the following workflow to check, if you have to forward information in the supply chain and/or notify the Chemicals Agency. You may start in the workflow at any point, depending on which information is available or easiest to obtain. For example, it may be easier to calculate the total amount of an SVHC in the article than to check a registration for that specific use.

The workload for notification is relatively low compared to that of registration and the amounts of the substance in the article only need to be known in tonnage ranges (for example 1, 10, 100 or 1000). Avoiding a notification by excluding exposures (Article 7(3)) may require more effort than a notification itself. It is recommended to evaluate the costs before going into a more thorough assessment instead of just fulfilling a notification.

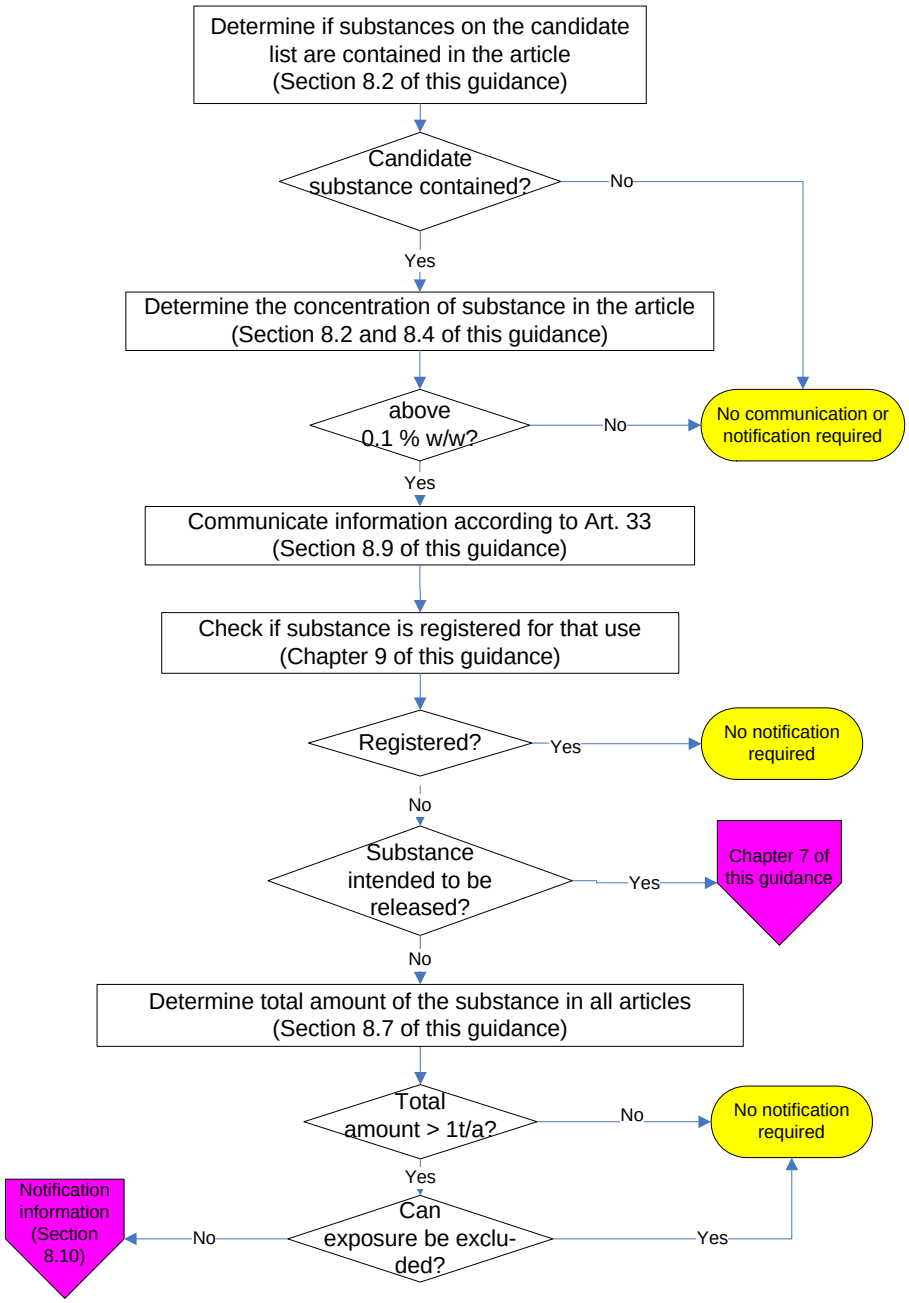

Figure 3 Checking the requirement to notify and to forward information on SVHC

w/w = weight per weight; Art = REACH Article, t/a = tonnes per year

4.4 Determination of the concentration of an SVHC – focus on articles with different components[12]

[12] Dissenting views (http://reach.jrc.it/docs/guidance_document/dissenting_en.pdf), questioning the application of the 0.1 % threshold to the entire article have been notified by six Member States in writing (Austria, Belgium, Denmark, France, Germany and Sweden) and publication of this part of the guidance document was not endorsed by these Member States.

For each article, it must be determined whether the concentration of the identified SVHC is > 0.1% (w/w) in order to know what information has to be communicated down the supply chain. A further assessment is needed to find out if a notification of these SVHCs is required. Methods for obtaining information on the concentrations of SVHCs in articles and the use of quantitative chemical analysis have been elaborated in previous chapters of this guidance (see Chapter **Error! Reference source not found.**, Section **Error! Reference source not found.** and Section 4.2). However, it should be noted that an article producer should consider the possibility of using mass balance for determining the concentration of SVHCs in his articles and also be aware of the possibility of accumulating an SVHC through a process. This chapter focuses on determining the concentration of an SVHC in articles with different components.

The SVHC may be contained in different concentrations in different components of the same article, e.g. one concentration in the chassis of a computer and another concentration in the transformer. The concentration threshold of 0.1% (w/w) refers to the average concentration of the entire article as produced or imported.

The principle to be applied when calculating the concentration of an SVHC in an article is illustrated by two cases:

1 Different components for a computer such as transformer, rectifier, mother board, memory, processor, hard drive, graphics card, network card, sound card and chassis are purchased by a producer of a computer. All these components are obtained from producers and importers within the EU and the content of SVHCs above 0.1% (w/w) should be indicated to the producer (Article 33) and possibly notified where needed by the suppliers of the components. The producer of the computer would therefore not have to notify any of those substances again.

   Furthermore, if no components contain above 0.1% of an SVHC on the candidate list, also the entire computer would not contain above 0.1% and no further considerations are needed.

   If one or more of the components contain more than 0.1% of an SVHC on the candidate list, the producer of the computer would have to check whether the computer he places on the market would contain above 0.1% of that SVHC – averaged over the weight of the computer. If yes, he will have to supply information according to Article 33.

   If the producer himself adds an SVHC to one or more parts of the computer, he will have to check whether the 0.1% threshold is exceeded for the computer he finally places on the market. If yes, he will have to provide information according to Article 33. He may additionally have to notify if the 1 tonne tonnage trigger for that SVHC is exceeded.

2 A chair is imported from Taiwan. It consists of a wooden part and a plastic part. The producer of the chair informs that the two parts contain xyz% and abc%, respectively of an SVHC on the candidate list. Based on this information, it is obligatory to check if the threshold of 0.1% is exceeded. This could be done by calculating the concentration of this SVHC in the whole chair as described below and illustrated in the example box below.

The average concentration of an SVHC in an article is calculated as follows:

$$\text{Conc. of SVHC}\,[\%] = \frac{\text{Amount of SVHC}\,[\text{g}]\cdot 100}{\text{Weight of the whole article}\,[\text{g}]}$$

Example 5 Calculation of a concentration

Example of calculating a concentration:

A chair consists of a wooden part and a plastic detail. The weight of the chair is 2.001 kg.

The wooden part of a chair contains 10 mg of an SVHC. The weight of the wooden part is 2 kg.

A plastic detail of the chair contains 1 mg of the same SVHC and the weight of the plastic detail is 1 g.

The SVHC concentration in the chair: $\frac{(10 \cdot 10^{-3} + 1 \cdot 10^{-3})\text{g} \cdot 100}{(2001)\text{g}} \% = 0.0005\% \text{ (w/w)}$, which is < 0.1%.

Conclusion: The producer/importer has neither to communicate information down the supply chain according to Art. 33 nor to notify according to Article 7(2).

If the exact concentration in the article or the article parts is not known, a first screening may be performed on the basis of the maximum amount or concentration in the whole article or the different parts. If this shows a concentration > 0.1%, a more precise determination of the SVHC amount or concentration should be made.

4.5 Check for an intended release of the SVHC[13]

If the SVHC is intended to be released, registration may apply (See chapter **Error! Reference source not found.**). As previously described, notification is not needed if a registration according to Article 7(1) is required. The obligation to forward information to customers may however still be applicable if the concentration of the substance in the entire article is greater than 0.1% (w/w).

4.6 Check for an existing registration for that specific use

According to Article 7(6) of REACH, substances in articles already registered for that use do not need to be notified. See further guidance in Chapter 6.

[13] Dissenting views (http://reach.jrc.it/docs/guidance_document/dissenting_en.pdf), questioning the application of the 0.1 % threshold to the entire article have been notified by six Member States in writing (Austria, Belgium, Denmark, France, Germany and Sweden) and publication of this part of the guidance document was not endorsed by these Member States.

4.7 Determining the total amount of substances on the candidate list in all articles[14]

It is possible that the concentration of a substance on the candidate list is greater than 0.1% (w/w) in several different articles, e.g. a bag and a belt. To find out if a notification is required, the total amount of the substance in all of these articles must be determined and summed up.

Calculate the total amount of the SVHC (g) in each article produced or imported per year with a concentration of the SVHC > 0.1% (w/w):

The amount in one article is:

$$\mathrm{Vol}_{\mathrm{SVHC}}[g/a] = (\text{max. conc. of SVHC in article}[\%] \cdot 0.01) \cdot (\text{weight of article}[g] \cdot 10^{-6}) \cdot (\text{number of article/a})$$

The total volume is:

$$\text{Total } \mathrm{Vol}_{\mathrm{SVHC}}\ [\mathrm{t/a}] = \sum \mathrm{Vol}_{\mathrm{SVHC}}\ [\mathrm{t/a}] \text{ of each type of article}$$

Example 6 Calculation of the total amount of a SVHC used in production or imported

Example of calculation of the amount of an SVHC:

A company imports 20000 pairs of shoes, 3000 belts, and 60000 bags per year to the EU market. A pair of shoes contains 0.05% (w/w) of an SVHC, a belt contains 0.15% (w/w), and a bag contains 2% (w/w) of the same SVHC. The weights of the articles are 0.7 kg per pair of shoes, 700 g per belt and 1 kg per bag.

Concentration in belt and bag > 0.1% (w/w) ⇒ calculate the total volume of the SVHC for each of the articles.

The total volume of the SVHC imported by the articles:

- Belts: $\mathrm{Vol}_{\mathrm{SVHC}}$ [t/a] = (0.15% · 0.01) · (700 [g] · 10^{-6}) · 3000 = 0.0032 t/a
- Bags: $\mathrm{Vol}_{\mathrm{SVHC}}$ [t/a] = (2% · 0.01) · (1000 [g] · 10^{-6}) · 60000 = 1.2 t/a

Sum up the total volume for all sorts of articles with a concentration of the SVHC > 0.1%:

$\sum \mathrm{Vol}_{\mathrm{SVHC}}$ = (0.0032 + 1.2) t/a = 1.2032 t/a, which is > 1 t/a

Conclusion: The company has to submit a notification for the SVHC in the bag and the belt. Furthermore, the company has to provide information for both the belt and the bag according to Article 33 of REACH.

4.8 Forwarding information according to Article 33

According to Article 33(1), any supplier of an article containing SVHCs on the candidate list in concentrations exceeding 0.1% w/w shall supply the recipients with sufficient information, available to the supplier, to allow safe use of the article. As a minimum, the name of the SVHC shall be provided. Article 33(2) requires the same type of information to be forwarded to consumers upon their request.

[14] Dissenting views (http://reach.jrc.it/docs/guidance_document/dissenting_en.pdf), questioning the application of the 0.1 % threshold to the entire article have been notified by six Member States in writing (Austria, Belgium, Denmark, France, Germany and Sweden) and publication of this part of the guidance document was not endorsed by these Member States.

In any case, providing the name of the SVHC contained in the article is obligatory. In addition to the name, it is obligatory to provide any information necessary to ensure safe use. This means that obligatory additional information depends on what a user needs to know to ensure safe use. In order to determine what information shall be provided to the recipient or to the consumer on request, the article supplier has to consider how the article is used, which exposures and risks could arise and which information, in particular on risk management, is required for the user of the article to ensure safe handling.

Assessing and communicating on safe use under REACH in general means addressing the life cycle of a substance from the stage of the respective actor. Article suppliers should consider the service life of the article and appropriate instructions for its disposal. Specific storage or transport conditions should also be considered, where relevant for safe use of the article.

The information necessary to ensure safe use of the article could be communicated in different ways and formats. The communicator should consider what type of information and level of detail is appropriate to the respective addressee, considering the conditions of their use and the level of knowledge. Information for the same article may thus be different regarding information type and detail (a professional user would e.g. normally not be informed that an article should be kept out of reach of children) and format (consumers may be informed with stickers, whereas a professional user would rather be provided with use instructions).

Whatever technique is used, ready access to the information should be guaranteed to any user[15].

Examples of information that could be provided to consumers:

- An article is supplied with a risk of human exposure if sucked by small children and/or for environmental exposure if discarded as household waste:
  "Contains substance X that is (very) dangerous to health and/or the environment. Keep out of reach of small children. Handle waste as hazardous waste."
- An item of clothing is supplied with a risk of dermal exposure if in contact with skin:
  "Contains substance Y which is (very) dangerous to health. Do not wear in direct contact with skin."

Examples of what information could be provided to professional users:

- Metal article e.g. a sheet that would normally be grinded during use and dust containing the SVHC may be inhaled:
  "Avoid inhalation of dust from grinding by using effective point ventilation systems and where necessary also appropriate personal protection."
- Plastic sheets from which the SVHC may leak to the environment if exposed to rain:
  "To avoid leakage to the environment do not use the sheets outdoors."
- Brake lining from which a large fraction will wear during normal use and expose the environment to the SVHC:
  "Will lead to exposure to the environment during outdoor use. Indoors: Only professional use."

[15] As the candidate list is subject to change, a link to a Website with up-to-date information could be provided in addition to a paper label. However, a link would not be sufficient since the information is then not readily available.

The following checklist could be used to decide what information may be required to forward to professional users.

- Exposure controls/Personal protection
- Handling and storage
- Disposal consideration
- Fire-fighting measures
- Transport information

The information could be included in already existing documents, such as instructions for use and packaging. Labels might be used in some cases. In addition, other techniques could be developed.

REACH does not specify a format for providing information with articles. You must choose a format that will ensure that the recipient can readily become aware of the information. Potential information items for inclusion are shown in Table 3.

Table 3 Information types for communicating on SVHCs in articles

Item	**Example**
Substance name	Diarsenic trioxide
CAS Number	1327-53-3
Registration number (if provided by supplier)	01-1234567-49-00
Classification and SVHC properties	Carc. Cat. 1; R45; May cause cancer T+; R28; Very toxic is swallowed C; R34; Causes burns N; R50/53; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Concentration in the article[16]	1% w/w
Information on safe handling including safe disposal if relevant	Prevent from heating above 60 °C Keep article out of reach of children This article should be disposed of as hazardous waste. Do not dispose of via normal household waste

4.9 Notification of a substance in articles

The information to be notified according to Article 7(2) shall include the following items:

- The identity and contact details of the producer or importer of the article
- The registration number(s) for the substance(s), if available
- The identity of the substance(s) (cf. Annex VI of REACH). This information will be available on the candidate list
- The classification of the substance(s), which will be available from the Agency

[16] Concentration ranges could be considered in order to preserve confidential business information

- A brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s) (cf. Section **Error! Reference source not found.**)
- The tonnage range of the substance contained in the articles, i.e. 1-10 tonnes, 10-100 tonnes etc. This information can be estimated as explained in Section 4.7.

5 OBTAINING INFORMATION ON SUBSTANCES IN ARTICLES

Companies producing, importing or placing articles on the market, do not always have the information in house, which is necessary to establish whether the requirements for substances in articles apply. Producers and importers of articles with intended release of substances need to know the identity of all *substances intended to be released* in these articles as well as the respective concentration in the articles. Furthermore, producers and importers of articles in general, as well as distributors of articles, need to know if and in what concentrations substances on the candidate list for authorisation are contained in their articles. In principle, this information on substances in articles can be obtained from two sources, either from communication in the supply chain or by means of chemical analyses.

5.1 Information via the supply chain

Identifying substances in articles and quantifying their amounts is in many cases only possible if the respective information is made available by the actors in the supply chain. Supply chain communication is therefore the most important way of gathering the information needed in order to identify one's obligations under REACH. This is due to the fact that chemical analysis, although a possible way to identify and quantify substances in articles, is time consuming, costly and difficult to organise. In this regard, establishing communication standards for the supply chain is an important task for the private sector in order to facilitate the implementation of REACH.

5.1.1 Standardised information from suppliers in the EEA

Information needed to identify and comply with requirements for substances in articles can often be derived from standardised information that is obtained from suppliers based in the EEA. **Suppliers of substances or mixtures**, for instance, have to provide their customers with safety data sheets, or, where a safety data sheet is not required, with available and relevant safety information and details on regulatory requirements (need for authorisation, restrictions imposed) according to Article 32. In case a substance requiring a safety data sheet has been registered in a quantity of 10 t/a or more, recipients of this substance (as such or in a mixture) are provided by their supplier with the relevant exposure scenarios in an annex to the safety data sheet. Exposure scenarios describe how a substance is used during its life cycle and recommend how to control exposure of humans and the environment. These exposure scenarios cover the incorporation of the substance in articles and the resulting life cycle stages of the substance, including the service life of the articles and the waste life cycle stage. Therefore the information contained in exposure scenarios can be useful particularly for article producers when preparing the information to be provided to customers as required by Article 33. Unlike suppliers of substances and mixtures, **suppliers of articles** do not always have to provide standardised information to their customers. Only when the articles supplied contain a substance included in the candidate list of substances for authorisation in a concentration above 0.1% (w/w), they must provide available and relevant safety information according to Article 33.

5.1.2 Requesting information up the supply chain

Importers of substances, mixtures and articles will not necessarily receive standardised information from their non-EEA suppliers. In this case and whenever standard information received from suppliers in the EEA is not sufficient to check compliance with REACH, companies have to obtain the

necessary information by pro-active requests in the supply chain. The following points should be taken into consideration when requesting information from other actors in the supply chain:

- It may be helpful to tell suppliers why the information is needed, which may be unknown, particularly to non-EEA suppliers.
- To avoid requests having to be passed up complex supply chains via several distributors, the producers of articles, formulators and manufacturers of substances could be identified and addressed directly to obtain the information required.
- In many cases the exact composition of articles or mixtures is not needed to clarify whether requirements for substances in articles have to be fulfilled. Certainty in particular that no notification or communication obligations for substances in articles apply can also be achieved by excluding or limiting the presence of substances that are on the candidate list of substances for authorisation. Suppliers could for example provide certificates which guarantee that certain substances are not used in the manufacture of their products or remain below certain concentrations in their products. A different approach would be to include respective criteria in supply contracts excluding or limiting the presence of certain substances in the products to be supplied.
- Requests in the supply chain should wherever possible be targeted and aim at excluding or limiting the presence of certain substances (e.g. those on the candidate list for authorisation) instead of asking for the exact composition of articles or mixtures, which is more often confidential information.
- Substances intended to be released from articles are usually released as part of mixtures, the concentration of which in the articles is know more often than the concentration of the individual *substances intended to be released*. If the maximum content of the *mixture intended to be released* in articles is known, critical levels for the concentration of substances in the mixture, above which a registration of substances in those articles might be required, can be calculated as shown in section 5.1.2.1. Information requests up the supply chain should then be focused on substances exceeding the concentration calculated to be critical.

There may however be cases where supply chain communication will not be successful. In these cases other means of obtaining information on substances in articles may be used, such as a combination of publicly available information sources (see appendix 4), branch knowledge and conclusions from chemical analysis (see appendix 5).

5.1.2.1 Critical concentration level for substances in the *mixture intended to be released*

If the maximum concentration of a *mixture intended to be released* incorporated in articles and the total production and import volume of these articles is known, the concentration limit for the substances in the mixture, above which registration is necessary, can be calculated using the equation below. Hereby it is assumed that only one mixture with the specific substance is used and in one type of article only.

$$Conc_{\max subs.\ in\ mixture} = \frac{1\,t/a}{Vol_{articles} \cdot Conc_{\max mixture\ in\ article}}$$

$Conc_{max\ subs.\ in\ mixture}$: maximum weight percentage of the substance that can be in the *mixture intended to be released* without triggering registration obligations; as a value between 0 and 1 (50% = 0.5, 25% = 0.25, 20% = 0.2, etc.).

$Vol_{articles}$: volume (in t/a) of articles produced and imported.

$Conc_{max\ mixture\ in\ article}$: maximum weight percentage of the *mixture intended to be released* in the article; as a value between 0 and 1 (50% = 0.5, 25% = 0.25, 20% = 0.2, etc.).

Example 7 Critical concentration level for substances in the *mixture intended to be released*

A smelling toy contains a mixture of fragrances that is intended to be released during use.

Assumption: The toy consists of a maximum 15% fragrances. A company imports 30 tonnes of these toys every year. This importer does not import or produce other articles.

$$Conc_{\max subs.\ in\ mixture} = \frac{1\,t/a}{30\,t/a \cdot 0.15} = 0.22$$

Conclusion: This means that registration is not necessary for substances contained in the fragrance mixture in a concentration of a maximum of 22% by weight. As this may not apply to all substances in the fragrance mixture, further information has to be sought. The importer of the toys could thus ask the supplier whether the concentration of 22% is exceeded for any of the substances contained in the fragrance mixture.

5.2 Chemical analysis of substances in articles

Theoretically, substances contained in articles can be identified and their concentrations quantified by applying analytical methods. If other approaches to obtaining information fail or become too complicated, conducting chemical analysis may thus be a "last resort" for checking/fulfilling REACH obligations in relation to the identity and the content of substances in an article. Chemical analyses may yield ambiguous results and/or be very costly and are thus not recommended as the preferred instrument for obtaining information.

5.2.1 Difficulties of chemical analyses

Difficulties related to chemical analysis of substances will be faced relating to the following issues and have to be kept in mind in case chemical analyses are conducted.

- Articles may be very complex and composed of different parts and materials. It is therefore difficult to create a sample for the analysis that represents the whole article.
- Substances that are included in the article matrix may have to be extracted from it[17].
  - This may result in chemical reactions that could "create" substances which do not exist in the article.
  - The extraction may not be exhaustive, thus the full content of substances in the matrix may not be obtainable.
- Various analytical methods are available to screen for the existence and identification of different substances in a sample.
  - Measurements in most cases will identify the chemical constituents in the sample but not necessarily "the substance" which were originally used to produce the article.

[17] Substances intended to be released from articles can in principle be separated from the articles without extraction or special methods, so taking respective samples for chemical analysis should normally be possible.

Note that substances may consist of several constituents (for more information please consult the Guidance on substance identification).

- Some methods may show the existence of certain elements (e.g. halogens) or the molecular weight rather than the existence substances.
- If a high number of different substances are contained, several analyses may be needed to identify all substances, and it is particularly difficult to assign an appropriate method if it is not clear what is being searched.
- The quantification of substances requires additional measurements.

5.2.2 Planning chemical analyses of substances in articles

Chemical analyses have to be planned carefully taking into account what information can be obtained with which methods. If an analysis is carried out, a strategy should be developed in collaboration with experienced laboratories and based on available methods. The testing strategy and interpretation of results should take into account any other available information on the article which is being analysed e.g. from industry sector organisations, research institutions and accredited chemical analysis laboratories. Furthermore, it should be noted that there are no formal requirements on which methods and laboratories to use; it is up to each company to judge the appropriateness of methods and laboratories.

The following steps are proposed, if analysis is regarded as necessary and helpful:

- Consult experts or sector information sources to narrow down which substances to look for (e.g. for many articles it can be excluded that gaseous substances are contained therein).
- Develop a strategy for testing as a tiered process, i.e. broad screenings, narrow screenings and identification by e.g. semi-quantitative methods.
- Identify from which part of the article to sample: separated liquids, gases or powders, extracts from article matrix or other types of sample from the article.
- Perform the chemical analysis for the identification of substances.

6 EXEMPTIONS FROM REQUIREMENTS FOR SUBSTANCES IN ARTICLES

Obligations to register or notify substances in articles identified as described in chapters 3 and 4 can still be avoided in certain cases. This chapter explains what you have to check to establish if you can benefit from an exemption from registration or notification obligations related to substances in articles. However, no exemption is possible for the obligation to communicate information on substances in articles according to Article 33.

6.1 General exemption of substances from registration and notification

A number of substances are exempted in general (i.e. whether as such, in mixtures or in articles) from registration and notification as sufficient information is known about these substances or registration and notification are simply deemed inappropriate or unnecessary. Annexes IV and V of the REACH Regulation specify which substances these are. The Navigator on the ECHA website should be used to check if any exemption based on an entry in Annex IV or V applies and a registration or notification under Article 7 would therefore not be required.

6.2 Exemption from registration and notification of substances recovered

The REACH Regulation exempts substances which are recovered in the EEA from registration and notification, provided a number of conditions are met. Producers of articles made of recovered material can therefore in principle benefit from this exemption. The conditions set by REACH which have to be respected in order to benefit from this exemption are described in section 1.6.4.5 of the Guidance on registration.

6.3 Exposure based exemption from notification

According to Article 7(3), notification is not required if the producer or importer of articles can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use, including disposal. This is the case in the following situations:

- There is no release of the substance of concern during normal and reasonably foreseeable conditions of use[18] or disposal.
- There is a release but the article is embedded during use and the substance will not escape to the environment or come into contact with humans during use or disposal.

This means that a producer/importer wanting to demonstrate ‘exclusion of exposure’ has to ensure that the substance of very high concern on the candidate list does not come in contact with the users of the article or with the environment, regardless of its dangerous properties. Note that all exposure routes at all life cycle stages (service life of the article and disposal) have to be considered. Ways of showing that no exposure occurs include arguments based on:

- Knowledge of the article and its service life, e.g. the SVHC is fully contained in the article, and the article is collected and disposed of in a manner that prevents any release to the environment

[18] The terms “normal conditions of use” and “reasonably foreseeable conditions of use” are explained in section 3.1.

and exposure to humans under normal and reasonably foreseeable conditions.

- Knowledge of the substances properties, e.g. the substance is fully immobile in the article due to the way it is integrated and because of its inherent physicochemical properties.
- Quantification based on exposure models, demonstrating no exposure during service life and disposal.
- Measurements proving that no emissions from the article take place even during its disposal.

Note that it may be more difficult to demonstrate "no exposure" than making a notification. Some key notions on exposure assessment are described in section 6.3.1, for further guidance on how demonstrating that no exposure occurs please consult chapters R14 to R18 of the Guidance on information requirements and chemical safety assessment.

There is no requirement to submit documentation to ECHA that supports an exemption from notification. However, a justification of the exemption that demonstrates exclusion of exposure should be prepared so that it can be presented to enforcement authorities on demand.

6.3.1 Potential for release

The potential for release of a substance from an article will depend on:

- Physicochemical properties of **the substance**, like vapour pressure, water solubility, stability in contact with air, water, etc.
- Structure and chemistry of **the article matrix** including physicochemical parameters and the way in which the substance is incorporated in it (chemically bonded or not).
- **The conditions of use and disposal** of the article, such as:
    - Location of use (indoor or outdoor use, private homes, workplace, etc.).
    - Physical conditions at place of use (temperature, ventilation, etc.).
    - Whether or not articles are part of a comprehensive waste collection scheme.
    - The disposal technology.

Some chemical substances are very firmly bound in the material, e.g. chromium in stainless steel, and the potential emission of chromium is therefore very low. Other substances are loosely incorporated in a matrix, e.g. softening additives in PVC. Such substances, like phthalates, are continuously emitted from the surface of the article. An alternative way in which substances may be released is through normal wear and tear of articles (abrasion). In this case, the substances are released together with the article matrix, e.g. additives in car tyres or the outside surface coatings of a car underbody.

6.4 Checking whether a substance in an article has been registered for that use

#This section is not part of the present consultation, it will be revised and submitted for consultation at a later stage.#

A registration or notification of a substance in an article is not required, if the substance has already been registered for that use (REACH Article 7(6)).

This refers to any registration of that use of the substance up the same supply chain or any other supply chain. It needs to be ensured that it is the same substance that has been registered. Comparing names, and EINECS or CAS numbers may not always be sufficient to establish whether substances are to be considered 'the same'.[19]

Registrants have to provide a brief general description of the identified use(s) in the registration dossier according to Annex VI Section 3.5. This part of the REACH requirements have been implemented in IUCLID 5 registration software to also cover whether a substance has been registered for that use in relation to the article requirements via a standardised use descriptor system.

This standardised system has also been developed to facilitate the communication and description of uses (see Guidance on the Chemical Safety Report). The system consists of four elements, specifying the industry sector, the preparation types, the processes and the article categories a substance could be used in. It also specifies whether the substance is foreseen to be intentionally released or not from an article. If the elements of the use description in a registration fit to the article containing the substance, then this use can be regarded as a registered use. The use descriptors have been implemented in the IUCLID 5 software as standardised pick-lists (with options for the registrant to make more specific or further entries if needed). Please refer to the Guidance on preparing the Chemical Safety Report and the IUCLID 5 guidance for further information about the pick lists and the context in which the lists are to be applied.

Consequently, a potential registrant or notifier of a substance in articles checking whether a substance has been registered ‘for that use’ has to check by which process the substance has been included in the article, and into which type of article the substance has been incorporated in line with the use descriptor system. Otherwise the substance is not considered registered for that use.

Information on non-dangerous substances and their registered use(s) will not normally be communicated along the supply chain, whereas for dangerous substances this should be communicated with the (extended) safety data sheet. However, the complete set of registered uses may not be identified in safety data sheets of preparations, as they are more specific, than those of the single substances.

Substances will be registered throughout the phase-in scheme until 2018. Thus, a substance may not yet have been registered at the time a producer or importer of an article checks if his use has already been registered. More information on how to handle this is provided in Section 2.5 and Section 7.6 of this guidance.

6.4.1 Information in the supply chain

If you need to find out which uses a substance has been registered for, the most likely option would be to ask the suppliers in your supply chain, or to identify and ask a manufacturer or importer of that substance. They may either be aware of the registered uses from safety data sheets or other information or may have carried out a registration already and could tell you if they have registered your use. They may also know other registrants who have registered that use. Registrants or future registrants could also make a respective request in the Substance Information Exchange Forum (SIEF) (see also Section **Error! Reference source not found.**). Confidentiality of information may however be a problem for either side and exclude such communication.

[19] Rules for the identification and naming of substances as well as criteria for substances being considered ‘the same’ or not are provided in the Guidance on Substance Identification.

You may start a request up the supply chain for registered uses of substances for which you have identified a possible registration or notification requirement. If you ask for a specific substance, this request may be forwarded straight up to the manufacture of the substance. Usually, however, substances are used in preparations and the request may therefore need to be differentiated for the different substances contained therein. If you ask for 'all substances in a preparation that you use', at each supply chain level, the request upstream may be forwarded to more actors as the different substances of a preparation may be supplied by various actors.

6.4.2 Information requests to the Agency[20]

You may also be exempted if a Registration of your use of the substance has been made by an actor in another supply chain.

Search for information on the Agency databases or make a request to the Agency to find out if a specific use of a substance has been registered. For this step, it is a prerequisite that the identity of the substance is known (as a minimum, an identification number, such as CAS, EINECS, ELINCS is required). On request, the Agency should be able to give a simple yes/no answer to the question: "Do I have to register my substance in articles according to Article 7(1)?" based on the use identifier given by the potential registrant.

In case the article producer/importer is still in doubt about whether his use has been registered, he should consider further dialogue in this supply chain or within the Substance Information Exchange Forum (SIEF).

[20] This section may have to be revised, once the Agency working procedures on this issue have been established.

APPENDIX 1: BORDERLINE CASES OF SUBSTANCES/MIXTURES IN CONTAINERS OR CARRIER MATERIALS

In order to find out under which Article of REACH substances are to be registered, the status of the object and the relation to its content need to be clarified. Section 2.3 of the guidance provides a workflow and explanation on how to distinguish between

a) articles with substances/mixtures forming an integral part thereof, and

b) articles (functioning as container or carrier material) with substances/mixtures contained within.

The following examples, the conclusions of which are summarised in the table below, illustrate how to apply the workflow and indicative questions in the main guidance and how to draw respective conclusions. The examples should be applied to guide decisions on similar borderline cases, e.g. writing materials would (in analogy with the printer cartridge) be considered as articles (functioning as containers) with substances/mixtures contained within.

Table 4 Summary of borderline cases described

Object	Conclusion	
	article with a substance/mixture forming an integral part thereof	**article** with a **substance/mixture** contained within
printer cartridge		x
spray can with paint		x
firecracker		x
thermometer with liquid	x	
printer ribbon		x
wet cleaning wipes		x
wax tapes for skis		x
adhesive tape for fixing carpets	x	
battery	x	
desiccant bag		x
breathalyzer		x

Table 5 Borderline cases of substances/mixtures in containers (part 1)

Object	**Spray can with paint**	**Printer cartridge**	**Firecracker**	**Thermometer with liquid**
Function	Bring paint onto surface	Bring ink onto paper	Explode, make light effects	Measure and indicate temperature
Question 3a: If the substance/mixture were to be removed or separated from the object and used independently from it or changed from the object to a similar type of object, would the substance/mixture still be capable in principle (though perhaps without convenience or sophistication) of carrying out the function?	**YES**, one could still make a painting even if the paint would be separated from the spray can.	**YES**, if the toner was removed and filled into any other type of printing or writing device, it could still execute its function.	**YES**, if the chemicals were removed, they could still explode and make light effects.	**NO**, if the liquid was removed it could still expand and contract with changing temperatures, but would not measure and indicate the surrounding temperature.
Question 3b: Does the object act mainly (i.e. according to the function) as a container or carrier for release or controlled delivery of the substance/mixture or its reaction products?	**YES**, the spray can is mainly intended to deliver the mixture in a controlled way (it controls speed and type of its release).	**YES**, the cartridge is mainly intended to deliver the toner in a controlled way (it provides the fit to the printer and controls the release).	**YES**, the function is to bring the substances or their reaction products into the air, thus to deliver them.	**NO**, it is not the function of the object to deliver a substance or mixture.
Question 3c: Is the substance/mixture predominantly consumed or eliminated during the use phase of the object, so that at the end of the useful life of the object the substance/mixture is not anymore in the object as it was in the beginning?	**YES**, the spray can is normally disposed of separately from the paint.	**YES**, the toner is normally consumed during use and the cartridge is disposed of separately.	**YES**, the explosive substances react and are separated from the container during use. Any containers or container parts remaining are disposed of separately.	**NO**, the liquid and the container are disposed of together.
Conclusion	article with substances or mixtures contained within	article with substances or mixtures contained within	article with substances or mixtures contained within	see table 6

Table 6 Additional indicative questions for borderline cases of substances/mixtures in containers (part 1)

Object	**Thermometer with liquid**
Question 4a: If the substance/mixture were to be removed or separated from the object or exchanged for a similar type of substance/mixture, would the object be unable to fulfil its intended purpose?	**YES**, the container loses its purpose without the liquid.
Question 4b: Is the main purpose of the object other than to deliver the substance/mixture or its re-action products?	**YES**, Delivering a substance/mixture is not the main function of the object. The thermometer contains the liquid and provides a shape to regulate its expansion, necessary to measure and to show the right temperature. It is not the purpose to deliver the liquid.
Question 4c: Is the object normally discarded with the substance/mixture at the end of its useful life, i.e. at disposal?	**YES**, the liquid and the container are disposed of together.
Conclusion	article with substances or mixtures forming an integral part thereof

Table 7 Borderline cases of substances/mixtures in containers (part 2)

Object	**Battery**	**Desiccant bag**	**Breathalyzer**
Function	Provide electric current	Absorb air humidity	Make a colour reaction
Question 3a: If the substance/mixture were to be removed or separated from the object and used independently from it or changed from the object to a similar type of object, would the substance/mixture still be capable in principle (though perhaps without convenience or sophistication) of carrying out the function?	**NO**, the electrolyte and the electrode active materials as such cannot provide any electric current outside the battery. Housed in other containers without the specific design of a battery, they would also fail to provide energy. The 'container part' of the battery, empty of the electrolyte, is also not able to fulfil its function. However, there are different types of electrolytes which could be used in one battery casing.	**YES**, the desiccant substance would still absorb humidity.	**YES**, in principle without sophistication the substance if it was removed could indicate alcohol in the breath. Cr(VI) would still under go the chemical reaction to Cr(III) in the presence of alcohol.
Question 3b: Does the object act mainly (i.e. according to the function) as a container or carrier for release or controlled delivery of the substance/mixture or its reaction products?	**NO**, the electrolyte and the electrode active materials are not released from the battery, thus the container does not have a function of 'delivering' it and does not control its release.	**NO**, the desiccant is not released from the bag.	**NO**, it is not the intention to deliver a substance/mixture, because the intention of this object is that the chemical reaction takes place within the object.
Question 3c: Is the substance/mixture predominantly consumed or eliminated during the use phase of the object, so that at the end of the useful life of the object the substance/mixture is not anymore in the object as it was in the beginning?	**YES**, the electrolyte is predominantly consumed during the use phase of the object, and is thus not any-more in the object as it was in the beginning of the useful life of the battery.	**YES**, the activity of the dessicant decreases with time; at the end of the useful life of the object the dessicant does not adsorb humidity anymore.	**YES**, as Cr(VI) undergoes a chemical reaction to become Cr(III). It is a single use application and would require a chemical reaction to convert back to Cr(VI).
Conclusion	article with substances or mixtures forming an integral part thereof (this is confirmed by a cross-check with questions 4a to 4c)	article with substances or mixtures contained within	article with substances or mixtures contained within

Table 8 Borderline cases of substances/mixtures on carrier materials

Object	**Printer ribbon**	**Wet cleaning wipes**
Function	Bring ink onto paper	Remove dirt from surfaces
Question 3a: If the substance/mixture were to be removed or separated from the object and used independently from it or changed from the object to a similar type of object, would the substance/mixture still be capable in principle (though perhaps without convenience or sophistication) of carrying out the function?	**YES**, if the ink was removed and filled into other materials / containers it could still fulfil its function.	**YES**, the cleaning effect could generally be achieved by using the same mixture with another type of wipe.
Question 3b: Does the object act mainly (i.e. according to the function) as a container or carrier for release or controlled delivery of the substance/mixture or its reaction products?	**YES**, the main function is to deliver the ink to the paper.	**NO**, the main function of the object is to remove dirt from surfaces.
Question 3c: Is the substance/mixture predominantly consumed or eliminated during the use phase of the object, so that at the end of the useful life of the object the substance/mixture is not anymore in the object as it was in the beginning?	**YES**, when the ribbon is disposed, most of the ink has been consumed.	**YES**, the cleaning agents are predominantly consumed[21] and the wipe is disposed of separately.
Conclusion	article with substances or mixtures contained within	article with substances or mixtures contained within

[21] This is regarded as true, although in reality a large part of the cleaning agent may not actually be consumed, as its *function* is to be released as far as practical.

Table 9 Applying indicative questions to pressure sensitive adhesive tapes[22]

	Wax tape for skis (example for adhesive tapes that deliver substances/mixtures onto a surface, whereas the carrier material serves only as a release liner and aid to easy application; the adhesive layer may change its shape upon application)	**Adhesive tape for fixing carpets** (example for adhesive tapes that do not deliver substances/mixtures onto a surface, and consist of adhesive layer(s) and a backing or internal reinforcement)
Object		
Function	Bring wax onto ski surface	Hold two substrates together
Question 3a: If the substance/mixture were to be removed or separated from the object and used independently from it or changed from the object to a similar type of object, would the substance/mixture still be capable in principle (though perhaps without convenience or sophistication) of carrying out the function?	**YES**, the adhesive layer is capable of carrying out its intended purpose (which is not necessarily mainly to adhere!), though with less convenience.	**NO**, the function of the tape is determined by the interaction between the backing or reinforcement and the adhesive. The adhesive layer without the backing material or the reinforcement is not capable of carrying out the intended purpose of the tape.
Question 3b: Does the object act mainly (i.e. according to the function) as a container or carrier for release or controlled delivery of the substance/mixture or its reaction products?	**YES**, the tape's function is the controlled delivery of a substance or mixture.	**NO**, the tape's function is not to simply control the release or delivery of the adhesive layer but to adhere to the substrate and to provide additional qualities through the backing or internal reinforcement.
Question 3c: Is the substance/mixture predominantly consumed or eliminated during the use phase of the object, so that at the end of the useful life of the object the substance/mixture is not anymore in the object as it was in the beginning?	**YES**, the adhering layer and the carrier material are disposed of separately at the end of their respective useful lives.	**NO**, the adhesive remains on the tape at the end of its useful life.
Conclusion	article with substances or mixtures contained within	article with substances or mixtures forming an integral part thereof (this is confirmed by a cross-check with questions 4a to 4c)

[22] Terms used in the table are defined according to EN 12481:
Backing: flexible material such as fabric, foil or paper which can be coated with a pressure sensitive adhesive.
Reinforcement: a material which strengthens the backing and/or the adhesive.
Release liner: a removable material which protects the adhesive face or faces.
Substrate: a surface or material to which the tape is applied.

APPENDIX 2: EXAMPLES OF SETTING THE BORDERLINE IN THE SEQUENCE OF PROCESSING NATURAL OR SYNTHETIC MATERIALS INTO FINAL ARTICLES

In section 2.3 the main guidance text contains explanations and indicative questions to support the evaluation of the importance of the chemical composition of objects versus their shape/surface/design in relation to the function. The indicative questions 6a to 6d can be used to determine the transition point from a substance/mixture to an article for a raw material during its processing. This appendix illustrates the application of the article definition to different types of raw materials. It exemplifies how the indicative questions 6a to 6d could be answered and how they could assist in deciding whether an object is to be considered an article.

It should be noted that the borderline between substance/mixture and article may be different for very similar types of materials (e.g. there might not be one solution for all types of fibres). Thus, it should be avoided to draw conclusions on the status of the same type of a raw material in different sectors, as it may fulfil different functions. Thus, whether or not a raw material is an article must be decided case-by-case. However, industry sectors may develop further guidance based on section 2.3 in the guidance and this appendix.

In the following, guidance on where and how to set the borderline during the refinement of raw materials and production of various final articles is given for four sectors: metals, textile (in cooperation with non-woven industry), paper and plastic. The examples are intended to illustrate the decision making process and it should be stressed that if in doubt, a careful examination in line with the indicative questions should be conducted. In line with this, the following examples should be applied with care taking into account the exceptions indicated in the text.

1 Aluminium processing as an example of metal processing

The example of aluminium processing shows the transition point in the processing of bauxite to final aluminium products. It should be noted that the processing of other metals (for example iron/steel) may show different transition points. The following figure shows the different processing stages and the respective status of the raw material.

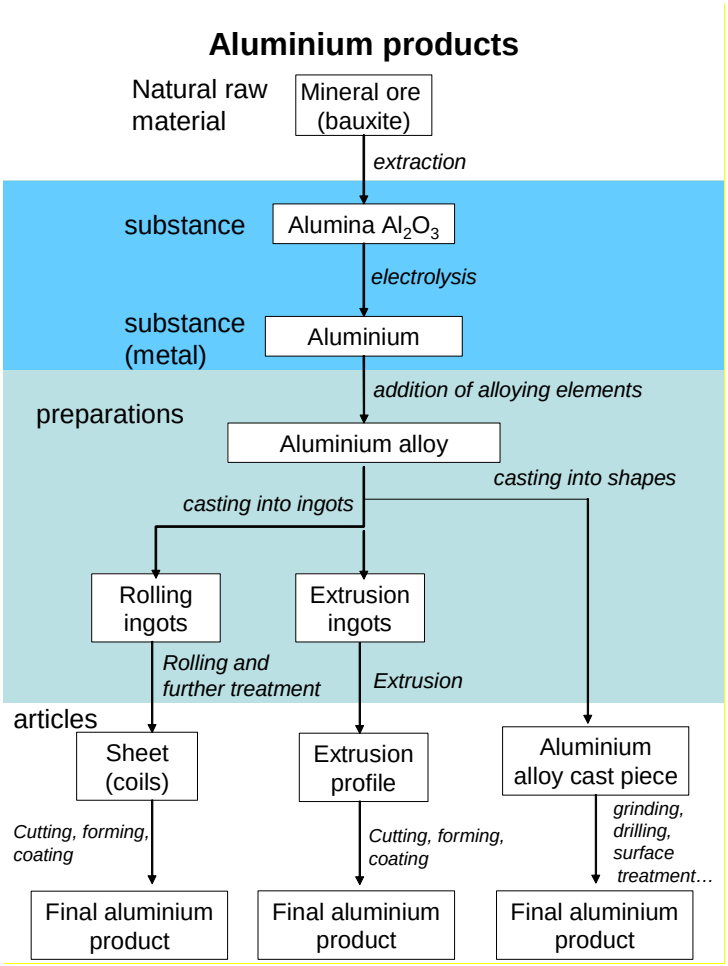

Figure 4 Transition from bauxite to final aluminium products

The transition point from mixture[23] to article is set between rolling ingots and sheets, extrusion ingots and extrusion profiles and aluminium alloy and alloy cast pieces. The decision process as supported by the indicative questions 6a to 6d in the main guidance could be as follows.

[23] formerly termed "preparation" as in the figure.

Table 10 Applying indicative questions to different stages of aluminium processing (part 1)

Object	**Rolling and extrusion Ingot**	**Coil / Extrusion profile**	**Final product, e.g. coated sheet/final product**
Question 6a: Does the object have a function other than being further processed?	**NO**, further processing such as cutting or stamping is required for achieving a definite function.	**YES**, aluminium extrusion profiles can often be directly used in construction work. Please note that other metal alloy coils may need considerable further processing and have no comparable end use.	**YES**, the coated sheet could be used for construction of vehicles. Modified extrusion profiles could be used in several applications such as tubes or, when anodised, as door and window frames.
Question 6b: Does the seller place the object on the market and/or is the customer mainly interested in acquiring the object because of its shape/surface/design (and less because of its chemical composition)?	**NO**, seller/buyer of rolling ingot offers/acquires a certain chemical composition. The shape of the ingot determines the nature of the next processing step (rolling), but is not considered more important than the chemical composition.	Ambiguous.	**YES**, the shape, surface and design of the material are normally of more importance for the buyer than the chemical composition.
Question 6c: When further processed, does the object only undergo only "light processing", i.e. no forming processes?	**NO**, before rolling/extruding, the ingots have no specific form. After the rolling/extrusion they are significantly enlarged and have a totally different shape, which is created deliberately during the process.	**YES**, the processing of coils to sheets and of extruded profiles to doors and window frames consists of "light processing" steps (e.g. cutting, coating). The materials have more or less the same shape before and after the process.	Not further processed.
Question 6d: When further processed, does the chemical composition of the object remain similar?	**NO**, the chemical composition could be changed during further processing of the material (e.g. application of surface coating).	**NO**, the chemical composition of the sheet could be changed during further processing (e.g. application of surface coating).	Not further processed.

Raw material types in the form of metal and alloy semi-finished products similar to coils and profiles are: bars, blanks (e.g. cut, machined, pressed, etc), coil (coated and uncoated), extrusion profiles, films and filaments, foil and ribbons, forgings, plate, pipe and tube (cast, seamless and welded), pipe and tube fittings, sintered semi-finished and final products, sheet and strip (coated and uncoated), stampings, wire rod and wire (coated and uncoated).

Below the two ways of processing aluminium ingots shown in figure 2 are discussed with regard to the borderline between mixture and article status.

Aluminium alloy - rolling ingots - coils

Rolling ingots do not normally have an end use function indicating that these would normally be mixtures. It is ambiguous and case dependent whether a coil has an end function in itself. In any case a cutting or stamping process is required for achieving a definite function. As this would generally be considered as light processing, this question indicates towards the coil being an article.

The interest of the buyer/seller in chemical composition versus shape/surface and design generally changes between the ingot and the coil/profile. Although the composition plays a role with regard to the quality of the material, the buyer would primarily look for the form of the objects. In the case of the rolling ingots, the shape is considered important (determines the next processing step), but normally not more important than the chemical composition. This is an indication that the ingot is a mixture, whereas the coil is normally an article.

Whereas the rolling ingots only determine into which type of processing the raw material is introduced next, the form of the coil already determines that only sheets can be produced from it. The rolling process significantly changes the form of the ingots in many ways. The cutting/stamping and further processing of the coil only results in modification of the basic shape and can be regarded as light processing. 'Light processing' in the sector covers for example cutting, drilling, piercing, surface treatment, coating, etc. but excludes processes such as melting, extrusion, sintering, etc. where the formed shape is destroyed or significantly changed. This is an indication that the status of the raw material is changed in the process of rolling into sheets/coils.

The basic chemical composition of the material (aluminium alloy) is not changed during the entire processing, although through coating or surface treatment (e.g. anodising) or lubrication (e.g. greasing, oiling, etc.) substances/mixtures may be added. This question is not a helpful indicator in this example, as it does not give clear indications on status of the raw material.

Aluminium alloy - extrusion ingots - extrusion profiles

Already the first question gives an unambiguous indication for the extrusion ingots having no end-use function and therefore indication for being mixtures, whereas the extrusion profiles, which can be used directly to fulfil a distinct function, have a clear indication for being articles.

The interest of the buyer/seller in chemical composition versus shape/surface and design generally changes between the ingot and the profile. The shape of the extrusion ingots is irrelevant with regard to the extrusion profile, thus the buyer of the ingots would only be interested in the chemical composition of the material. This is a clear indication that the ingots are mixtures.

The extrusion process significantly changes the form of the ingots in many ways, whereas the processing steps carried out with the extrusion profiles only result in modifications of that basic shape. This shows that the transition point of the material should be after the extrusion process.

The basic chemical composition of the material (aluminium alloy) is not changed during the entire processing, although through coating or surface treatment (e.g. anodising) or lubrication (e.g. greasing, oiling, etc.) substances/mixtures may be added. Also in this case, the question is not helpful in determining the transition point.

Table 11 Applying indicative questions to different stages of aluminium processing (part 2)

Object	Alloy ingot for remelting	Alloy cast piece	Final aluminium product
Question 6a: Does the object have a function other than being further processed?	**NO**.	**YES**.	**YES**, aluminium final products are used in the construction of vehicles, domestic appliances and, when anodized, for architectural and building applications.
Question 6b: Does the seller place the object on the market and/or is the customer mainly interested in acquiring the object because of its shape/surface/design (and less because of its chemical composition)?	**NO**, seller/buyer of alloy remelting ingots offers / acquires a certain chemical composition rather than a certain shape. The shape of the ingot does not determine the nature of next processing steps (melting and casting).	**YES**, the buyer of an alloy cast piece (casting) is interested in it having already the basic shape and design. The chemical composition is (normally) of less importance as compared with the shape/surface/design.	**YES**, the shape, surface and design of the material is normally of more importance for the buyer than the chemical composition.
Question 6c: When further processed, does the object only undergo only "light processing", i.e. no forming processes?	**NO**, as the shape of alloy remelting ingots is entirely lost during the melting process, they have no specific form. After casting, a totally different shape is developed, which is created deliberately during the process.	**YES**, the processing of alloy cast pieces (castings) to finished products consists of e.g. grinding, drilling, surface treatment. The materials have more or less the same shape before and after the process.	Not further processed.
Question 6d: When further processed, does the chemical composition of the object remain similar?	**NO**, the chemical composition of the alloy ingot is not changed during remelting, but afterwards the chemical composition of the alloy cast piece (casting) could be changed during further processing (e.g. anodizing).	**NO**, the chemical composition of the alloy cast piece (casting) could be changed during further processing (e.g. anodizing).	Not further processed.

Raw material types similar to the aluminium alloy cast piece are: castings (e.g. centrifugal, die, investment, sand, etc.), continuous cast shapes (e.g. bars, billets, blooms, rounds, slabs). A case-by-case consideration should normally be done to make the final decision on a material's status.

2 Textile and non-woven processing

Please note that this example cannot be directly applied for all types of (man-made) fibres. The figure shows the various processing steps and methods applied in the textile and non-woven industry. Irrespectively of the type of raw material (synthetic or natural material), the processing stage 'man-made textile and non-woven fibres' is regarded as an article. Thus, any further processing is seen as processing of articles.

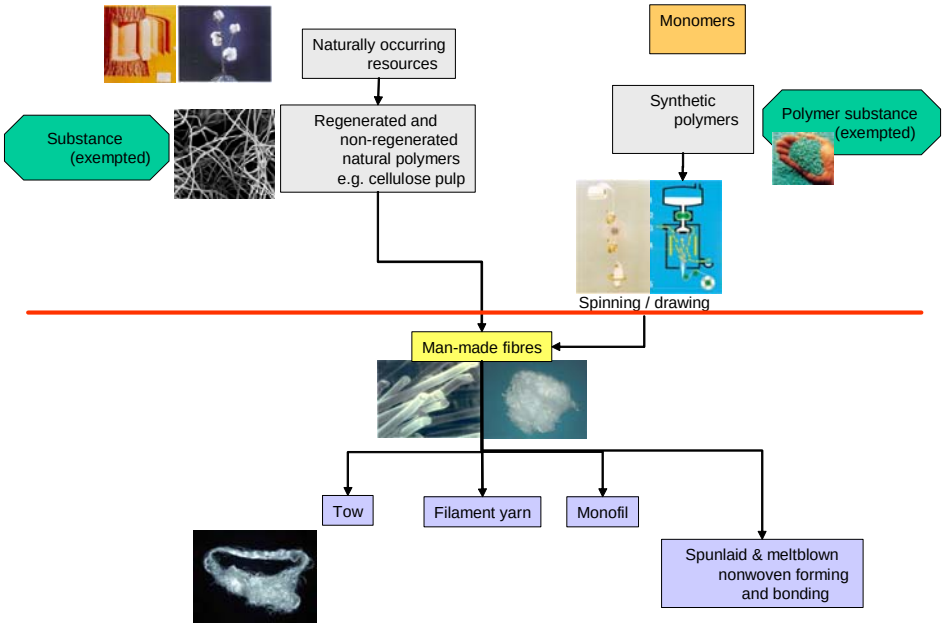

Figure 5 Transition from raw materials to final textile/non-woven products

Table 12 Applying indicative questions to different stages of textile/non-woven processing

Object	Synthetic polymer	Man-made fibre	Tow-rope
Question 6a: Does the object have a function other than being further processed?	**NO**.	**YES**, man-made fibres could for example be used as filling material for pillows or dental floss.	**YES**, tow-ropes have various functions.
Question 6b: Does the seller place the object on the market and/or is the customer mainly interested in acquiring the object because of its shape/surface/design (and less because of its chemical composition)?	**NO**, the interest in polymers is clearly in its chemical nature and not in its shape.	**YES**, the shape, surface and design of the material is normally more important for the person acquiring a man-made fibre.	**YES**, the shape of the tow-rope is more important for the buyer than the chemical composition.
Question 6c: When further processed, does the object only undergo only "light processing", i.e. no forming processes?	**NO**, the polymer does not yet have a specific form. By spinning/drawing fibres are produced which have a shape and design ('diameter') which are deliberately formed during processing.	**YES**, before the processing the fibres already have a specific form which is further developed in the next processing steps, such as cutting, twisting, finishing. The fibre itself exists in the same state as before but has been 'bundled'.	Not further processed.
Question 6d: When further processed, does the chemical composition of the object remain similar?	**NO**, the composition is changed before extrusion (additives, cross-sectionalisation).	**YES**, the chemical composition of the man- made fibre may be changed in order to enhance its processability, or through dyeing. The basic composition of the fibre is however the same.	Not further processed.

For the man-made fibre, for some applications the first question can be answered unambiguously, as the man-made fibres already have a function other than being further processed whilst for other applications the main function is the further processing. Thus the fibre in principle can be an article already. The same applies to the tow rope.

The buyer of a man-made fibre is normally most interested in acquiring a material with a specific shape, rather than a certain composition. The fact that fibres with different composition can substitute each other is another indicator of the greater relevance of physical properties.

The buyer of a tow-rope is undoubtedly more interested in the shape of the tow-rope than in its chemical composition.

The type of extrusion/drawing determines the diameter of the fibre and therefore it is the processing step that deliberately forms the shape of the fibre. Further properties like strength, elongation and shrink are given to the fibres in this step as well. The man-made fibres are 'assembled' in different processes to form the final products, like the tow rope. These processes are mainly mechanical and do not change the base structure of the fibre, but simply 'aggregate' it to larger units.

The basic chemical composition of the polymer may be changed after the extrusion/drawing through various types of processing (depending on the type of further processing).

The example shows that the stage at which the function is determined by shape, surface and design may be very early in the raw materials processing. Furthermore, the design is the relevant physical property of the fibre, as its overall shape does not change significantly in the further processing.

3 Polymer processing

In the polymer processing industry, the transition point from mixture[24] to article is defined after the conversion of polymer pellets. The conversion process is what transforms the mixture into an article. The figure shows one example product / process which can be regarded as typical for the polymer processing industry and therefore represents also other processes like calendaring, injection moulding, etc.

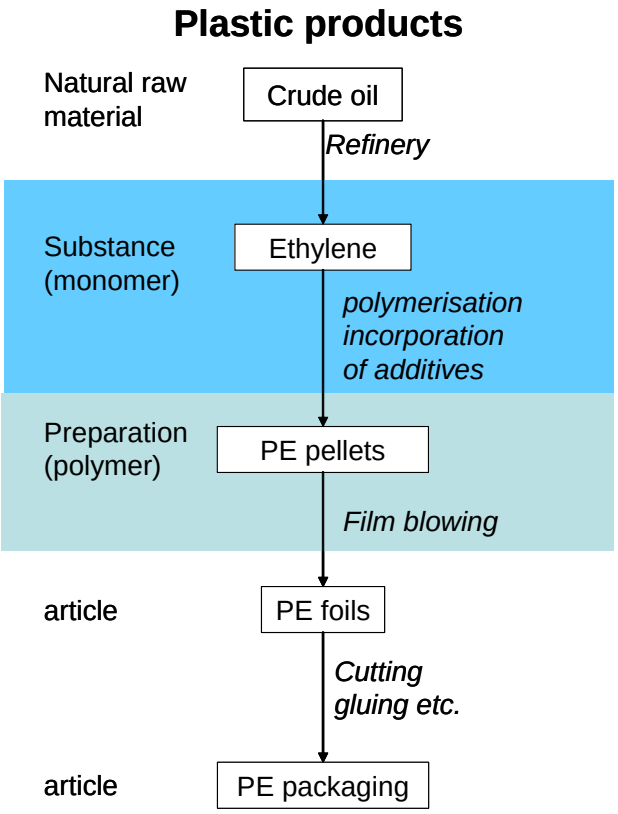

Figure 6 Transition from crude oil to plastic products

[24] formerly termed "preparation" as in the figure.

Table 13 Applying indicative questions to different stages of polymer processing

Object	Polymer pellet	PE-foils	PE packaging
Question 6a: Does the object have a function other than being further processed?	**NO**.	**YES**, direct application as packaging possible, also without further processing.	**YES**, packaging.
Question 6b: Does the seller place the object on the market and/or is the customer mainly interested in acquiring the object because of its shape/surface/design (and less because of its chemical composition)?	**NO**, the converter selects polymer pellets according to their chemical composition. The shape is not relevant.	**YES**, the buyer of foils is most interested in its shape. For many functions foils of different chemical composition can be used.	**YES**.
Question 6c: When further processed, does the object only undergo only "light processing", i.e. no forming processes?	**NO**, the conversion unit causes the deliberate formation of a shape of the polymer material, which determines its function.	**YES**, further processing doesn't change the design but only modifies it.	Not further processed.
Question 6d: When further processed, does the chemical composition of the object remain similar?	**NO**, before extrusion, additives are mixed into the raw material to obtain certain functionalities.	**YES**, the chemical composition of the foil itself does not change in the further processing steps, but it could be printed onto.	Not further processed.

Whereas the polymer pellets do not have an end use function yet, the converted materials are likely to have one. In the example, the PE foil can directly be used for packaging and can also be used and modified in further processing.

In the conversion unit, the structure and design of the polymer compounds is changed. In the resulting material the design and structure is kept during further processing.

For the polymer sector, this means that processes including for example, but not limited to, pipe extrusion, film blowing, blow moulding, sheet forming, rotomoulding, foaming, compression moulding, fibre spinning or tape slitting calendaring, coating or injection moulding mark the 'red line' between mixture and article.

4 Paper processing

The transition point from mixture[25] to article is between the stock and the dried paper.

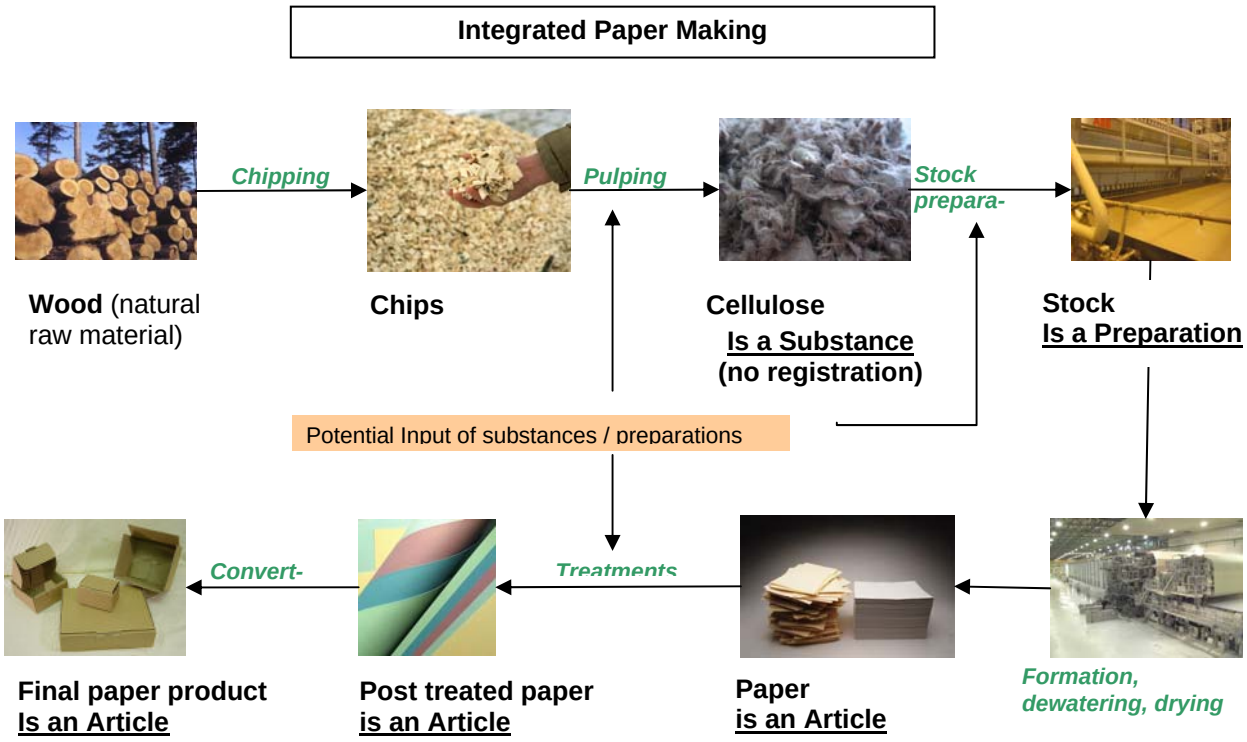

Figure 7 Illustrative example of the general transition point from wood to paper articles

[25] formerly termed "preparation" as in the figure.

Table 14 Applying indicative questions to different stages of paper processing

Object	**Stock**	**Paper**	**Postcard**
Question 6a: Does the object have a function other than being further processed?	**NO**.	**YES**, could be used e.g. for packaging.	**YES**.
Question 6b: Does the seller place the object on the market and/or is the customer mainly interested in acquiring the object because of its shape/surface/design (and less because of its chemical composition)?	**NO**, stock is mostly liquid and thus does not have a shape, surface or design, yet.	**YES**, for the buyer the shape of the paper is most relevant.	**YES**.
Question 6c: When further processed, does the object only undergo only "light processing", i.e. no forming processes?	**NO**, after dewatering/drying the stock is given a specific shape, surface and design for the first time.	**YES**, further processing (here: cutting, printing) does not change the basic design. Although shape & surface are modified, the properties of the 'paper' already determine the function.	Not further processed.
Question 6d: When further processed, does the chemical composition of the object remain similar?	**NO**, chemicals may be added.	**YES**, just surface treatment, gluing etc. may add substances.	Not further processed.

The paper as obtained from the paper machine could already have an end use function, e.g. packaging of filling material. Although it is further processed to better fulfil a specific purpose, the paper already has a function apart from being raw material for further processing.

The dewatered paper is the first stage of the raw material, which does have a specific shape, surface and design. Any previous production stages of the raw material can therefore not represent an article status.

The further treatment of paper may change the overall shape of paper significantly. However, the design is not changed.

APPENDIX 3: ILLUSTRATIVE CASES FOR CHECKING IF REQUIREMENTS UNDER ARTICLE 7 AND ARTICLE 33 MAY APPLY[26]

#This appendix is not part of the present consultation, it will be revised and submitted for consultation at a later stage.#

Case study on intended release from articles - work processes under REACH Article 7(1)

Scented children's toys

Description of case

Scented children's toys are chosen as an example of articles with intended release.

As no specific toy study was identified, a study on scented felt tip pen/markers was used to establish some basic information (Danish EPA-unpublished[27]). It is *assumed* that the results from that study are representative in the case of these scented toys and the same process of data collection is assumed to have taken place for children's toys.

Please note that in case a felt tip pen would have been considered, the release of ink (in an analogy with other writing/printing materials – see Appendix 2) would be considered a preparation in a container, whereas the scent in such a pen would provide an accessory function and therefore be a case for registration under Article 7(1).

The case is chosen to illustrate the difficulties that an importer of articles may face if he cannot get any information on the substances contained in the imported article from his suppliers.

The following is assumed:

- Import per year: 1 million scented toys
- Weight of toy part containing the fragrance: 2 g
- No information on content of substances to be released
- No information on registration
- Results on the analysis from the survey report are assumed to be performed on the toys by the importer

Substance identity

In order to identify the substances intended to be released, the importer of the scented toys could take the same approach as in the Danish study on felt tip pens, the process of which is quoted here:

---

[26] Dissenting views (http://reach.jrc.it/docs/guidance_document/dissenting_en.pdf), questioning the application of the 0.1% threshold to the entire article have been notified by six Member States in writing (Austria, Belgium, Denmark, France, Germany and Sweden) and publication of this part of the guidance document was not endorsed by these Member States.

[27] The survey report concerns the release of fragrance substances from children's play toys including scented markers. In the report fragrance substances and volatile substances were analysed. The study included a screening of substances contained in the inner part of the pen as well as the emission of substances from the pen.

In the Danish study, in order to obtain information on the substances to be released from the pens the following analyses were done:

1 Analysis on fragrances (24 in total) classified as sensitising by EU's Scientific Committee on Cosmetics (SCCNFP 1999). Pens with different smells, Lemon and Strawberry, were examined. The analysis was carried out on the inner part containing the fragrance.

2 The pen with lemon scent was examined in an emission test to analyse the release.

3 Screening for extractable organic compounds by GC/MS.

A total of 11 sensitising fragrance substances were found in the analysis on fragrances and substance names and CAS numbers could be identified. During the emission test various compounds were detected and identified by substance name. Only one substance was identified by name in the screening for extractable compounds. The CAS numbers were searched in an online database for toxicological data (Thomson Microdex). Classification was searched for in lists from the Danish EPA. It was not possible to find the CAS number for all the identified substances using the available substance name.

Transferring these results to the importer making a chemical analysis for the children's toys, although able to identify a few substances by chemical name, from which he could also derive a CAS number, he may not be able to derive further information on their identity, in terms of their composition. To illustrate the further work process it is assumed that the substance D-limonene, which is a fragrance, exceeds the tonnage threshold in the children's toys of the importer and is thus chosen for registration.

Check for existing registration

Having the substance name and CAS number available the importer has the possibility to ask the Agency if the substance has been registered. Assuming that it has not been registered, yet the importer would proceed.

Information on concentration of the substance

In the Danish survey, the concentration of D-limonene was determined for the inner part of the pen. The classification was obtained from data bases.

Table 15 Further information gathering on D-limonene in the pens (Danish Survey)

Substance	***CAS no***	***Classification***	***Concentration (mg/kg (inner part))***
D-limonene	*5989-27-5*	*R10 Xi;R38 R43 N;R50/53*	*800*

Information on amount of substance used

Based on the assumptions for the case of the importer, the quantity of D-limonene in the scented toys can be calculated as the amount in each toy multiplied by the amount of toys imported annually. The annual amount of D-limonene in the toys is 1.6 kg/a, which is below 1 t/a.

(800 mg/kg × 0.002 kg/toy × 1,000,000 toys/a)

It can also be calculated how many toys the importer can import before reaching the threshold of 1 t/a on D-limonene:

$$\text{Number}_{\text{article}}\ [\text{number of toys/a}] < \frac{1\,[t/a]}{1.6\ mg/toy} = 625 \text{ mill. toys/a}$$

Illustration of the decision process on registration

Example: Toy with lemon scent (D-limonene)

Consult Chapter 1:

Are you the first EU producer or importer of the object?

YES

Is your object an article?

YES, the company imports toys which are articles, because the shape determines its purpose.

Consult Chapter 4 "Checking if requirements under Article 7 or 33 apply":

All types of requirements could apply, as substances are released during the use of the article. The release is an additional quality of the toy and the release is therefore intended, otherwise the article would not smell. Furthermore, SVHCs could be contained in the toy as well.

Go to Chapter 5 and 6 on registration of substances intended to be released and on SVHCs in articles

As the importer has no information except the results from the chemical analysis he could do the following:

1) Collect information on sector knowledge and typical content of substances in this type of article, standards like the toys directive etc. He would compare that information with the candidate list for authorisation and may have doubts whether he can exclude SVHCs. He does not find information on the fragrances intended to be released.

2) Check the supply chain requesting if any of the substances on the candidate list is included in the article/substances / preparations used to produce the article or receive confirmation that they are not present in the article. Check the supply chain and ask if the supplier of the fragrance substances can be identified. If yes, he may try to obtain a safety data sheet.

3) Plan and perform screening for substances on the candidate list by analytical methods if no information is obtained from the suppliers and content of SVHCs is likely (→ results above).

4) Check if identified substances are listed on the candidate list. (The emission test revealed the presence of compounds classified with R50/53 and R51/53. After establishment of the candidate list the list should be consulted for these compounds, as they may potentially fulfil the criteria as PBT/vPvB).

5) Calculate the amount of substances identified in the screening analysis and assess whether the tonnage threshold could be exceeded for registration.

Work process for calculating the amount (Step 5)

1. Is the total volume of articles > 1 t/a (all articles should be considered and summed up)?

YES. 1 million toys containing 2 g of parts containing fragrance makes the total volume of articles at least 2 t/a.

2. Total amount of the preparation > 1 t/a (all such articles in a company should be considered)?

YES. The fragrance is included in light felt of very low weight, thus the total volume of fragrance is approx. 2 t/a.

3. Identify each substance intended to be released from the article.
A total of 11 fragrance compounds were identified to be contained in the toy. During the emission test various compounds were detected and some of the detected compounds were identified with a CAS number and classification. The output from the analysis was the substance name only. The C&L inventory to be established should be consulted in order to obtain a CAS number and classification.

Further steps in this case are focused on D-limonene, which was identified in the chemical analysis.

4. Substances exempted from registration?
The guidance should be consulted after establishment to find out if the substance is exempted from registration.

5. Check for existing registration for that use
Having the substance name and CAS number available the importer has the possibility to ask the Agency if the substance has been registered.

6. Determine the amount of each substance intended to be released (all such articles in a company should be considered and summed up)
Based on the chemical analysis, the content of D-limonene intended to be released is determined to be 800 mg/kg in the inner part of the toy. The content of D-limonene in the toy is 1.6 mg as the weight of the inner part was 2g.

7. Total amount > 1 t/a?
Is the total amount of this substance in all such articles in the company above the threshold volume of 1 t/a. It is assumed that this toy is the only article containing D-limonene and imported by the company. The annual amount of D-limonene is calculated to be 1.6 kg.

Registration of D-limonene is not required for use in felt tipped pens

Comments on the case

In the Danish survey, only pens with two different fragrances were analysed; strawberry and lemon. In the example, the importer may import toys with several other fragrances, which also have to be examined. Each individual substance to be released has to be identified.

Only 24 selected fragrances were analysed for content in the article. There are more substances present in the felt tip pen, therefore an emission test was also done. In the emission test a range of volatile substances released into the air was identified. Here, only the release was analysed and not the content. The emission test did not include the fragrances.

The analysis for fragrances and the emission test, where specific known compounds were searched for in the entire article (extraction of content of the pen) and in the substances released (emissions were captured and analysed) was supplemented by a GC-MS screening for extractable organic compounds, where any compound is detected and characterised by a spectrum. However, the compounds found in the emission test were not found in the GC-MS analysis, hence the content of the volatile substances could not be determined using this method.

This case illustrates how difficult it is to provide full documentation on substances to be released from the article based on chemical analysis. If possible, the documentation of the identity and quantity of substances to be released from the article should be based on composition of the formulation used for the article. In case of imported articles the documentation might include supporting documents as letters from the suppliers or by certificates stating the content of e.g. fragrances in the article.

Case studies on notification of substances in articles according to Article 7(2) under REACH

CASE 1: Clothes

Description

Clothing was selected to exemplify a situation where exposure could be expected. Furthermore, the example represents a case from a sector subject to intense (media) interest and comprehensive knowledge about chemical substances in their articles. The company NN, which participated in this case, has already established a programme, which sets demand to the content of dangerous substances in products from their suppliers. This has resulted in a phase-out of SVHCs in their textiles.

Criteria for selecting clothes

- Users and application: A large group of users and a wide application; The users include vulnerable groups such as children
- Type of material: Represents a material used in many other articles than clothing, which could make the case applicable for other producers/importers of articles
- Exposure scenarios: An example of possible direct exposure to skin and migration of substances
- Supply chain pattern: Represents a supply chain with high degree of imported articles and minor production within the EU
- Documentation: A Swedish company, NN provided information on their import of belt buckles

Producer/Importer of articles

The selected company imports belt buckles and jewels from a non-EU Member State. Therefore, the role of the company in the supply chain is as EU-importer of articles in relation to the belt buckles.

Substance identity

The company must consult the candidate list for authorisation. This should be done as soon as the list is made available by the Agency. Metallic lead, which was focused on in this case study, is not classified in the Annex I of Directive 67/548/EEC. However, an ongoing voluntary risk assessment is being conducted by the lead industry. It is assumed in the example that metallic lead is a possible candidate to Annex XIV[28].

The company explained that it is often difficult to obtain complete lists of chemicals from the suppliers. However, this is not necessary when a company has to check whether he has obligations according to the Articles 7(2) and 33. The suppliers could be asked directly about the content of the specific substances on the candidate list.

[28] Note that substances fulfilling the criteria of article 57 can be included on the candidate list only according to the procedure described in article 59. For more information see the Guidance on Preparing an Annex XV dossier for identifying SVHC and Guidance on Inclusion of Substances to Annex XIV of REACH.

Check for existing registration

To be done when REACH enters into force.

Information on concentration of the substance

There is no obligation to deliver SDS for articles or other information from non-EU Member States. The alternative ways to obtain information suggested in Chapter 4, 5 and 8 of this guidance could be applied, based on considerations about the simplest way to obtain the information required.

In this case, the company has an upper limit for the content of lead in the belt buckles at 0.3% (w/w) and in their jewellery at 0.01% (w/w). The use of these maximum concentrations in the assessment will give a worst case scenario.

The alloy used in the buckle was not made known in this case. However, it should be noticed that the chemical compositions of most alloys are published as national, European or international standards. If an alloy is not standardised, its chemical composition can usual be obtained by routine chemical analysis.

Information on amount of substance used

The total yearly amount of lead in the articles of the company was estimated on the basis of the amount of belt buckles imported the year before. The calculations were based on the total amount of belt buckles imported and the maximum concentration of lead in a buckle at 0.3%.

Illustration of the decision process on registration

Example: Company A - Metallic lead in belt buckles

Consult Chapter 1:

Are you the first EU producer or importer of the object?

YES

Is your object an article?

YES, belt buckles and jewels are articles

Use Chapter 4 "Checking if requirements under Article 7 or 33 apply":

1. Is there an intended release from the article?

NO

Conclusion for registration: No need for registration.

2. Does the article contain SVHCs - included in the candidate list?

The list has to be checked when it is available. Metallic lead (7439-92-1) is not classified in the Annex I of Directive 67/548EEC but it is a substance with properties of very high concern, which might be included in the candidate list. In this example it is assumed that it will be on this list.

YES

Go to Chapter 6 "Checking if Article 33 applies and if notification is required":

1. Determine the concentration of the SVHC, which in this example is lead

The company limit for lead in jewels is 0.01% (w/w), which is below the threshold limit at 0.1% (w/w). For lead in a functional item as a buckle the company limit is 0.3% (w/w). Thus the maximum concentration of lead in the buckles exceeds the threshold limit. It is not possible for the company to analyze large parties of buckles and they assume that the concentration in all buckles is 0.3% (w/w). The company imports approx. 13,000,000 buckles per year (in total approx. 650 different orders/styles).

Based on experience from tests it is known that most of the buckles contain much less than 0.1% of lead, however, it is not documented by chemical analysis or certificates from the supplier.

Concentration above 0.1% (w/w)?

YES. **Conclusion after this step: communicate information according to Art. 33 and continue to the next step in the assessment.**

2. Is the SVHC (lead) intended released?

NO. Continue

3. Has the substance already been registered for that use?

To be checked after REACH has entered into force. It is assumed that lead isn't registered for that use: → NO.

4. Determine the amount of the SVHC (lead) present in all articles

The buckles are the only articles brought into the EU by the company with a lead concentration above the threshold limit at 0.1%. The total amount of lead brought into the EU per year in all the buckles is:

The import of buckles in 2005: 13,000,000 items

The weight of one buckle: 100 g

The maximum lead concentration in a buckle: 0.3% (w/w)

Calculation of the total lead amount in the buckles in 2005:

- The total amount of lead: $(0.3 \cdot 0.01) \cdot (100 \cdot 10^{-6}) \cdot 13{,}000{,}000 = 3.9$ t per year

5. Is the total amount of the lead > 1 t/a?

YES. The total amount of lead brought into the EU-market is 3.9 t/a. This amount exceeds the threshold limit at 1 t/a.

6. Can exposure be excluded during normal or reasonable foreseeable conditions of use?

The function of the substance in the articles:

A small amount of lead lowers the melting point of the alloy. Lead would almost certainly be present as discrete particles in the matrix of the alloy and as such it would retain its own intrinsic properties.

The use(s) of the article:

Normal use(s): The importer sells the belt buckles to companies, which are producing belts of e.g. leather for both children and adults.

Reasonable foreseeable use(s): If the producer of the belts treats the buckle in such a way that particles are emitted from the buckle e.g. at grinding or sand papering, appropriate protection has to be used. If soldering or welding is used, lead will be emitted in the form of gas and appropriate protection has to be used. Furthermore, children may suck on the buckle in the end use situation.

Potential for emission during use(s) and disposal – Looking at the routes of exposure:

The routes of exposure in the case of metallic lead are by inhalation and by ingestion. Inhalation can be discounted in this case. However, it is within the realms of possibility that lead may be transferred from the buckle to the hands of the consumer and subsequently ingested.

Furthermore, it cannot be excluded that there will be a release of lead from the metal buckle after disposal.

Lead has been used in articles for many years. Therefore, it would be obviously to look for further information for 'that use' of lead in sector organisations, the open literature and databases. Look for emission of lead from buckles and similar materials and exposure of humans and the environment.

Can exposure to humans or environment be excluded?

NO

Conclusion: Notification is required

Go to Section 6.11

Communicate information to the recipients according to Art. 33

Comment on the case

The case illustrates the possibility of using the maximum concentration or company upper limit of a specific SVHCs in articles as a worst case scenario for assessing whether an importer has an obligation under Articles 7(2) and 33. The use of the maximum concentration leads to the conclusion that both notification and communication of information is required. A next step could include a more precise determination of the lead concentration in the buckle by chemical analysis if applicable. The information to be delivered within the supply chain, according to Article 33 could e.g. include recommendations of protective equipment to be used during production of the finished belt and instructions on waste handling.

The results obtained completing the workflows 1 and 2 in this guidance could be documented in a table e.g. as in the example above either on paper or electronically. Certificates from suppliers of the articles stating the limits of the SVHCs, results of possible chemical analyses and data of the imported articles volumes could be annexed. Documentation procedures to be followed during the assessment of obligation under Article 7 and 33 could be implemented e.g. as a part of a possible existing quality management system.

CASE 2: Automotive tyres

Description of the case

Tyres were selected as a case due to existing knowledge about the polycyclic aromatic hydrocarbons (PAHs) contained in high aromatic (HA) extender oils, which are used in the production of tyres. The present case study should, however, not be considered as a complete study covering all aspect of the use and risks of PAHs in tyres. Furthermore, the case is not based on the knowledge of a single producer or importer but the sector knowledge within EU.

Automotive tyres are a complex and high-tech safety product that consists of a mixture of synthetic and natural rubbers, textile and metal reinforcing materials and a wide range of additives (e.g. high aromatic extender oils, zinc oxide, etc.) to ensure the finished tyre's performance, durability and safety. As tyres are the vehicle's only contact point with the road surface, they are of great importance to road safety. The tyre is here considered to cover both winter and summer tyres for cars, trucks, buses and trailers.

Users are in contact with new tyres via two routes. One is through the 'original equipment market' where tyres are mounted on the wheels of a new car. The other is the 'replacement market' where old tyres are replaced with new ones. The retreating market belongs to the replacement market, but it is a special case as it is only the tread, which is new.

The so-called 'End of life tyres' (ELTs) are covered by producer responsibility in the majority of EU member states. These ELTs are used for various applications, such as: alternative fuels, retreating, and material recycling. In Sweden the predominant use of unwanted tyres is as alternative fuel. A smaller part is recycled and retreaded. Granulates and shredded tyres could also be used in civil engineering projects as materials beneath the road surface and beneath buildings.

Criteria for selecting tyres

- User groups and application: Widespread use
- Supply chain pattern: Represent a supply chain with a considerable part (70%) of the production located within the EU
- Exposure scenarios: Exemplifies exposure to environment and a case where substances are contained in wear off from the article
- Documentation: Existing knowledge from a former project performed by KemI, Sweden (1994)[29] and information delivered by BLIC (The European Association of the Rubber Industry)

Producer/Importer of articles

The case has not been developed for a specific company but illustrates a general scenario where the tyre is produced within the EU. The scenario is also applicable for imported tyres.

Substance identity

The company must consult the list of SVHCs on the candidate list for authorisation. It should be done as soon as the list is made available by the Agency (Chapter 6).

[29] KemI (1994). Nya hjulspår – en produktstudie av gummidäck (New Wheel Tracks - a product study of rubber tyres). Report 6/94

It was decided to focus on the high aromatic (HA) extender oils, which are classified as category 2 carcinogens on the basis of their content of PAHs that are present as impurities in the oil. It is assumed that some of the PAHs will be on the candidate list of SVHCs mentioned above.

PAHs are a complex 'group' of substances and many of them are harmful to health and the environment. They are in fact the largest group in number of carcinogenic substances known today. Many of their effects are linked to the flat structure of the molecules and their ability to affect the DNA in the cell nucleus. Most living organisms can convert PAHs, but the products formed during the degradation are often more harmful than the original substance.

Several of the individual PAHs contained in HA oils are classified as Category 2 carcinogens in the Community wide classification list (KIFS 2001:3). The PAHs classified according to this system are listed in Table 13. Several of them are also included in the Water Framework Directive and international conventions due to their inherent hazardous properties.

It has to be noticed that the marketing and use of these HA-oils in tyres will be banned as of the 1st of January 2010. The tyre industry is currently working on the substitution of HA-oils, with alternative non-carcinogenic oils.

Table 16 Some important properties of some of the PAHs in HA oil

Substance	**Persistent**	**Bioaccumulative**	**Carcinogenic[30] (Cat. 2)**
Antanthrene			(+)
Benzo(a)anthracene	+	+	+
Benzo(a)pyrene	+	+	+
Benzo(b)fluoranthene	+	+	+
Benzo(e)pyrene		+	+
Benzo(g,h,I)perylene	+	+	-
Chrysene	+	+	+
Dibenzo(a,h)antracene	+	+	+
Fluoranthene	+	+	-
Indeno (1,2,3-c,d)pyrene	+	+	-
Pyrene Benzo(j)fluoranthene Benzo(k)fluoranthene	+	+	- + +

The criteria for persistence and bioaccumulation originate from the TGD[31]
The criteria for persistence and bio-accumulability originate from the TGD[32].
+ = persistent, bioaccumulative or classified as category 2 carcinogenic in the Community-wide classification list (KIFS 2001:3).
(+) = has caused cancer in experimental animals but is not classified as carcinogenic.
? = too few studies are available to assess whether the substance is carcinogenic.
- = negative result.
Blank box = studies lacking.

[30] Source IPCS, 1998.

[31] Technical guidance document in the program for existing chemicals

[32] Technical Guidance Document/Technical guidance document in the programme for existing substances in the EU.

Check for existing registration

To be done when REACH comes into force.

Information on concentration of the substance

The content of HA-oils in a tyre depends on which kind of tyre is under examination. An average passenger car tyre for the EU market contains approximately 600 g of HA-oil. The oil is dissolving in the rubber mixture but is not reacting chemically. The PAH content in these HA-oils is less than 400 ppm and the typical average values vary between 100 - 200 ppm.

The concentration of PAHs in tyres was calculated for the worst case scenario and the average situation on the bases of the total weight of a tyre and the PAH content of the extender oils (Table 9). The calculation was based on Life Cycle Assessment (LCA) of an average European passenger car tyre made by BLIC.

Table 17 Calculation of amounts of PAHs in average passenger car tires on the EU market

Weight of an average European passenger car tyre	oil content in the tyre	PAHs content (ppm = µg/g) in the oil					
		400		200		100	
		mg in tyre	% in tyre	Mg in tyre	%	mg in tyre	%
8700 g	600 g	240	0,003	120	0,001	60	0,0007
		= 27,6 ppm		= 13,8 ppm		= 6,9 ppm	

The figures in Table 9 show that the total concentration of PAHs in tyre is much below the threshold limit for notification (Art. 7(2)) and communication of information down streams (Art. 33) at 0.1 % (w/w). Therefore, it is obvious that the concentration of individual PAHs is << 0.1%.

Information on amount of the substance produced per company and year

This is not relevant in this case as the concentration limits are not exceeded. This case does not provide any company specific data on production volumes.

Illustration on the decision process for one company checking his obligation according to Articles 7 and 33)

Example: Tyres containing high aromatic extender oils

Consult Chapter 1:

1. Are you the first EU producer or importer of the object?

YES

2. Is the object an article?

YES, tyres are articles

Use Chapter 4 "Checking if requirements under Article 7 or 33 apply"

3. Is there an intended release from the article?

NO

Conclusion on registration: No need for registration

4. Does the article contain SVHCs – included in the candidate list?

YES. HA oils classified as Category 2 Carcinogen due to their content of PAHs, which are an impurity generated in the production process of the HA oil. For the purposes of this example, it is assumed that DEHP has been included on the candidate list.

It shall be noticed, that following the 27th Adaptation to Technical Progress (ATP) of Directive 76/769/EC, the marketing and use of high aromatic oils for the product of tyres will be banned as of 1 January 2010 and a substitution process is ongoing.

Go to chapter 6: "Check if Article 33 applies and if notification is required"

5. Determine the concentration of the SVHCs

The concentration of the PAHs (group of substances) in the oil is 400 ppm in a worst case scenario and between 100 and 200 ppm (mg/kg) in average. It shall be noticed that this is the value for the PAHs as a group of substances. The concentration of PAHs per tyre from the oil varies between 27 (worst case) and 7 ppm, as illustrated in Table 12. This demonstrates that the PAH content in the tyre is below threshold at 0.1%.

6. Concentration above 0.1% (w/w)?

NO → STOP: It is not necessary to continue the assessment process.

Conclusion: Notification is not needed. Communication of information to recipients is not required

Comment on the case

The case illustrates how sector knowledge may be used in the assessment of whether a producer/importer has obligation under Articles 7 or 33.

Based on the knowledge of the PAHs content in the aromatic oil applied in the production of tyres, it can be concluded that the concentration of the possible SVHCs in the tyre are well below the threshold limit of 0.1%. Therefore, neither notification according to the Article 7(2) nor communication of information to the recipients according to Article 33 is required.

The results obtained completing the workflows in this guidance could be documented in a table e.g. as in the example above and the results of chemical analyses and the data for the yearly produced/imported articles volumes could be annexed. The documentation procedures to be applied during the assessment could be implemented e.g. as a part of a possible existing quality management system.

CASE 3: Bath mattress

Description

The case of bath mattresses presented below illustrates the different steps in the notification process and could be used as a guidance to understand the different steps in the flow chart. Di-(ethylhexyl)-phthalate (DEHP) in bath mattresses has been used as an example due to the following reasons:

Criteria for selecting Bath mattresses

- Users and application: Large user groups. The users include vulnerable groups such as children
- Type of material: Represent a material used in many other articles, which could make the case applicable for a range of different article producers/importers
- Exposure scenarios: An example of possible direct exposure to skin and migration of substances
- Supply chain pattern: Represents a supply chain with a high degree of imported articles
- Documentation: The case is built on a real example but has been adjusted to illustrate the different steps in the notification process
- Likeliness for the substance to be included in the candidate list and/or Annex XIV. DEHP is a CMR substance and may be on the candidate list for eventual inclusion in Annex XIV

Producer/Importer of articles

The bath mattresses are imported from a non-EU Member State and then distributed to retailers within the EU.

Substance identity

The physical and chemical properties of the phthalates have made them suitable as plasticisers in polymers such as plastic and rubber

Plasticisers are not permanently bound to the PVC polymer, and phthalates are therefore released from plastic products throughout their lifetimes. DEHP are classified as toxic and toxic to reproduction, i.e. they cause reduced ability to reproduce and damage to the unborn child.

The company must consult the candidate list for authorisation. It should be done as soon as the list is made available by the Agency (Chapter 6). In this example it is assumed that DEHP is a possible candidate for inclusion in Annex XIV.

Check for existing registration

To be done when REACH comes into force.

Information on concentration of the substance

In accordance with the legislation the company has substituted DEHP in toys but it is still used as softener in other articles. The importer of the mattress has been informed that the concentration of DEHP is 30% (w/w).

Information on amount of substance used

The total yearly amount of DEHP in the articles of the company was estimated on the basis of the amount of mattresses imported the year before. The calculations were based on the total amount of bath mattresses imported and the concentration of DEHP in a mattress at 30.0%. (See calculations below)

Illustration of the decision process on registration

Example: Company B – DEHP in bath mattresses

Consult Chapter 1

1. Are you the first EU producer or importer of the object in the supply chain?

YES, we import bath mattresses

2. Is your object an article?

YES, the bath mattress is an article

Use Chapter 4 "Checking if requirements under Article 7 or 33 apply":

3. Is there an intended release from the article

NO

Conclusion for registration: No need for registration

4. Does the article contain an SVHC included in the candidate list?

The list has to be checked when available. DEHP is classified as toxic and toxic to reproduction and which are criteria for inclusion on the candidate list. For the purposes of this example, it is assumed that DEHP has been included on the candidate list. → YES

Go to Chapter 6: "Check if Article 33 applies and if notification is required"

5. Determine the concentration of the SVHC, which in this example is DEHP

To determine the concentration limit the company asked their supplier for information. The supplier informed that the concentration of DEHP was 30% (w/w) in the mattresses. No test protocols were available from the supplier to confirm concentration levels and the company did not find any reason to question the information given by the supplier.

6. Concentration above 0.1% (w/w)?

YES. The concentration of DEHP in the bath mattresses exceed the threshold limit at 0.1%

Conclusion for this step: "Communicate information according to Art. 33" and continue to the next step in the assessment.

7. Communicate information according to article 33

As the bath mattress contains more than 0.1% DEHP and is distributed to retailers within the EU. The company has to give information to allow safe use of the article. Information to be considered as important is the following:

- *Substance name: di(ethylhexyl)phthalate*
- *CAS. No: 117-81-7*
- *Registration No: not available for the time being*
- *Classification: R 60-R61 is classified as toxic and toxic to reproduction, i.e. the substance causes reduced ability to reproduce and damage to the unborn child*
- *Exposure control: Avoid long term dermal contact by children or pregnant women*

8. Is the SVHC intended to be released?

NO. Continue

9. WF3: Has the substance already been registered for that use?

To be checked after REACH has entered into force. It is assumed that DEHP isn't registered for that use: → NO.

10. Determine the amount of the SVHC (DEHP) present in all articles?

The DEHP concentration in the mattresses is > 0.1% and therefore, the total amount of DEHP brought into the EU-market in the mattresses has to be considered. The total amount of DEHP per year in all imported mattresses is:

- The import of mattresses in 2005: 150,000 items
- The weight of one mattress: 900 g
- The maximum DEHP concentration in a mattress: 30% (w/w)

Calculation of the total DEHP amount in 2005:

The total amount of DEHP: $(30 \cdot 0.1) \cdot (900 \cdot 10^{-6}) \cdot 150{,}000 = 40.5$ t per year

11. Is the total amount of the DEHP > 1 t/a?

YES. The total imported amount of DEHP is 40.5 t/a. This amount exceeds the threshold limit of 1 t/a.

12. Can exposure be excluded during normal or reasonable foreseeable conditions of use?

The function of the substance in the articles: Plasticisers are not permanently bound to the PVC polymer, and phthalates are therefore released from plastic products throughout their lifetimes.

The use(s) of the article:

→ Normal use(s): In bath mattresses for adults

→ Reasonable foreseeable use(s): It is very likely that the mattresses also will be used by children or fertile women.

Potential for emission during use(s) and disposal – Looking at the routes of exposure:

Dermal exposure could be considered to be the most likely way of exposure. It could be assumed that naked skin often would be in direct contact with the article during use. Exposure through inhalation may occur if the article is used in-doors. Exposure through ingestion is also possible as it could be considered to be reasonable foreseeable that children might suck on the mattress, although due to the size and shape of the product exposure through ingestion is regarded as limited.

Furthermore as the product is mainly used in direct sunshine in temperatures above 20 degrees the temperature of the material could be 50 degrees, which could contribute to a considerable emission of DEHP.

Can exposure to humans or the environment be excluded?

NO

Conclusion: Notification is required

Go to Section 6.11

Communicate information according to Art. 33

Comment on the case

The case shows how information from the suppliers may be used in the assessment. Notification of the use of the substances in the article as well as communication of information is required. The case gives examples of the information to be communicated to recipients of the article.

The results obtained completing the workflows in this guidance could be documented in a table e.g. as in the example above. Certificates from suppliers of the bath mattress stating the identity and concentration limits of the SVHCs, potential results of chemical analyses, and the data of the yearly imported volumes of bath mattress could be annexed. The documentation procedures to be applied during the assessment of the obligation under REACH could be implemented e.g. as a part of a possible existing quality management system.

APPENDIX 4: INFORMATION SOURCES ON SUBSTANCES IN ARTICLES

The list below contains examples of available information sources on substances in articles. They provide various information, e.g. which substances to expect in certain types of articles, which substances can be ruled out of being present in certain articles, which type of substances can be expected to be released from articles, etc.

Name	Source	Content
Information sources on substances in miscellaneous articles		
Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII to the REACH Regulation (EC) No 1907/2006)	http://www.echa.europa.eu/reach/legislation_en.asp	Restrictions on use and marketing of substances in various mixtures and articles, e.g. textiles and treated wood.
Series "Survey of Chemical Substances in Consumer Products"	http://www.mst.dk/Udgivelser/Publications	Survey and health assessments of chemical substances in different consumer products, such as jewelleries, hobby products for children, headphones and hearing protection aids, artificial nails and nail hardeners, etc.
Different Eco-labels: EU Eco-label "Flower" Nordic Eco-label Blue Angel Eco-label Austrian Eco-label Thai Green Label	http://www.eco-label.com, http://www.ecolabel.eu http://www.svanen.nu http://www.blauer-engel.de http://www.umweltzeichen.at http://www.tei.or.th/greenlabel	Eco-label requirements limiting and excluding the use of certain substances in consumer goods.
European Information System on "Risks from chemicals released from consumer products/articles"	http://web.jrc.ec.europa.eu/eis-chemrisks	Exposure information on chemicals related to consumer products and articles (e.g. toys and textiles).
Emission Scenario Documents (ESD)	http://www.oecd.org/document/46/0,3343,en_2649_34373_2412462_1_1_1_1,00.html	Documents that describe the sources, production processes, pathways and use patterns of substances in selected industry sectors (e.g. industries of plastics, rubber, textiles, leather, metal, paper, etc.)
ESD for biocidal products (or treated materials)	http://ecb.jrc.ec.europa.eu/documents/Biocides/EMISSION_SCENARIO_DOCUMENTS	Documents used to estimate the initial release of substances from biocidal products (or treated materials) to the environment.
Information sources on substances in child care products		
Standard EN 14350-2 "Child use and care articles - Drinking equipment - Chemical requirements and test methods"	European Standards (ENs) can be obtained from national members of CEN (http://www.cen.eu/cenorm/members/national+members)	Limits the release of certain substances from drinking equipment for children.
Information sources on substances in construction material		
TOXPROOF certificate	http://www.tuv.com/de/toxproof_zertifikat.html	Certificate that documents the absence of particular hazardous substances in construction materials.
AgBB evaluation scheme	http://www.umweltbundesamt.de/building-products/agbb.htm	Quality standards related to human health for building products for indoor use (e.g. exclusion of CMR)
Information sources on substances in electrical and electronic equipment		
Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive	http://ec.europa.eu/environment/waste/weee http://www.rohs.gov.uk	Six substances are banned in electrical and electronic equipment: Pb, Hg, Cd, Cr VI, PBB and PBDE.

Name	Source	Content
2002/95/EC)		
Information sources on substances in food contact materials		
Recommendations of the Federal Institute for Risk Assessment on Plastics Intended to Come into Contact with Food	http://kse.zadi.de/kse/faces/DBEmpfehlung_en.jsp	Recommendations for substances in polymers.
Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs	http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm	Lists specifying substances for use in food contact materials of plastic and possible restrictions for usage.
Directive 78/142/EEC relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs	http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm	Limits the content of vinyl chloride monomer in food contact materials.
Information sources on substances in textiles		
Oeko-Tex Standard 100	http://www.oeko-tex.com	Limit values for certain substances in textiles.
Information sources on substances in vehicles		
Directive 2000/53/EC on end-of life vehicles (ELV)	http://ec.europa.eu/environment/waste/elv_index.htm	Requirements regarding the substances in materials and components of vehicles and end-of life vehicles.
International Dismantling Information System (IDIS)	http://www.idis2.com	The IDIS was developed by the automotive industry to meet the legal obligations of the ELV Directive and provide information to dismantling companies about the content of the banned heavy metals in car components.

APPENDIX 5: METHODS FOR THE ANALYSIS OF SUBSTANCES IN ARTICLES

The list below contains examples of analytical methods for substances in articles, and in particular methods for the determination of substances released from articles. Please note that the division of the list into different parts based on different types of article is not strict.

Name	Source	Content
Methods for the analysis of substances in miscellaneous articles		
Standards EN 14362-1 and EN 14362-2 "Textiles - Methods for determination of certain aromatic amines derived from azo colorants"	European Standards (ENs) can be obtained from national members of CEN (http://www.cen.eu/cenorm/members/national+members)	Part 1 describes a method for detection of the use of certain azo colorants accessible without extraction. Part 2 describes a method to detect the use of certain azo colorants accessible by extracting the fibres.
Standard ISO 14025 "Environmental labels and declarations - Type III environmental declarations - Principles and procedures"	http://www.iso.org	Standardised test Methods for chemical analysis of potential emission from articles.
ChemTest module of the EU Exposure Assessment Toolbox.	http://web.jrc.ec.europa.eu/eis-chemrisks/toolbox.cfm	Exposure testing methods, e.g. to quantify emissions of volatile chemicals from consumer products.
Methods for the analysis of substances in child care products and toys		
Standards DIN V 53160-1 and DIN V 53160-2 "Determination of the colourfastness of articles for common use"	http://www.din.de	Methods to determine the release of substances from articles in contact with saliva (e.g. toothbrushes) or sweat.
Standard EN 71-3 "Safety of toys - Migration of certain elements"	European Standards (ENs) can be obtained from national members of CEN (http://www.cen.eu/cenorm/members/national+members)	Method to measure the migration of heavy metals, inorganic and organic substances from articles in contact with saliva or gastric acid.
Methods for the analysis of substances in food contact materials		
Directive 82/711/EEC	http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm	Basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs.
Standard EN 1186-1 "Materials and articles in contact with foodstuffs - Plastics - Part 1"	European Standards (ENs) can be obtained from national members of CEN (http://www.cen.eu/cenorm/members/national+members)	Guide to the selection of conditions and test methods for overall migration.
Standard EN 13130-1 "Materials and articles in contact with foodstuffs - Plastics substances subject to limitation - Part 1"	European Standards (ENs) can be obtained from national members of CEN (http://www.cen.eu/cenorm/members/national+members)	Guide to test methods for the specific migration of substances from plastics to foods and food simulants and the determination of substances in plastics and the selection of conditions of exposure to food simulants.
Methods for the analysis of substances in plastic articles		
Standard EN 1122 "Plastics - Determination of cadmium - Wet decomposition method"	http://www.din.de	Method for quantification of cadmium in plastic articles. Other analysis methods include: - NAA (neutron activation analysis) - AAS (atomic absorption spectroscopy) - XRF (x-ray fluorescence spectroscopy)
Methods for the analysis of substances in furniture (including textile and leather parts)		
German Federal Health Bulletin 10/91 (p. 487-483)	http://www.bundesgesundheitsblatt.de	Test methods for the analysis of wood-based materials.

Name	Source	Content
VDI guideline 3485 "Ambient air measurement; measurement of gaseous phenolic compounds; p-nitroaniline method"	http://www.vdi.de	Method for the measurement of phenolic compounds emitted from articles.
Standards EN 717-1, EN 717-2 and EN 717-3 "Wood-based panels - Determination of formaldehyde release"	European Standards (ENs) can be obtained from national members of CEN (http://www.cen.eu/cenorm/members/national+members)	Methods (chamber method, gas analysis method, flask method) to determine formaldehyde release from articles.
Standard DIN 75201 "Determination of the windscreen fogging characteristics of trim materials in motor vehicles" Standard ISO 6452 "Determination of fogging characteristics of trim materials in the interior of automobiles"	http://www.din.de http://www.iso.org	Methods to determine the condensable emissions from leather parts in cars.
Standards ISO 14184-1 and ISO 14184-2 "Textiles - Determination of formaldehyde"	http://www.iso.org	Methods to determine the formaldehyde emission from padding materials and textiles. Water extraction method to determine free and hydrolyzed formaldehyde, and vapour absorption method to determine released formaldehyde.

APPENDIX 6: LEGISLATION RESTRICTING THE USE OF SUBSTANCES IN ARTICLES

Instrument	Coverage	Conditions	Notes
(REACH) Regulation (EC) No 1907/2006 as amended by Regulation (EC) No 552/2009	Certain dangerous substances, mixtures and articles	• Specified in Annex XVII	
(Biocides) Directive 98/8/EC	Biocidal products	• Substances included in Annex I may be used as active substances in biocidal products, Annex I may contain substance specific conditions • Authorisation of biocidal products at national level	• The use of certain biocides is restricted by Regulation (EC) No 1907/2006 • Restrictions on non-active substances should be under Regulation (EC) No 1907/2006
Directive 94/62/EC	Packaging and packaging waste	• Concentration limits for heavy metal content in packaging materials	
Directive 76/768/EEC	Cosmetics	• Lists of banned and permitted substances for use in cosmetic products	
Regulation (EC) No 842/2006	Greenhouse gases	• Restrictions on fluorinated greenhouse gases	
(RoHS[33]) Directive 2002/95/EC	Electrical and electronic equipment falling under categories set in Annex IA to (WEEE[34]) Directive 2002/96/EC	• New equipment may not contain Pb, Hg, Cd, Cr(VI), PBB, PBDE • Exemptions listed in an Annex	
Amendment 2006/690/EC	The use of Pb in crystal glass in specific materials and components used in electrical and electronic equipment	• Exemptions for applications of Pb in crystal glass	
Amendment 2006/691/EC	Exemptions for applications of Pb and Cd in electrical and electronic equipment	• Exemptions granted based on a review process	
Amendment 2006/692/EC	Exemptions for applications of Cr(VI) in electrical and electronic equipment	• Exempted until 1/07/2007	

[33] Restriction of Hazardous Substances

[34] Waste Electrical and Electronic Equipment

Instrument	Coverage	Conditions	Notes
Directive 89/106/EEC Directive 89/686/EEC Directive 93/42/EEC Directive 98/79/EC Directive 90/385/EEC	Construction products Personal protective equipment Medical devices In vitro diagnostic medical devices Active implantable medical devices	• Contain general provisions on the materials from which the products covered can be made, especially specifying that they should not affect health of users and not release toxic gases • Directive 90/385/EEC also has a provision on bioavailability of substances in the devices	
Directive 2006/66/EC	Batteries and accumulators		
(ELV[35]) Directive 2000/53/EC	Vehicles and end-of life vehicles	• The use of Pb, Hg, Cg and Cr(VI) is prohibited in vehicles and their components	
(GPS[36]) Directive 2001/95/EEC	All consumer products or aspects of those products that are not covered by specific European safety legislation	• A number of measures, including published standards and codes of good practice may be taken into account in assessing safety	• Products must provide levels of safety that consumers can reasonably expect
(Toys) Directive 88/378/EEC	Toys as defined in Article 1	• Limit values for bioavailability of metals resulting from the use of toys	• Use of certain substances in toys restricted by Regulation (EC) No 1907/2006
Directive 93/11/EEC	Elastomer or rubber teats and soothers	• List of permitted, authorised and banned nitrosamines and N-nitrosatable substances in elastomer or rubber teats and soothers	
Directive 89/107/EEC	Additives to be used in foodstuffs	• Positive list of substances (only these to be used in foodstuffs and only certain conditions specified therein)	
Regulation (EC) No 1935/2004	Materials and articles intended to come into contact with foodstuffs	• In Annex I groups of materials and articles are listed which shall be subject to specific directives	• Aims to ensure that all materials and articles in their finished state that come in contact to foodstuffs do not transfer substances in quantities that endanger human health or bring an unacceptable change in the composition of the foodstuffs

[35] End-of-Life Vehicles

[36] General Product Safety

Instrument	Coverage	Conditions	Notes
Directive 2002/72/EC	Plastic materials and articles intended to come into contact with foodstuffs	• Positive lists with authorised substances which excludes all others from use in a certain application • Annex II 'monomers and other starting substances' • Information on impurities in substances and constituents of mixtures • Overall and specific migration limits	• The aim of a positive list of substances is to protect consumer against health risks due to exposure to substances migrating into food
Directive 84/500/EEC	Ceramic materials and articles intended to come into contact with foodstuffs	• Determining the symbol that may accompany materials and articles intended to come into contact with foodstuffs	
Directive 78/142/EEC	Materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs	• Migration limits for vinyl-chloride monomer in food contact materials	
Directive 93/10/EEC	Materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs	• Migration limits for cellulose in food contact materials	
Regulation (EC) No 1895/2005	Certain epoxy derivatives in materials and articles intended to come into contact with food	• Contains list of permitted substances	