ECHA
European Chemicals Agency

Helsinki, 1 April 2011

**NOTE TO THE READER**

**Subject: Guidance on requirements for substances in articles**

Dear User of this Guidance,

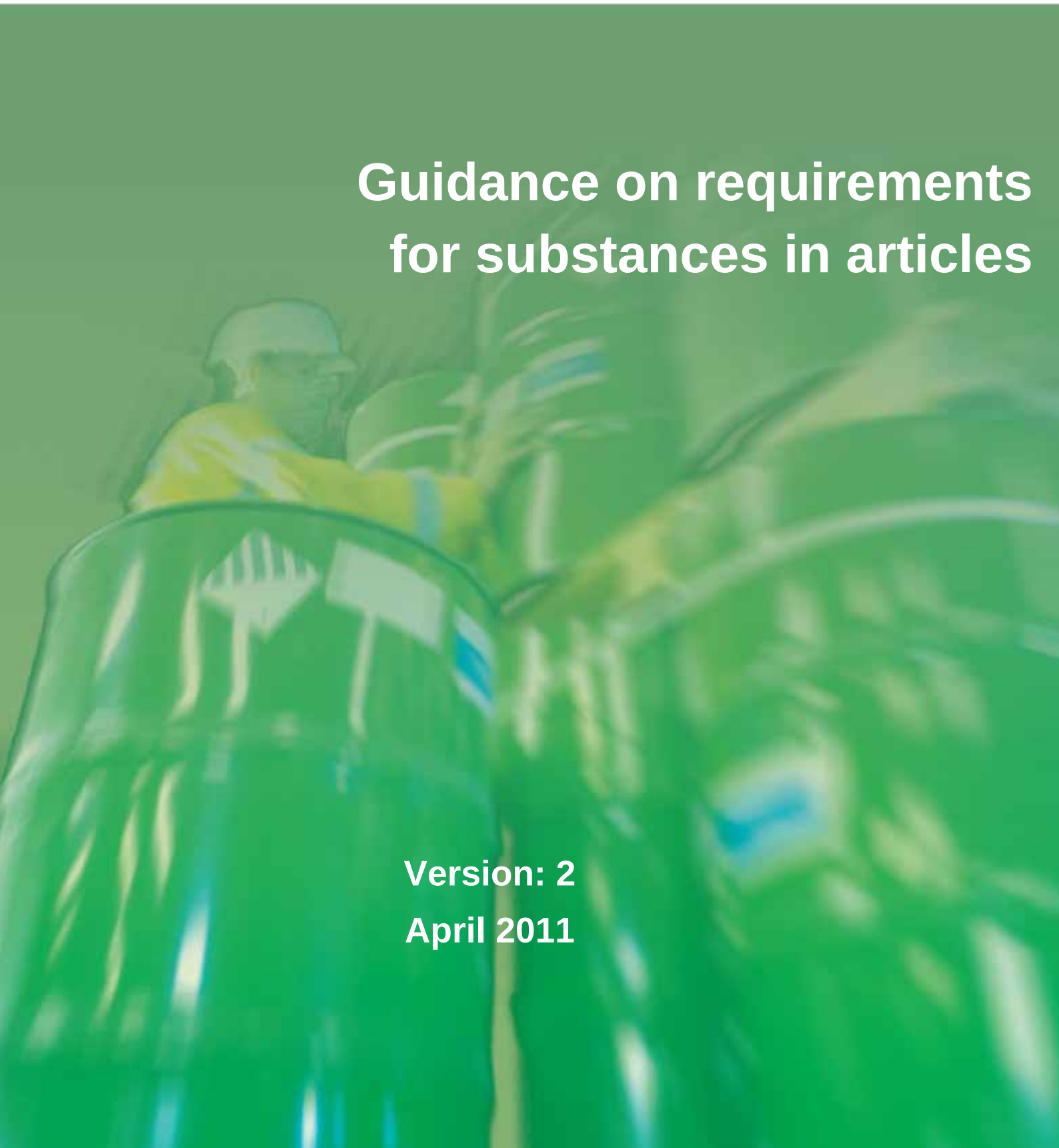
When reading this ECHA Guidance document, please be aware that it did not find full support by consulted national authorities of EU/EEA Member States in the stage of its final consultation, as reflected in the minutes that you can access via this link.

Consequently, companies may face diverging enforcement practices as to some of its aspects.

Geert Dancet
Executive Director

ECHA
http://echa.europa.eu

# Guidance on requirements for substances in articles



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***Guidance on requirements for substances in articles***

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# PREFACE

This guidance document is part of a series of guidance documents that are aimed at helping 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 |
| 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**[2]. It is aimed at:

- Persons responsible for REACH compliance within companies producing, importing and/or supplying articles in the European Economic Area (EEA), in particular purchasing, production and sales managers.
- Only Representatives[3] 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 outlined in table 1). This might be the case for companies producing, importing and/or supplying articles, who, like industry in general, have the responsibility to determine their obligations under REACH.

In this context, a company is an **article producer**[4] 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**[5] is any company located inside the EEA that imports articles from countries that are located outside the EEA. Article producers and importers (as well as other actors in the supply chain such as retailers) are also **article suppliers**[6], 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 (see also section 1.3).** If an article producer, for example, purchases substances inside the EEA

[2] article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition (Article 3(3)).

[3] 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.

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

[5] 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)).

[6] 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)), including retailers (Article 3(14)).

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 obligations, 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 of Very High Concern for authorisation | substances included in Candidate List of Substances of Very High Concern 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.

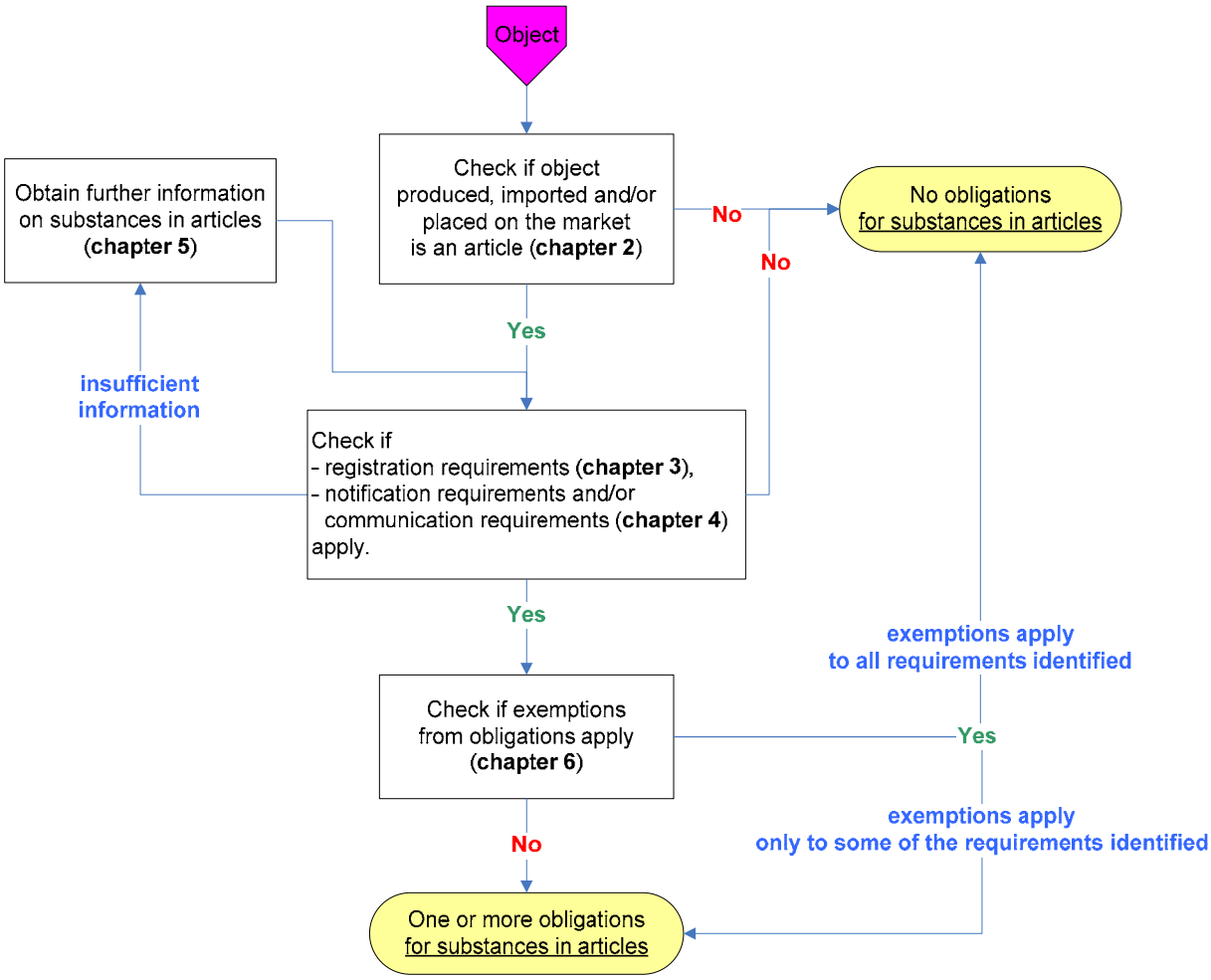


**Figure 1: General process of identifying obligations for substances in articles according to Articles 7 and 33**

## 1.3. Topics covered by other guidance documents

Authorisation and restriction requirements do not only affect companies using substances for the production of articles, 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**. This means that in order to import articles into the EEA an authorisation cannot be required. However, if an EEA-based producer of articles incorporates a substance as such or in a mixture[7] 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 as amended[8]. 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 aside from REACH is provided in Appendix 6 of this guidance.

[7] Following the 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.

[8] Please note that the REACH Regulation can be changed through legal amendments and that all amending Regulations passed have to be taken into account when looking into the legal text. The Regulations amending the REACH Regulation can be found on ECHA's website.

# 2. DECIDING WHAT IS AN ARTICLE UNDER REACH

When determining if and which requirements apply, the first step is to check whether the objects[9] 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 laptop 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. Buildings are not considered to be articles, so long as they remain fixed to the land on which they stand[10].

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.

[9] The term "object" can in principle refer to any product in the supply chain.

[10] Buildings do not constitute articles under REACH so long as they remain fixed to the land on which they stand. The same applies to other (large) structures such as bridges, as well as smaller structures such as garden swings, etc, so long as they remain fixed to the land.

The shape, surface and design of an object are **not to be confused with physical characteristics that result from the chemistry of the material(s) the object is made of**. Examples of such material characteristics or properties include: cleavage, density, ductility, electrical conductivity, hardness, magnetism, melting point, etc.

**Example 1: Blasting grit**

Grit for abrasive blasting needs to be hard and have sharp edges to be applied as blasting medium (e.g. for glass engraving or stone etching). The hardness and the cleavage properties of the materials used as blasting grit, such as corundum or steel, depend on the chemistry of these materials, and should not be confused with the shape, surface or design of an object.

Furthermore it is to be noted that 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 laptop).

A set of objects that are merely collected together to be supplied does, on the contrary, not have a particular production step during which a specific shape, surface or design is given to the set or kit. This applies regardless of whether the objects are

- used separately (like the different casseroles and pans of a cookware set),
- used together (like in a portable power tool consisting of tool, battery and charger), or
- assembled into a single object (like a flat pack furniture).

Therefore **a set of objects cannot be regarded as one article, but has to be regarded as many articles, substances and/or mixtures**.

## 2.3. 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. Deciding whether an object is an article or not

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

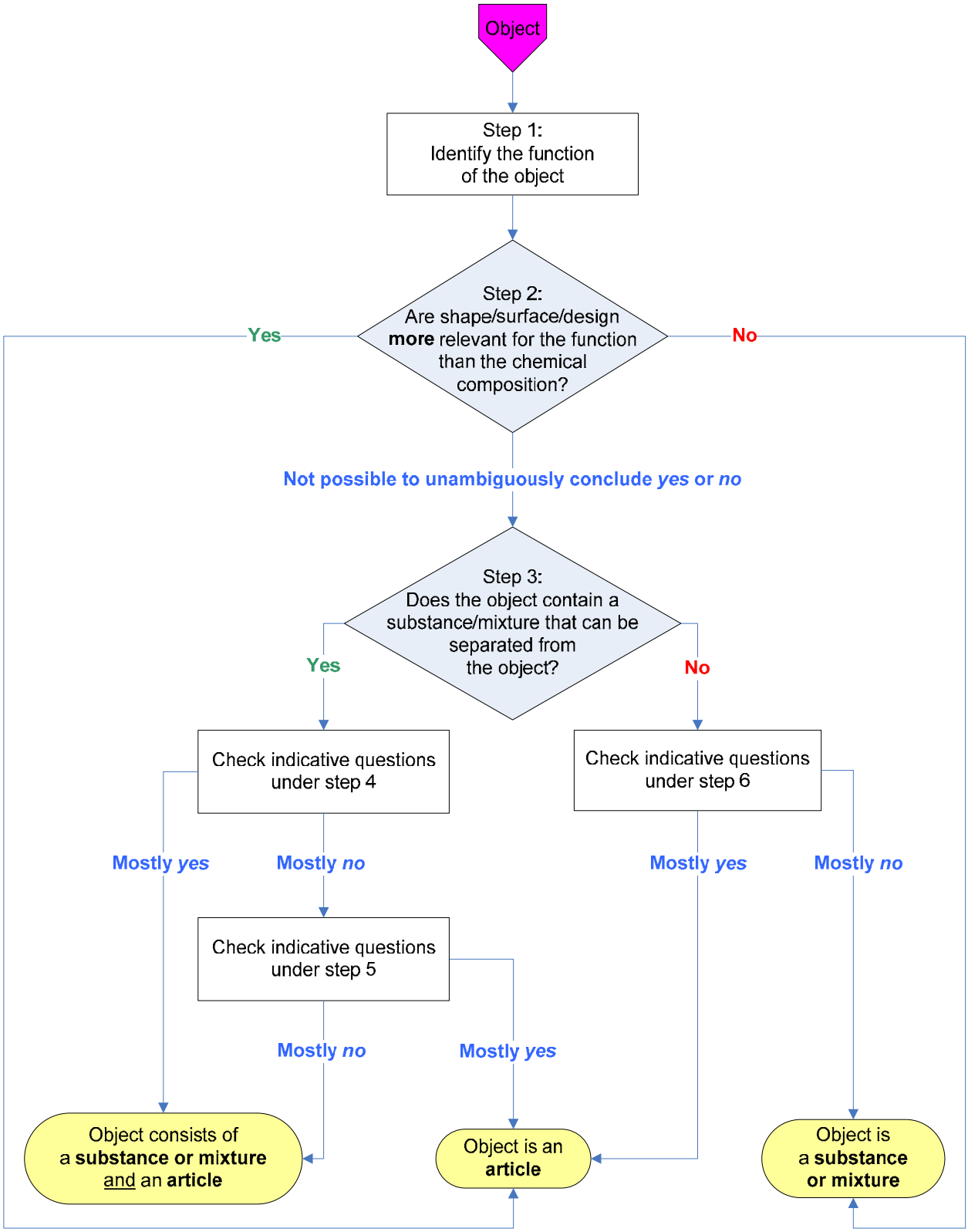


**Figure 2: Decision-making on whether an object is an article or not**

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

**Step 2**: In many cases applying the REACH definition of an article is straightforward. The decision on whether an object is an article or not can then directly be 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 or design of the object is more 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.**

**Example 2: Wax crayon**

A wax crayon consists of paraffin wax and pigments and is used for colouring and drawing on paper. As its shape/surface/design are not more relevant for the function of the crayon (to bring pigment to paper) than its chemical composition, it is to be regarded as a mixture.

**If it is not possible to unambiguously conclude whether the object fulfils the REACH definition of an article or not, a deeper assessment is needed; for this proceed with step 3.**

**Step 3**: Determine if the object, which may be constructed in a very simple or highly sophisticated manner, contains a substance or mixture that can be physically separated from the object (e.g. by pouring or wringing out). The substance or mixture in question, which can be solid, liquid or gaseous, can be enclosed in the object (like e.g. the liquid in a thermometer or the aerosol in a spray can), or the object can carry it on its surface (like e.g. a wet cleaning wipe).

**If this applies to the object, proceed with step 4, otherwise proceed with step 6.**

**Step 4**: 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 4a: If the substance/mixture were to be removed or separated from the object and used independently from it, 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 4b: 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 4c: Is the substance/mixture consumed (i.e. used up e.g. due to a chemical or physical modification) or eliminated (i.e. released from the object) during the use phase of the object, thereby rendering the object useless and leading to the end of its service life?*

**If you can answer these questions predominantly with *yes* (i.e. 2 of 3) rather than *no*, then the object should be regarded as a combination of an article (functioning as a container or a carrier material) and a substance/mixture.**

It is to be noted that an importer or supplier of such an object is also considered to be an importer or supplier of a substance/mixture. As such he might also have obligations other

than those of importers and suppliers of articles described in this guidance document. This means that substances in a container or on a carrier material might e.g. have to be registered, or be supplied with a safety data sheet. **Importers and suppliers of a "combination of an article and a substance/mixture" therefore have to separately check if obligations for the article apply and if obligations for the substance/mixture apply.** Chapters 3 and 4 describe how to identify the obligations for the article; in order to identify the obligations for the substance/mixture (which is on the article's surface or enclosed in it) you are advised to run the Navigator.

**Example 3: Printer cartridge**

Answering the above indicative questions: 4a) if the toner/ink was moved from the cartridge, it would still be possible to bring it to paper, although with a loss of quality and convenience; 4b) the function of the cartridge is to hold the toner/ink in place inside a printer and it controls the speed and mode of release; 4c) the cartridge is disposed of without the toner/ink, which is consumed during the service life of the cartridge. The answers to the questions allow the conclusion that a printer cartridge is a combination of an article (functioning as container) and a substance/mixture.

**Step 5**: If the answers to the indicative questions under step 4 are mostly 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 a combination of an article (functioning as a container or a carrier material) and a substance/mixture.

*Question 5a: If the substance/mixture were to be removed or separated from the object, would the object be unable to fulfil its intended purpose?*

*Question 5b: Is the main purpose of the object other than to deliver the substance/mixture or its reaction products?*

*Question 5c: Is the object normally discarded with the substance/mixture at the end of its service life, i.e. at disposal?*

**If you can answer these questions with *yes* rather than *no*, then the function of the object is likely to be determined rather by the physical properties shape, surface and design, than by the chemical composition. The object is then regarded as an article with an integral substance/mixture (i.e. the substance/mixture forms an integral part of the article).** The substances (as such or in a mixture) that form an integral part of the article have only to be registered under the conditions described in section 3.2.

**Example 4: Thermometer**

Answering the above questions: 5a) the empty thermometer would fail to show the temperature; thus the object would no longer be useful; 5b) the main function of the thermometer is to show the temperature, this is not a delivery of a substance or mixture; 5c) the thermometer is normally disposed of together with its chemical content. So answering these questions leads to the conclusion that a thermometer is an article and the liquid within an integral part of it.

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

**Step 6**: According to the assessment made under step 3, the object does not contain a substance or mixture that can be physically separated. Deciding whether the object fulfils the REACH definition of an article or not may however still be difficult in certain cases. Common examples are raw materials and semi-finished products that are further processed to final articles, but other cases might exist. In these cases, where making a decision is difficult, 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 undergo only "light processing", i.e. no gross changes in shape?*
*"Light processing", such as drilling, surface grinding or coating, 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.*
*Processes leading to gross changes in shape, meaning changes of depth, width <u>and</u> height of an object, are not regarded as "light processing". These can for example be primary shaping processes (such as casting or sintering) or forming processes (such as extrusion, forging or rolling). If the object preserves at least one of its characteristic dimensions (depth, width and/or height) when further processed, the process can be regarded as "light processing".*

*Question 6d: When further processed, does the chemical composition of the object remain the same?*
*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 answer 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 <u>article</u>. Predominantly answering *no* to the questions indicates that the object is a <u>substance or mixture</u>.** Appendix 2 illustrates how to apply these indicative questions and gives examples from four different industry sectors.

## 2.5. Documentation

From Article 36(1)[11] of the REACH Regulation it follows that downstream users (article producers are considered also as downstream users under REACH, if they use a substance or mixture in the production of their articles) have to keep available all the information they require to carry out their REACH obligations. But even if it has been identified that no obligations under REACH apply, these companies should consider documenting the results of their compliance checking. This includes documenting the decision-making on whether certain products are articles, substances or mixtures as well as the checking if specific requirements apply for these. **Documenting this is recommended to producers and importers of articles in general, as it facilitates demonstrating REACH compliance towards customers and (inspecting/enforcing) authorities.**

Checklists or other standardised tools developed by industry associations and other organisations can help companies to document their REACH compliance checking.

[11] "Each manufacturer, importer, downstream user and distributor shall assemble and keep available all the information he requires to carry out his duties under this Regulation for a period of at least 10 years after he last manufactured, imported, supplied or used the substance or mixture […]"

# 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.

If the release of a substance from an object fulfils the main function of the object (defined according to section 2.1), the release is not regarded as “intended release” for the purpose of REACH. In this case the object usually would be considered as a combination of an article (functioning as a container or a carrier material) and a substance/mixture, and not as an article with intended release of a substance/mixture.

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[12]. **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.

[12] 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”.

**Example 5: 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.

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[13] 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, but the release does not contribute to the functioning of the article.

  *Examples: wear and tear of materials under conditions of high friction, e.g. break linings, tyre; leakage of lubricant used to reduce the friction between two moving parts.*

- 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

Registration of substances in articles is required when all conditions listed under Article 7(1) of the REACH Regulation are fulfilled:

- The substance is intended to be released under normal or reasonably foreseeable

[13] A size is a chemical that is applied to a fabric to improve the strength and abrasion resistance of the yarn and reduce its hairiness. After the weaving process the fabric is desized (washed).

conditions of use[14] (this can be established by applying the criteria in section 3.1).

- The total amount of the substance present in all articles with intended release (i.e. including the amounts that are not intended to be released) produced or imported by one actor exceeds 1 tonne per year[15].

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 do 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 exemption 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 either of the following equations:

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

$$Vol_{subs.} = Vol_{articles} \cdot Conc_{\max subs.\ in\ article}$$

$Vol_{subs.}$: 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 fraction of the *mixture intended to be released* in the article; value between 0 and 1 (50% = 0.5, 25% = 0.25, 20% = 0.2, etc.).

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

[14] Both of the conditions must be met, i.e. the intention to be released and the normal or reasonable foreseeable conditions of use.

[15] For a phase-in substance in articles that have been imported or produced for at least three consecutive years, quantities per year shall be calculated on the basis of the average volume of this substance for the three preceding calendar years. Guidance on the calculation of yearly substance tonnages and examples can be found in section 1.6.2.3 of the Guidance on registration.

**Example 6: 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 substance volumes in all those articles have to be summed up[16].

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.

## 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 on their own or in mixtures. Detailed guidance on registration and data sharing is provided in the Guidance on registration and the Guidance on data sharing.

[16] Example: A 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.

# 4. REQUIREMENTS CONCERNING SUBSTANCES OF VERY HIGH CONCERN

Under REACH each producer, importer and supplier of articles bears responsibility for his articles' safeness. This especially applies, if the articles contain substances that may have very serious effects on human health or the environment. In order to ensure a high level of protection from the use of such substances in articles as pursued by REACH, their presence in articles needs to be laid open and communicated in the supply chain, as this is a prerequisite for the identification and application of appropriate risk management measures.

## 4.1. Candidate List for authorisation

Substances fulfilling one or more of the criteria defined in Article 57 of the REACH Regulation can be identified as "substances of very high concern" (SVHC) and put on the "Candidate List for authorisation". These SVHC can be:

- substances meeting the criteria for classification as carcinogenic, mutagenic or reprotoxic (CMR) category 1 or 2
- persistent, bioaccumulative and toxic (PBT) substances or very persistent and very bioaccumulative (vPvB) substances
- substances for which there is evidence for similar concern, such as endocrine disruptors

The Candidate List is available on the website of ECHA. It has been established according to the procedure described in Article 59 of the REACH Regulation. If a substance listed on the Candidate List is contained in articles, this may trigger certain obligations for companies producing, importing or supplying these articles. These obligations are discussed further in the following sections.

It should be noted that the Candidate List is regularly updated when more substances are identified as SVHC. On the website of ECHA a registry of intentions is published. One of the aims of this registry is to allow interested parties to be aware of substances which might be identified as SVHC before they are included in the Candidate List. This facilitates a timely preparation for complying with possible obligations that could result when a substance is finally put on the Candidate List. Therefore article producers, importers and suppliers are advised to regularly check the registry of intentions on ECHA's website.

Where the time window gained by checking the registry of intentions is deemed insufficient, companies may proactively identify substances used in their supply chain that have the potential to be included in the Candidate List. These substances, which have to fulfil at least one of the criteria for SVHC mentioned above, can be identified utilising for example the following sources of information:

- Lists of harmonised classification and labelling of hazardous substances contained in Tables 3.1 and 3.2 of Annex VI of the CLP Regulation (EC) No 1272/2008 which is available from the website of the European Commission
- Monographs Database of the International Agency for Research on Cancer (IARC)
- PBT Information System within the European chemical Substances Information System (ESIS)

- Commission Staff Working Document SEC(2007)1635 on the implementation of the "Community Strategy for Endocrine Disrupters"
- List of Chemicals for Priority Action of the OSPAR Commission
- SIN List database of the International Chemical Secretariat (ChemSec)
- Trade Union Priority List of the European Trade Union Confederation (ETUC)

It is important to notice that the legal obligations described in this chapter only apply to the substances included in the Candidate List. Other sources of information such as those listed above provided here are just meant to help companies in identifying (if needed) substances that might potentially be included in the Candidate List.

## 4.2. Notification according to Article 7(2)

Notification of substances in articles is required of producers and importers of articles when all conditions of Article 7(2) are met:

- The substance is included in the Candidate List for authorisation.
- The substance is present in articles produced and/or imported above a concentration of 0.1% (w/w).
- The total amount of the substance present in all articles produced and/or imported, which contain more than 0.1% (w/w) of the substance, exceeds 1 tonne per actor per year.

The substance concentration threshold of 0.1% (w/w) applies to the article as produced or imported. In practice, however, companies may already be collecting information not only on the whole article but also on parts thereof. Companies may, on a voluntary basis, prepare their notification to ECHA on this basis.

The obligation to notify substances in articles also applies to packaging materials, which may be produced or imported separately as packaging of imported goods. Packaging is to be assessed separately from any object it contains.

A notification is not required for a substance in articles which have been produced or imported before the substance has been included on the Candidate List for authorisation[17]. Furthermore, in certain cases an exemption from the obligation to notify applies (see chapter 6).

A notification of substances in articles shall be made at the latest 6 months after it has been included on the Candidate List of Substances of Very High Concern for authorisation, but only starting from 1 June 2011. This means that for substances included in the Candidate List before 1 December 2010, the notifications have to be submitted not later than 1 June 2011. For substances included in the Candidate List on or after 1 December 2010, the notifications have to be submitted no later than 6 months after the inclusion.

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

17 This is due to fact that the notification obligation is linked not only to the presence of a SVHC in articles above certain concentrations and in certain volumes, but also to the role of being an importer or producer of articles. Hence if the producer/importer no longer acts in the role of being an importer or producer of articles at the time when the obligation starts to apply, he does not need to notify.

- the identity and contact details of the producer or importer of the articles
- the registration number for the substance, if available
- the identity of the SVHC (this information is available from the Candidate List and the supporting documentation)
- the classification of the substance (this information is available from the Candidate List and the supporting documentation)
- a brief description of the use(s) of the substance in the article(s) as specified in section 3.5 of Annex VI and of the uses of the article(s)
- the tonnage range of the substance contained in the articles, i.e. 1-10 tonnes, 10-100 tonnes, 100-1000 tonnes or ≥1000 tonnes.

More detailed information is given on how to provide this information within the notification in the Data Submission Manual for substances in articles notifications, available on the ECHA website,

## 4.3. Obligations according to Article 33

The aim of Article 33 is to ensure that sufficient information is communicated down the supply chain to allow the safe use of articles.

A supplier of articles containing a SVHC included on the Candidate List for authorisation in a concentration above 0.1% (w/w) has to provide relevant safety information about this substance available to him to the recipients of these articles (Article 33(1)). If no particular information is necessary to allow safe use of the article containing a substance from the Candidate List, as a minimum the name of the substance in question has to be communicated to the recipients. The information is to be provided to the recipients automatically, i.e. as soon as the substance has been included on the Candidate List for authorisation. Note that the term “recipients” refers to industrial or professional users and distributors, but not to consumers.

Upon request of a consumer, the same supplier of articles has to provide relevant safety information about the SVHC available to him also to this consumer (Article 33(2)). If no particular information is necessary to allow safe use of the article, as a minimum the name of the substance in question has to be communicated to the consumer. The consumer has to be provided with this information within 45 calendar days of the request and free of charge. It is also to be noted that a retailer supplying articles, for example, does not comply with this obligation just by referring the consumer to his own supplier, or the producer of the articles.

As concerns the obligations to communicate information on substances in articles in general (i.e. communication with recipients and consumers), please note that:

- There is no tonnage trigger for these obligations (i.e. they also apply below 1 tonne per year).
- Packaging is always to be treated as article(s) separate from the contents of the packaging. Therefore, the obligations to communicate information on substances in articles also apply to packaging materials.
- The substance concentration threshold of 0.1% (w/w) applies to the article as supplied. In practice, however, companies may already be collecting information not only on the whole article but also on parts thereof. Companies may, on a voluntary basis, follow this approach when communicating in accordance with Article 33.

- The obligations also apply to articles which were produced or imported before the substance was included in the Candidate List and are supplied after the inclusion. Thus, the date of supply of the article is the relevant date.

- The substance name to be communicated is the one appearing on the Candidate List for authorisation.

### 4.3.1. Communicating information according to Article 33

In order for an article supplier to determine **what information he shall communicate** according to Article 33, he has to consider:

- what the downstream life-cycle stages of the article are up to final disposal (transport, storage, uses)

- what the potential routes of exposure are during each of these life-cycle stages

- what the hazards of the SVHC are for human health and the environment

- what types of exposure control / personal protection measures are likely to be appropriate during each of the life-cycle stages in order for the handling of the article to be considered safe

These considerations are required in order to identify any risks arising from the SVHC in the article, and thus determine which information has to be provided to the user, in addition to the name of the SVHC, in order for him to control these risks. This means that the obligatory additional information depends on what a user needs to know to be able to use the article safely and not on how available this safety information is. It should not be assumed that simply providing the name of the substance will in every case be sufficient to allow safe use of the article.

Information for any one article may differ regarding information type and detail according to who the recipient is. A professional user would, for example, normally not be informed that an article should be kept out of reach of children, whereas such information would tend to be appropriate for consumers.

The most appropriate **format for provision of information** may also vary, depending on the content and the addressee of the information. Standard answering letters might be a suitable medium to inform consumers, whereas a professional user might be better informed through separate use instructions.

REACH does not specify a format for providing information according to Article 33; possible formats could for example be:

- modification of existing documents, such as instructions for use and packaging

- information on labels

- link to a website with up-to-date information

- standard communication formats developed by industry sector associations

In any case, you must choose a format that will ensure that the information is **readily available to the recipient of the article or the consumer**, always taking into account the particular situation of use.

## 4.4. Determination of the concentration of a SVHC on the Candidate List in articles with different components

A SVHC on the Candidate List may be contained in different concentrations in different components of the same article, e.g. one concentration in the chassis of a laptop and another concentration in the transformer. For obligations according to Article 7(2) and 33 to apply, the concentration of this SVHC has to exceed 0.1% (w/w) in the entire article as identified according to chapter 2. In order to check this condition firstly it needs to be known for each component whether it contains above 0.1% (w/w) of the SVHC or not (if not yet available, this information can be obtained by different means as described in chapter 5).

To illustrate the cases that may arise when checking the 0.1% threshold, the example of the laptop assembled from different components, such as transformer, motherboard, memory, processor, chassis, etc. is taken up:

If **no component contains above 0.1% (w/w) of a SVHC on the Candidate List**, also the entire laptop does not contain above 0.1% (w/w).

If **one or more components contain above 0.1% (w/w) of a SVHC on the Candidate List**, the producer/importer of laptops needs to:

1. find out the concentration of the SVHC in each component
   and the mass of each component containing the SVHC (whether above 0.1% (w/w) or below),

2. calculate the mass of the SVHC in each of these *n* components as follows,

$$m_{SVHC\ in\ component} = m_{component} \cdot Conc_{SVHC\ in\ component}[\%] \cdot 0.01$$

3. calculate the average concentration of the SVHC in the laptop using the formula below and check if it is above 0.1% (w/w).

$$Conc_{SVHC\ in\ whole\ article}[\%] = \frac{m_{SVHC\ in\ component\ A} + m_{SVHC\ in\ component\ B} +_{...} + m_{SVHC\ in\ component\ n}}{m_{whole\ article}} \cdot 100$$

Likewise, if **a producer of laptops adds himself a SVHC** to one or more parts of the laptop, he has to follow the same approach in order to check whether the 0.1% threshold is exceeded for the laptop he finally places on the market.

**Example 7: Calculation of the average concentration of a SVHC in an article**

A chair consists of a wooden part and a plastic part. The weight of the chair is 2.001 kg. The wooden part of the chair contains 10 mg of an SVHC. The weight of the wooden part is 2 kg. The plastic part of the chair contains 1 mg of the same SVHC and weighs 1 g.

The concentration of the SVHC in the chair is calculated using the formula above.

$$Conc_{SVHC\ in\ whole\ article}[\%] = \frac{10 \cdot 10^{-3} g + 1 \cdot 10^{-3} g}{2001 g} \cdot 100 = 0.0005\%$$

*Conclusion:* The average concentration of the SVHC in the chair does not exceed 0.1% (w/w). Obligations according to Article 7(2) and 33 do not apply.

## 4.5. Determining the total amount of a SVHC on the Candidate List in different articles

It is possible that the concentration of a SVHC on the Candidate List is greater than 0.1% (w/w) in different article types produced and/or imported, e.g. bags and belts. To find out if a notification is required, the total amount of the substance in each of these article types must be determined and summed up.

To calculate the total amount of the SVHC in each article type produced and/or imported per year with a concentration of the SVHC above 0.1% (w/w) use the following formula:

$$Vol_{SVHC\ in\ one\ article\ type}[t/a] = \left(Conc_{SVHC\ in\ whole\ article}[\%] \cdot 10^{-2}\right) \cdot \left(m_{article}[g/article] \cdot 10^{-6}\right) \cdot n_{articles}[articles/a]$$

The total amount of the SVHC in all articles produced and/or imported, which contain more than 0.1% (w/w) of the substance, is obtained by summing up the amounts calculated for each article type:

$$Vol_{SVHC\ in\ all\ article\ types}[t/a] = Vol_{SVHC\ in\ article\ type\ A}[t/a] + Vol_{SVHC\ in\ article\ type\ B}[t/a] +_{...} + Vol_{SVHC\ in\ article\ type\ n}[t/a]$$

**Example 8: Calculation of the total amount of a SVHC in different articles**

A company imports 20000 pairs of shoes, 50000 belts, and 40000 bags per year into the EEA. A pair of shoes contains 0.05% (w/w) of a SVHC on the Candidate List, a belt contains 0.75% (w/w), and a bag contains 2% (w/w) of the same SVHC. The weights of these articles are 0.7 kg per pair of shoes, 700 g per belt and 1 kg per bag.

The concentration of the SVHC in the belts and bags is above 0.1% (w/w).

The total amount of the SVHC in each article type produced and/or imported per year with a concentration of the SVHC above 0.1% (w/w) is calculated using the formula above.

$$Vol_{SVHC\ in\ belts} = \left(0.75 \cdot 10^{-2}\right) \cdot \left(700 g / article \cdot 10^{-6}\right) \cdot 50000\ \ articles / a = 0.26\ \ t / a$$

$$Vol_{SVHC\ in\ bags} = \left(2 \cdot 10^{-2}\right) \cdot \left(1000 g / article \cdot 10^{-6}\right) \cdot 40000\ \ articles / a = 0.8\ \ t / a$$

Summing up the values obtained for each article type, the total amount of the SVHC in all articles produced and/or imported, which contain more than 0.1% (w/w) of the substance, is obtained.

$$Vol_{SVHC\ in\ all\ article\ types} = 0.26\ \ t / a + 0.8\ \ t / a = 1.06\ \ t / a$$

*Conclusion:* The total amount of the SVHC in all articles produced and/or imported, which contain more than 0.1% (w/w) of the substance is over one tonne per year. Hence, the company has to submit a notification for the SVHC in the bags and the belts. Furthermore, the company has to provide information for both the belts and the bags according to Article 33 of the REACH Regulation.

# 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.

The success of a company in obtaining this information will largely depend on whether it has a quality management system in place or not. Quality management systems can include product tests performed in-house, supplier audits and third party certifications. Normally these measures are routinely performed to achieve improvements in processes and products as well as customer satisfaction. If such routines are already in place, less effort will be needed to obtain the required information on substances in articles, whether this is done through 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. This obligation also applies when the substance or mixture is supplied in a container or on a carrier material.

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 (on its own 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 of Very High Concern for authorisation in a concentration above 0.1% (w/w), they must provide available and relevant safety information according to Article 33, including, as a minimum, the name of that substance.

### 5.1.2. Requesting information up the supply chain

Where the information received is not sufficient to check compliance with REACH, producers, importers and suppliers of articles may consider obtaining 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. For this, several publications are available on ECHA's website, that explain the background and implications of REACH. Some of these documents are available in different languages helping to overcome language barriers.

- 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.

- It is recommended that requests in the supply chain are 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 more often known 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.

Some industry sectors have developed information systems and tools that can be used to obtain and communicate information on substances in articles within the supply chain in an efficient manner. 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 branch knowledge, publicly available information sources (see appendix 4) and conclusions from chemical analysis (see appendix 5).

### 5.1.2.1. Critical concentration level for substances in a *mixture intended to be released*

The concentration limit for a substance in a *mixture intended to be released from articles*, above which registration is necessary, can be calculated using the equation below. For this, the maximum concentration of the mixture incorporated in articles and the total production and import volume of these articles has to be known. This calculation is based on the assumption that the substance is only present in the articles as part of the mixture which is intended to be released.

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

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

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

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

**Example 9: Critical concentration level for substance 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.

### 5.1.2.2. Evaluation of information received from suppliers

When information is requested up the supply chain, suppliers often provide **declarations of compliance** for their products. The content of these declarations needs to be carefully assessed in order to ensure they serve as evidence for the own compliance with REACH. In doing so the following aspects ought to be considered:

- What is being declared? Is this relevant to the own compliance check?
- Does the declaration clearly relate to the supplier and the products supplied?
- Who is making the declaration, and does the signer have the authority to sign of behalf of

the supplying company?

- Is there reason for concern over the validity of the declaration?
  If yes, access to any documentation supporting the declaration should be requested.

Likewise it is not advisable to trust blindly on the adequacy of **scientific test reports** provided by suppliers. Such a report should be closely examined to make sure that it can indeed be used to demonstrate compliance. The following points should be taken into account when scientific test reports are used to document compliance checking.

- A scientific test report should include the following elements:
  - Name and address the laboratory involved in the analysis
  - Date of receipt of the sample and date of performance of the test
  - Unique identification of the report (such as a serial number) and date of issue
  - Clear identification and description of the sample and the substance(s) for which testing was performed
  - Sample preparation methods and analytical methods used, including references to the standards used and any deviations from them
  - The limit of detection (LOD) or limit of quantification (LOQ) of the test method
  - Results of the test (with unit of measurement) including uncertainty of the test results
  - Name and signature of the individual authorizing the report
- It should be checked whether the concentration of a substance obtained in the test is really below the relevant limit (e.g. below the 0.1% threshold or the critical concentration level for substances in a *mixture intended to be released*).
- The raw materials and processing of a product can change over time, leading to alterations of the product batches supplied. Therefore it needs to be ensured that the test documented in the report was conducted with the relevant type of product (i.e. the same type as the products supplied).
- There should be some level of understanding of the methods used in the test. If the presentation of the methods is not clear then an explanation should be sought from the supplier to avoid confusion and possible non-compliance.

## 5.2. Chemical analysis of substances in articles

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 an option to obtain information on the composition of articles. This is particularly the case when an article consists of a homogenous material, but also for complex, small articles, shredding and testing of a sample might be a feasible approach.

For certain articles (e.g. toys, shoes) it is even common practice to perform chemical analyses of materials used in the production or of final products. Such analyses performed

routinely for checking of compliance with other legislation or product quality control can also serve to obtain information needed for compliance with REACH.

Although chemical analyses may be helpful in certain situations, it is to be noted that they 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 in articles 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[18].
  - 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. 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) rather than the existence of 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. There are no formal requirements on which methods and laboratories to use; it is up to each company to judge the

[18] 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.

appropriateness of methods and laboratories. However, whenever possible and appropriate, existing standard methods and appropriate accredited laboratories should be used. Examples of standard methods for sampling and analysis of substances in articles can be found in appendix 5.

The following steps are proposed, when planning chemical analyses:

- 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 which part(s) of the article to analyse: liquids, gases or powders contained in the article, extracts from the article matrix, article parts likely to contain a particular SVHC, etc.
- 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 do not apply in certain cases. This chapter explains what you have to check to establish if you are covered by 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 on their own, 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 (Article 2(7)(a) and (b)). 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 (Article 2(7)(d)). Producers of articles made of recovered substances 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[19], including disposal.

Exposure to a substance in an article is possible even if the substance is not released from the article, but just on the surface of it. Therefore, **a producer/importer wanting to demonstrate 'exclusion of exposure' has to ensure that the SVHC on the Candidate List does not come into contact with humans or the environment**, regardless of its dangerous properties. Note that all exposure routes at all life cycle stages have to be considered (service life of the article and waste stage).

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

[19] The terms "normal conditions of use" and "reasonably foreseeable conditions of use" are explained in section 3.1.

exposure should be prepared so that it can be presented to enforcement authorities on request. Such a justification could include for example one or more of the following elements:

- A proof that no emissions from the article take place even during its disposal.
- If the substance is contained in the article by technical means: a reasoning why the article is unlikely to be opened or to break leading to a release of the substance, in particular during the waste stage.
- If the substance is embedded in the matrix of the article: a description of the stability of the article matrix and the bonds between the substance and the matrix during the different life cycle stages of the article.
- A proof that the substance remains fully immobile inside the article and does not migrate out of it (e.g. due to the inherent physicochemical properties of the substance, or a special coating of the article).
- A proof that the amounts of substance released from the article are contained by technical means or directly destroyed (e.g. during thermal treatment of waste).

These arguments can be based on measurements (e.g. leaching and migration tests), modelling, literature or other sources of information. Any justification should further include:

- The substance name.
- A description of the article, its normal and reasonably foreseeable conditions of use, and the disposal pathways.
- Information on the concentration of the substance in the article or its parts, including substance amounts in the article matrix and non-integrated (residual) amounts.

**Note that it may be more difficult and costly 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.

### 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. Exemption from registration and notification of substances already registered for a use

According to Article 7(6) a registration or notification of a substance in articles is not required, if the substance has already been registered for that use (i.e. the process by which the substance is included in the articles). This refers to any registration of that use of the substance in the same supply chain or any other supply chain.

On the same basis a producer or importer of articles would be exempted from notification of a substance if he has already registered it for that use himself. In other words, in the particular case that a producer or importer of articles has registration and notification obligations for the same substance in his articles, he would be exempted from the obligation to notify this substance, once he has registered it for that use.

A substance has already been registered for a particular use, if two conditions are fulfilled:

- The substance in question is the same as a substance that has already been registered.
- The use in question is the same as one of the uses described in a registration of this substance that was already made.

To ensure that the substance in question is the same as a substance that has already been registered, comparing names, and EINECS or CAS numbers of both substances may not always be sufficient. When deciding whether or not two substances can be regarded as the same, the "criteria for checking if substances are the same" given in chapter 5 of the Guidance on substance identification should be applied.

A potential registrant or notifier of a substance in articles would also have to check if the use of the substance in his articles is the same as one of the uses described in a registration of this substance that was already made. For this he has to describe the function of the substance in the article (e.g. pigment, flame retardant), the process by which the substance is included in the articles and into which type of article. This use description should be in line with the use descriptor system explained in chapter R.12 of the Guidance on information requirements and chemical safety assessment. The use descriptor system consists of five elements, specifying the industry sector, the type of mixture, the environmental release, the process and the article category of a substance use. It also specifies whether a substance is foreseen to be intentionally released from an article or not. Please note that (due to the generic architecture of the use descriptor system) using only the elements of the use descriptor system to describe a substance will not be sufficient to conclude on the sameness of two uses for the purpose of establishing whether an exemption on the basis of Article 7(6) applies. **Therefore, the use in question has to be described more in detail than just by using elements of the use descriptor system.** To come to a conclusion on whether the substance is considered as registered "for that use" or not, the potential registrant or notifier has to compare the description of his use with those uses already registered for the

substance. The conclusion obtained and the considerations that led to it should be well documented in order to be able to demonstrate REACH compliance towards authorities, when required.

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.

### 6.4.1. Information sources to determine if a substance is already registered for a use

Article producers and importers seeking to apply the provisions of Article 7(6) are reminded that it is necessary to actively find out if the substance in their articles is already registered for their use before establishing that they do not need to register or notify it. It is not considered sufficient to simply assume that this is the case without documenting it for the purposes of checking by enforcement authorities. Different types of sources of information may be of use in determining whether a substance is already registered for a particular use.

**Safety data sheets** (SDS) contain information on uses of the substance or mixture as far as they are known by the supplier. Where there are many possible uses, only the most important or common uses are listed. If a SDS in addition includes a registration number, it may be possible, depending on the detailedness of the use descriptions in the SDS, to conclude that a particular use of this substance or mixture has already been registered. However, in case of doubt, confirmation of the sameness of both uses (i.e. the use of the substance in the articles and one of the uses registered) should be sought from the actual registrant up the supply chain.

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 (on its own or in a mixture) are provided by their supplier with the relevant **exposure scenarios** in an annex to the safety data sheet. If relevant to the recipients of this substance, these exposure scenarios also cover the uses by which the substance is incorporated in articles. Therefore the information contained in exposure scenarios can be used by article producers to establish whether their use of the substance has already been registered up the supply chain.

A supplier of a substance (on its own or in a mixture) might choose to provide details on uses for which this substance has been registered on his **company website**. Depending upon the information made available, it may be possible to check whether or not the substance has been registered for the use concerned.

In most cases, if you need to find out for which uses a substance has been registered, you will have to ask other actors up your supply chain. Alternatively you could identify and ask a manufacturer or importer of that substance from any supply chain for the uses he has registered this substance for, or whether he has registered it for a particular use. **Supply chain communication** can be initiated in different ways:

- A good way to identify manufacturers and importers of a substance who might have registered it for a particular use, is to launch a corresponding request within the Substance Information Exchange Forum for this substance (SIEF), provided that you have pre-registered the substance and become a participant in that SIEF.

- You may also contact trade associations, who might have information on the registration status of a particular substance and the uses the substance has been registered for.

- As a downstream user, a producer of articles has the right to make the use by which he includes a substance (on its own or in a mixture) in his articles known to his supplier requesting that his use becomes an identified use[20]. The supplier has several options to react to a use made known to him (further information is provided in chapter 8 of the Guidance for downstream users). However, in the course of the dialogue initiated with the supplier, the article producer may obtain the confirmation that the substance has been or will be registered for his use.

The ECHA dissemination database for substance information, which can be accessed via the ECHA website: http://apps.echa.europa.eu/registered/registered-sub.aspx contains information on registered substances provided by companies in their registration dossiers. It includes a variety of information on the substances which companies manufacture or import and may include information on the uses of the substance, unless the companies have claimed this information as confidential, including use of the substance in articles. However, since the description of the use available here consists only of elements of the use descriptor system, the information will normally not be sufficient to conclude on the sameness of two uses for the purpose of establishing whether an exemption on the basis of Article 7(6) applies.

[20] Please note that this is not an option for importers of articles as they are not downstream users.

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

Section 2.3 of the guidance provides a workflow and explanation on how to distinguish between

a) articles with an integral substance/mixture, and

b) combinations of an article (functioning as a container or a carrier material) and a substance/mixture.

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. Please note that the range of borderline cases included in this Appendix is not exhaustive. 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 combinations of an article (functioning as a container) and a substance/mixture.

**Table 2: Summary of borderline cases described in Appendix 1**

| Object | Conclusion | |
|---|---|---|
| | **article** with an integral substance/mixture | combination of an **article** (functioning as a container or a carrier material) and a **substance/mixture** |
| **printer cartridge** | | x |
| **spray can with paint** | | x |
| **fireworks** | | x |
| **thermometer with liquid** | x | |
| **printer ribbon** | | x |
| **wet cleaning wipe** | | x |
| **wax tape for skis** | | x |
| **adhesive tape for fixing carpets** | x | |
| **battery** | x | |
| **desiccant bag** | | x |
| **detector tube** | x | |
| **candle** | | x |

**Table 3: Borderline cases of substances/mixtures in containers (continued in table 4)**

| Object | Spray can with paint | Printer cartridge | Fireworks | Thermometer with liquid |
|---|---|---|---|---|
| **Function** | Bring paint onto surface | Bring toner/ink onto paper | Explode, make light effects | Measure and indicate temperature |
| **Question 4a**: If the substance/mixture were to be removed or separated from the object and used independently from it, 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/ink 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 4b**: 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/ink 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 4c**: Is the substance/mixture consumed (i.e. used up e.g. due to a chemical or physical modification) or eliminated (i.e. released from the object) during the use phase of the object, thereby rendering the object useless and leading to the end of its service life? | **YES**, the spray can is normally disposed of separately from the paint. | **YES**, the toner/ink 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** | combination of an article and a substance /mixture | combination of an article and a substance /mixture | combination of an article and a substance /mixture | see table 5 |

**Table 4: Borderline cases of substances/mixtures in containers (continuation of table 3)**

| Object | Battery | Desiccant bag | Detector tube[21] |
|---|---|---|---|
| **Function** | Provide electric current | Absorb air humidity | Measure concentration of substances in air |
| **Question 4a**: If the substance/mixture were to be removed or separated from the object and used independently from it, 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. | **NO**, the printed scale on the detector tube is necessary to read the measured concentration. |
| **Question 4b**: 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, because the intention of this object is that the chemical reaction takes place within the object. |
| **Question 4c**: Is the substance/mixture consumed (i.e. used up e.g. due to a chemical or physical modification) or eliminated (i.e. released from the object) during the use phase of the object, thereby rendering the object useless and leading to the end of its service life? | **YES**, the electrolyte is predominantly consumed during the use phase of the object, as the battery does not provide electric current anymore at the end of its service life. | **YES**, the activity of the desiccant decreases with time; at the end of the service life of the object the desiccant does not adsorb humidity anymore. | **YES**, at the end of the object's service life, i.e. after the substance has undergone the colour reaction, the substance is used up i.e. its useful properties are exhausted. |
| **Conclusion** | see table 5 | combination of an article and a substance/mixture | see table 5 |

21 A detector tube is a glass tube containing chemical reagents in which a colour change may be produced when an air sample is drawn through it. The length of the stain produced, relative to a graduated scale on the tube, provides a measure of the concentration of a specified chemical agent in the air sample. The European Standard that governs the requirements for detector tubes is EN 1231.

**Table 5: Additional indicative questions for borderline cases of subs./mixtures in containers**

| Object | Thermometer with liquid | Battery | Detector tube |
|---|---|---|---|
| **Question 5a**: If the substance/mixture were to be removed or separated from the object, would the object be unable to fulfil its intended purpose? | **YES**, the object will not function without the liquid. | **YES**, the mixtures need to be in a container (each in a separate compartment with the necessary electrodes) in order to provide an electric current. | **YES**, without the chemical reagent in the tube no concentration measurements could be made. |
| **Question 5b**: Is the main purpose of the object other than to deliver the substance/mixture or its reaction 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. | **YES**, the main purpose is to provide electric current. | **YES**, the substance/mixture in the detector tube reacts inside the tube and is not meant to be dispensed by the tube. |
| **Question 5c**: Is the object normally discarded with the substance/mixture at the end of its service life, i.e. at disposal? | **YES**, the liquid and the container are disposed of together. | **YES**, when disposed, a battery still contains the mixtures. | **YES**, the detector tube still contains the chemical reagent when disposed. |
| **Conclusion** | article with an integral substance/mixture | article with an integral substance/mixture | article with an integral substance/mixture |

**Table 6: Borderline cases of substances/mixtures on carrier materials**

| Object | Printer ribbon | Wet cleaning wipe | Candle |
|---|---|---|---|
| **Function** | Bring ink onto paper | Remove dirt from surfaces | Create a flame |
| **Question 4a**: If the substance/mixture were to be removed or separated from the object and used independently from it, would the substance/mixture still be capable in principle (though perhaps without convenience or sophistication) of carrying out the function? | **YES**, the ink itself could still fulfil the function of bringing ink onto paper. | **YES**, the cleaning effect could generally be achieved by using the mixture itself though with less convenience. | **NO**, without the wick the mixture would not create a flame. |
| **Question 4b**: 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. | **YES**, the wick delivers the mixture in a controlled way to the flame. |
| **Question 4c**: Is the substance/mixture consumed (i.e. used up e.g. due to a chemical or physical modification) or eliminated (i.e. released from the object) during the use phase of the object, thereby rendering the object useless and leading to the end of its service life? | **YES**, when the ribbon is disposed, most of the ink has been consumed. | **YES**, the cleaning agents are predominantly consumed[22] and the wipe is disposed of separately. | **YES**, the mixture is burnt during the use phase of the candle. |
| **Conclusion** | combination of an article and a substance/mixture | combination of an article and a substance/mixture | combination of an article and a substance/mixture |

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

**Table 7: Applying indicative questions to pressure sensitive adhesive tapes**[23]

| **Object** | **Wax tape for skis**<br><br>(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**<br><br>(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) |
|---|---|---|
| **Function** | Bring wax onto ski surface | Hold two substrates together |
| **Question 4a**: If the substance/mixture were to be removed or separated from the object and used independently from it, 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. |
| **Question 4b**: 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. |
| **Question 4c**: Is the substance/mixture consumed (i.e. used up e.g. due to a chemical or physical modification) or eliminated (i.e. released from the object) during the use phase of the object, thereby rendering the object useless and leading to the end of its service life? | **YES**, the adhering layer and the carrier material are disposed of separately at the end of their respective useful lives. | **NO**, the adhesive is not consumed or eliminated during the use phase of the adhesive tape. |
| **Conclusion** | combination of an article and a substance/mixture | see table 8 |

[23] 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.

**Table 8: Applying additional indicative questions to pressure sensitive adhesive tapes**

| Object | Adhesive tape for fixing carpets |
|---|---|
| **Question 5a**: If the substance/mixture were to be removed or separated from the object, would the object be unable to fulfil its intended purpose? | **YES**, the adhesive layer without the backing material or the reinforcement is not capable of carrying out the intended purpose of the tape. |
| **Question 5b**: Is the main purpose of the object other than to deliver the substance/mixture or its re-action products? | **YES**, the tape's function is to adhere to the substrate and to provide additional qualities through the backing or internal reinforcement. |
| **Question 5c**: Is the object normally discarded with the substance/mixture at the end of its service life, i.e. at disposal? | **YES**, the adhesive remains on the tape at the end of its service life. |
| **Conclusion** | article with an integral substance/mixture |

# 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.

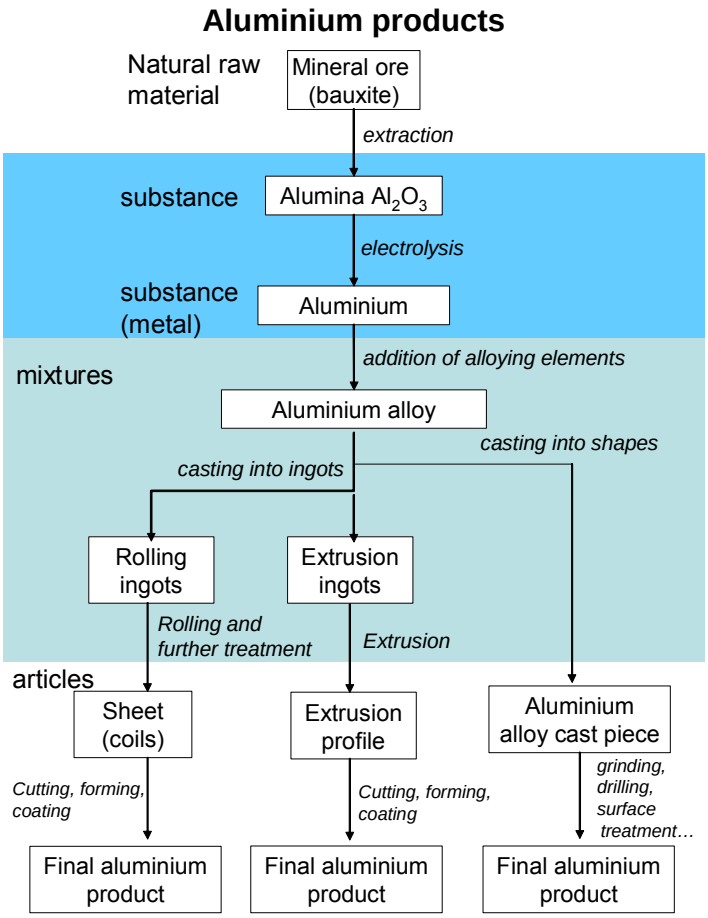


**Figure 3: Transition from bauxite to final aluminium products**

The transition point from mixture[24] 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.

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

**Table 9: 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 gross changes in shape? | **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 the same? | **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. |
| **Conclusion** | substance/mixture | article | article |

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 3 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 10: 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.<br>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 gross changes in shape? | **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 the same? | **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. |
| **Conclusion** | substance/mixture | article | article |

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;** there are, for example, great differences between man made mineral fibres and synthetic polymers. 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.

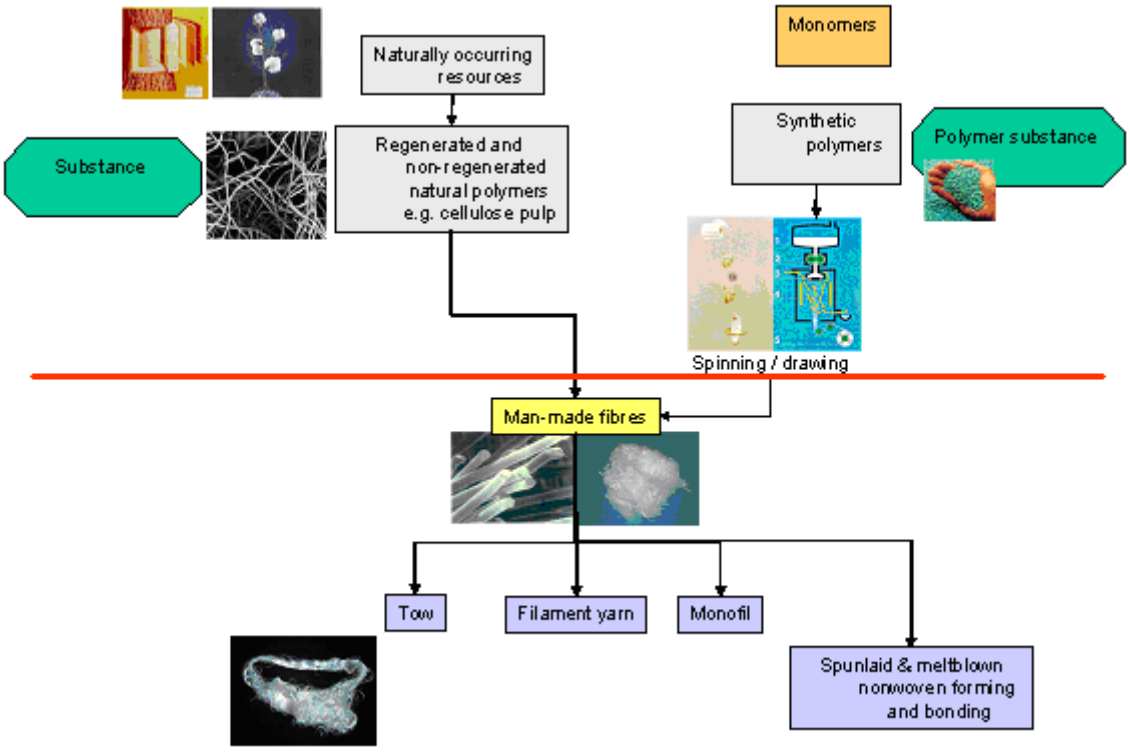


**Figure 4: Transition from raw materials to final textile/non-woven products**

**Table 11: 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 gross changes in shape? | **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 the same? | **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. |
| **Conclusion** | substance/mixture | article | article |

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 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.

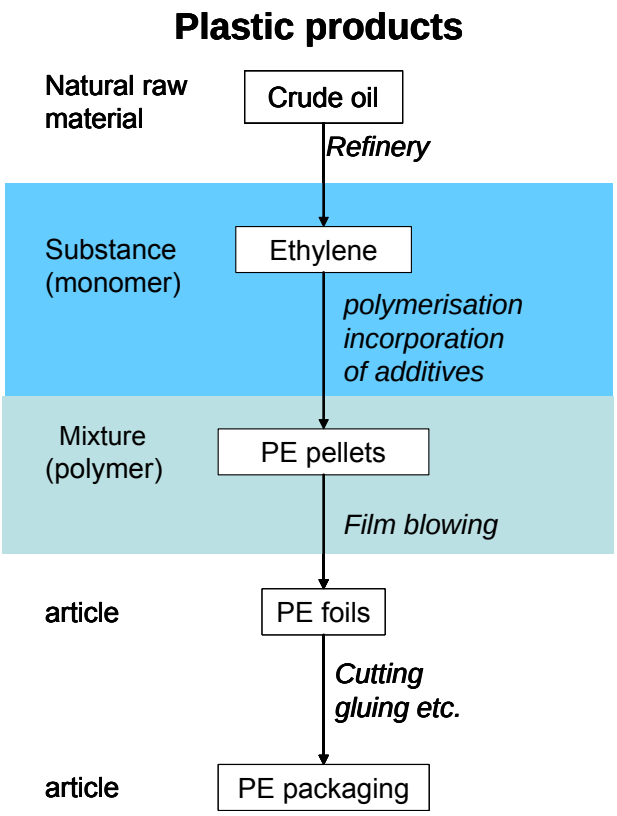


**Figure 5: Transition from crude oil to plastic products**

**Table 12: 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 gross changes in shape? | **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 the same? | **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. |
| **Conclusion** | substance/mixture | article | article |

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 to article is between the stock and the dried paper.

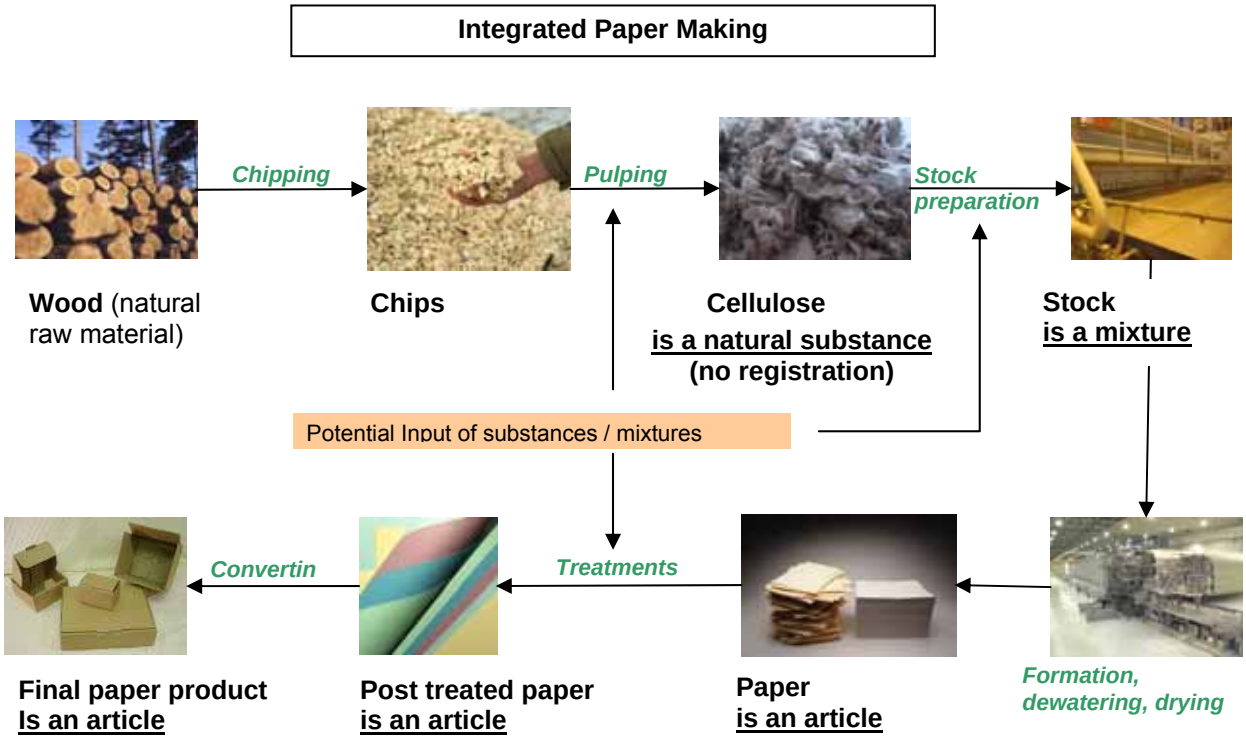


**Figure 6: Illustrative example of the general transition point from wood to paper articles**

**Table 13: 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 gross changes in shape? | **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 the same? | **NO**, chemicals may be added. | **YES**, just surface treatment, gluing etc. may add substances. | Not further processed. |
| **Conclusion** | substance/mixture | article | article |

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 APPLY

## 1) Scented children's toys

Scented children's toys are articles with intended release. 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

**Substance identification**

In order to obtain information on the substances to be released from the scented toys the importer does the following analyses:

1. Analysis on fragrances (24 in total) classified as sensitising by EU's Scientific Committee on Cosmetics (SCCNFP 1999). Toys with different smells, lemon and strawberry are examined. The analysis is carried out on the part containing the fragrance.
2. The toy with lemon scent is 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 are found in the analysis on fragrances; substance names and CAS numbers can be identified. During the emission test various compounds are detected and identified by substance name. Only one substance is identified by name in the screening for extractable compounds. The CAS numbers are searched in an online database for toxicological data (Thomson Microdex). Classification is searched for in lists from the Danish EPA. It is not possible to find the CAS number for all the identified substances using the available substance name.

**Information on concentration of the substance**

The concentration of D-limonene was determined for the part containing the fragrance. The classification was obtained from databases.

**Table 14: Information on D-limonene in the toys**

| *Substance* | *CAS no.* | *Classification* | *Concentration in toy part containing the fragrance (mg/kg)* |
|---|---|---|---|
| *D-limonene* | *5989-27-5* | *R10 (Flam. Liq. 3; H226)*<br>*Xi;R38 (Skin Irrit. 2; H315)*<br>*R43 (Skin Sens. 1; H317)*<br>*N;R50/53 (Aquatic Acute 1; H400 - Aquatic Chronic 1; H410)* | *800* |

**Information on amount of substance used**

The quantity of D-limonene in the scented toys can be calculated as the amount in each toy (800 mg/kg × 0.002 kg/toy = 1.6 mg/toy) multiplied by the amount of toys imported annually (1,000,000 toys/a). The annual amount of D-limonene in the toys imported is 1.6 kg/a, which is below 1 t/a.

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

$$Number_{\max articles} = \frac{1\,t/a}{Conc_{subs.(w/article)}} = \frac{1\,t/a}{1.6\,mg/toy} = \frac{1\,t/a}{1.6 \cdot 10^{-9}\,t/toy} = 625 \cdot 10^{6}\,toys/a$$

$Number_{max\ articles}$: maximum number of articles that can be produced and imported per year without triggering registration obligations.

$Conc_{subs.\ (w/article)}$: content of the substance in one article.

The importer can import 625 million toys before reaching the threshold of 1 t/a for D-limonene and trigger registration obligations.

**Illustration of the decision process**

**Example: Toy with lemon scent (D-limonene)**

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

YES.

**Is your object an article?** *(consult chapter 2)*

YES. The company imports toys which are articles, because the shape determines their function.

**Is there an intended release of substances from the article?** *(consult chapter 3)*

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.

**Does the article contain a SVHC included in the Candidate List?** *(consult chapters 4 and 5)*

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 the presence of SVHC. 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 or the substances/mixtures used to produce the article or receive confirmation that SVHC are not present in the article. Check the supply chain and ask if the supplier of the fragrance substances can be identified. If yes, the importer of toys 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 SVHC is likely (see 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 (Aquatic Acute 1; H400 - Aquatic Chronic 1; H410) and R51/53 (Aquatic Chronic 2; H411). These compounds may potentially fulfil the criteria as PBT/vPvB substances, and thus be identified as SVHC).

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

**Is the total amount of the fragrance mixture > 1 t/a (all such articles in a company should be considered)?**

YES. The total volume of fragrance is approx. 2 t/a.

**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.

**Substances exempted from registration?**

NO.

**Check for existing registration for that use.**

The substance has not been registered.

**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 2 g.

**Total amount > 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/a, which is below 1 t/a.

**Registration of D-limonene in the toys is not required.**

**Comments on the case**

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 toy, 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 toy) 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 e.g. the content of fragrances in the article.

## 2) Clothes

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, which participated in this case, has already established a programme, which limits the content of dangerous substances in products from its suppliers. This has resulted in a phase-out of SVHC in its 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 proportion of imported articles and minor production within the EEA.
- Documentation: A Swedish company provided information on their import of belt buckles.

**Producer/Importer of articles**

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

**Substance identity**

The company must consult the Candidate List for authorisation. Metallic lead, which was focused on in this case study, is not classified in the Annex I of Directive 67/548/EEC. However, for the purpose of this example only, it is assumed that metallic lead fulfils the criteria for identification as SVHC and thus is included in the Candidate List.

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 it 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.

**Check for existing registration**

To be done according to section 6.4 of this guidance.

**Information on concentration of the substance**

There is no obligation on non-EEA suppliers to provide an SDS or other information for articles. The alternative ways to obtain information suggested in chapter 5 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 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 usually 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**

**Example: Metallic lead in belt buckles**

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

YES.

**Is your object an article?** *(consult chapter 2)*

YES. Belt buckles and jewels are articles.

**Is there an intended release of substances from the article?** *(consult chapter 3)*

NO.

**Conclusion on registration: No need for registration.**

**Does the article contain a SVHC included in the Candidate List?** *(consult chapters 4 and 5)*

The Candidate List for authorisation has to be checked. 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 is on the Candidate List.

YES.

**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.**

**Is the SVHC (lead) intended to be released?**

NO.

**Has the substance already been registered for that use?**

NO.

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

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

The import of buckles in the year before: 13,000,000 items

The weight of one buckle: 100 g

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

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

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

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

**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 e.g. of leather for both children and adults.

Reasonably 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. during 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 neglected in this case. However, it is possible 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.**

**Comments on the case**

The case illustrates the possibility of using the maximum concentration or company upper limit of a specific SVHC 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 belt and instructions on waste handling.

The results obtained applying this guidance could be documented in a table as in the example above. Certificates from suppliers of the articles stating the limits of the SVHC, results of possible chemical analyses and data of the imported articles volumes could be annexed. Documentation procedures to be followed during the assessment of obligations under Article 7 and 33 could be implemented, for example, as a part of an existing quality management system.

## 3) Automotive tyres

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 on sector knowledge.

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 onto 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)[25] 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 EEA. The scenario is also applicable for imported tyres.

**Substance identity**

The company must consult the Candidate List for authorisation.

[25] 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. For the purpose of this example only, it is assumed that some of the PAHs are on the Candidate List.

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 the table below. Several of them are also included in the Water Framework Directive and international conventions due to their inherent hazardous properties.

**Table 15: Some important properties of some of the PAHs in HA oil**

| Substance | Persistent | Bioaccumulative | Carcinogenic[26] (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[27].
+ = 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.
- = negative result.
Blank box = studies lacking.

### 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 and 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

[26] Source IPCS, 1998
[27] Technical guidance document in the program for existing chemicals

extender oils (see table below). The calculation was based on a Life Cycle Assessment of an average European passenger car tyre made by BLIC.

**Table 16: 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 | % in tyre | mg in tyre | % 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 show that the total concentration of PAHs in tyres is much below the threshold limit for notification (Art. 7(2)) and communication of information down streams (Art. 33) of 0.1 % (w/w). Therefore, it is obvious that the concentration of individual PAHs is << 0.1%.

**Check for existing registration**

To be done according to section 6.4 of this guidance.

**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**

**Example: Tyres containing high aromatic extender oils**

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

YES.

**Is your object an article?** *(consult chapter 2)*

YES, tyres are articles.

**Is there an intended release of substances from the article?** *(consult chapter 3)*

NO.

**Conclusion on registration: No need for registration.**

**Does the article contain a SVHC included in the Candidate List?** *(consult chapters 4 and 5)*

YES. HA oils are 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 PAHs have been included on the Candidate List.

**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 17. This demonstrates that the PAH content in the tyre is below the threshold of 0.1%.

**Concentration above 0.1% (w/w)?**

NO.

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

**Comments on the case**

The case illustrates how sector knowledge may be used in the assessment of whether a producer/importer has obligations 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 applying this guidance could be documented in a table as in the example above to which the results of chemical analyses and the data for the yearly produced/imported article volumes could be annexed. The documentation procedures to be applied during the assessment could be implemented, for example, as a part of an existing quality management system.

## 4) Inflatable sleeping mattress

The case of inflatable sleeping mattresses[28] 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 inflatable sleeping mattresses has been used as an example due to the following reasons:

Criteria for selecting inflatable sleeping mattresses:

- Users and application: Large user groups.
- 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 proportion 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.
- DEHP is a CMR substance and has been included in the Candidate List for authorisation and on the Annex XIV Authorisation list.

**Producer/Importer of articles**

The inflatable sleeping mattresses are imported from a non-EEA country and then distributed to retailers within the EEA.

**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 is classified as toxic and toxic to reproduction, i.e. they cause reduced ability to reproduce and damage to the unborn child. The substance has been included in the Candidate List for authorisation and on the Annex XIV Authorisation list.

**Check for existing registration**

To be done according to section 6.4 of this guidance.

[28] Please note that DEHP is restricted in toys or childcare articles by restriction entry 51 of Annex XVII of REACH and such articles containing DEHP in a concentration higher than 0,1% of the plasticised material should not be placed on the market.

**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 inflatable sleeping mattresses imported and the concentration of DEHP in a mattress of 30% (see calculations below).

**Illustration of the decision process**

**Example: DEHP in inflatable sleeping mattresses**

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

YES.

**Is your object an article?** *(consult chapter 2)*

YES, the inflatable sleeping mattress is an article.

**Is there an intended release of substances from the article?** *(consult chapter 3)*

NO.

**Conclusion on registration: No need for registration.**

**Does the article contain a SVHC included in the Candidate List?** *(consult chapters 4 and 5)*

YES. DEHP has been included on the Candidate List.

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

To determine the concentration limit the company asked its 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.

**Concentration above 0.1% (w/w)?**

YES. The concentration of DEHP in the inflatable sleeping mattresses exceeds the threshold limit of 0.1%

**Conclusion after this step: communicate information according to Art. 33.**

As the inflatable sleeping mattress contains more than 0.1% DEHP and is distributed to retailers within the EEA. 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: R60-61 (Repr. 1A; H360FD), the substance 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*

**Is the SVHC intended to be released?**

NO.

**Has the substance already been registered for that use?**

NO. It is assumed that DEHP is not registered for that use.

**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 EEA in the mattresses has to be considered. The total amount of DEHP per year in all imported mattresses is:

The import of mattresses the year before: 150,000 items

The weight of one mattress: 900 g

The maximum DEHP concentration in a mattress: 30% (w/w)

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

**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.

**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 inflatable sleeping mattresses for adults.

Reasonably 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:*

Exposure through inhalation may occur since the article is used indoors. Exposure during the waste phase depend on the waste management method but can not be excluded. *Can exposure to humans or the environment be excluded?*

NO

**Conclusion: Notification is required**

**Comments 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 applying this guidance could be documented in a table as in the example above. Certificates from suppliers of the inflatable sleeping mattress stating the identity and concentration limits of the SVHCs, potential results of chemical analyses, and the data of the yearly imported volumes of inflatable sleeping mattress could be annexed. The documentation procedures to be applied during the assessment of the obligation under REACH could be implemented, for example, as a part of an existing quality management system.

# APPENDIX 4: INFORMATION SOURCES ON SUBSTANCES IN ARTICLES

The non-exhaustive 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 REACH Regulation, as amended) | http://echa.europa.eu/legislation/reach_legislation_en.asp | Restrictions on use and marketing of substances in various mixtures and articles, e.g. textiles and treated wood. |
| ECHA's public database with information on registered substances | http://apps.echa.europa.eu/registered/registered-sub.aspx | The information in this database was provided by companies in their registration dossiers, such as e.g. information on the identified uses of substances, which include uses of substances in articles (please note that the database allows only searches for substances, not for articles). |
| Substance-specific documents relating to Annex XIV Recommendations on ECHA's website | http://echa.europa.eu/chem_data/authorisation_process/annex_xiv_rec/subst_spec_docs_en.asp | For each of the prioritised substances, documents providing further background information also on the uses of substances are accessible. |
| News & Press Archive of ECHA | http://echa.europa.eu/news/archive_en.asp | Press releases of ECHA on the addition of substances to the Candidate List for authorisation also contain information on potential uses of these substances that was submitted to ECHA in Annex XV dossiers by EU Member States. |
| Monographs Database of the International Agency for Research on Cancer (IARC) | http://monographs.iarc.fr | IARC Monographs on the Evaluation of Carcinogenic Risks to Humans also contain information on production and use of substances. |
| SIN List database of the International Chemical Secretariat (ChemSec) | http://www.chemsec.org/list/sin-database | Database contains information on information on substance uses and allows searches for use and function. |
| Series "Survey of Chemical Substances in Consumer Products" | http://www.mst.dk/English/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:<br>EU Eco-label "Flower"<br>Nordic Eco-label<br>Blue Angel Eco-label<br>Austrian Eco-label<br>Thai Green Label | http://www.eco-label.com, http://www.ecolabel.eu<br>http://www.svanen.nu<br>http://www.blauer-engel.de<br>http://www.umweltzeichen.at<br>http://www.tei.or.th/greenlabel | Eco-label requirements limiting and excluding the use of certain substances in consumer goods. |
| 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. |

| Name | Source | Content |
|---|---|---|
| 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.) |
| **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/cen/Members/Pages/default.aspx) | Limits the release of certain substances from drinking equipment for children. |
| **Information sources on substances in construction material** | | |
| AgBB evaluation scheme | http://www.umweltbundesamt.de/produkte-e/bauprodukte/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 2002/95/EC) | http://ec.europa.eu/environment/waste/weee<br>http://www.rohs.gov.uk | Six substances are banned in electrical and electronic equipment: Pb, Hg, Cd, Cr VI, PBB and PBDE. |
| **Information sources on substances in food contact materials** | | |
| Recommendations of the German 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)<br><br>International Dismantling Information System (IDIS) | http://ec.europa.eu/environment/waste/elv_index.htm<br><br>http://www.idis2.com | Requirements regarding the substances in materials and components of vehicles and end-of life vehicles.<br>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 SAMPLING AND ANALYSIS OF SUBSTANCES IN ARTICLES

The non-exhaustive list below contains examples of sampling methods and 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. More methods for different sectors and products can be obtained on the websites of CEN and its national members.

| Name | Source | Content |
|---|---|---|
| **Methods for the sampling and analysis of substances in miscellaneous articles** | | |
| 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. |
| Collection of methods of the German Federal Office of Consumer Protection and Food Safety (BVL) | http://www.methodensammlung-bvl.de | Methods for sampling and analysis of different articles of daily use. |
| **Methods for the sampling and analysis of substances in electrotechnical products** | | |
| Standard IEC/PAS 62596 "Electrotechnical products - Determination of restricted substances - Sampling procedure - Guidelines" | http://www.iec.ch | Strategies to obtain samples from electrotechnical products, electronic assemblies, electronic components that can be used for analytical testing to determine the levels of restricted substances. |
| Standard IEC 62321 "Electrotechnical products - Determination of levels of six regulated substances […]" | http://www.iec.ch | Methods to determine the levels of lead (Pb), mercury (Hg), cadmium (Cd), hexavalent chromium (Cr(VI)) contained in inorganic and organic compounds, and two types of brominated flame retardants, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) contained in electrotechnical products. |
| **Methods for the sampling and 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/cen/Members/Pages/default.aspx) | Method to measure the migration of heavy metals, inorganic and organic substances from articles in contact with saliva or gastric acid. |
| **Methods for the sampling and 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. |

| Name | Source | Content |
|---|---|---|
| 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/cen/Members/Pages/default.aspx) | 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/cen/Members/Pages/default.aspx) | 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 sampling and 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.<br>Other analysis methods include:<br>- NAA (neutron activation analysis)<br>- AAS (atomic absorption spectros.)<br>- XRF (x-ray fluorescence spectros.) |
| **Methods for the sampling and analyses of substances in building products, furniture, textile and leather** | | |
| German Federal Health Bulletin 10/91 (p. 487-483) | http://www.bundesgesundheitsblatt.de | Test methods for the analysis of wood-based materials. |
| 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/cen/Members/Pages/default.aspx) | 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"<br><br>Standard ISO 6452 "Determination of fogging characteristics of trim materials in the interior of automobiles" | http://www.din.de<br><br>http://www.iso.org | Methods to determine the condensable emissions from leather parts in cars. |
| 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/cen/Members/Pages/default.aspx) | Part 1 describes a method for detection of the use of certain azo colorants accessible without extraction.<br>Part 2 describes a method to detect the use of certain azo colorants accessible by extracting the fibres. |
| Standards ISO 14184-1 and ISO 14184-2 "Textiles - Determination of formaldehyde" | http://www.iso.org<br><br>These standards can also be obtained as European Standards (EN ISO 14184-1 and EN ISO 14184-2) from national members of CEN (http://www.cen.eu/cen/Members/Pages/default.aspx) | Methods to determine the formaldehyde emission from padding materials and textiles.<br>Water extraction method to determine free and hydrolyzed formaldehyde, and vapour absorption method to determine released formaldehyde. |
| Standards ISO 16000-5, ISO 16000-9, ISO 16000-10 and ISO 16000-11 "Indoor air - Determination of the emission of volatile organic compounds from building products and furnishing" | http://www.iso.org<br><br>These standards can also be obtained as European Standards (EN ISO 16000-5, EN ISO 16000-9, EN ISO 16000-10 and EN ISO 16000-11) from national members of CEN (http://www.cen.eu/cen/Members/Pages/default.aspx) | Sampling, storage of samples and preparation of test specimens; determination with emission test chamber method and emission test cell method. |

# APPENDIX 6: OTHER LEGISLATION RESTRICTING THE USE OF SUBSTANCES IN ARTICLES

| Instrument | Coverage | Conditions | Notes |
|---|---|---|---|
| (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<br>• Authorisation of biocidal products at national level | • The use of certain biocides is restricted by Regulation (EC) No 1907/2006<br>• 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[29]) Directive 2002/95/EC | Electrical and electronic equipment falling under categories set in Annex IA to (WEEE[30]) Directive 2002/96/EC | • New equipment may not contain Pb, Hg, Cd, Cr(VI), PBB, PBDE<br>• 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 | |

[29] Restriction of Hazardous Substances
[30] Waste Electrical and Electronic Equipment

| Instrument | Coverage | Conditions | Notes |
|---|---|---|---|
| Directive 89/106/EEC<br>Directive 89/686/EEC<br>Directive 93/42/EEC<br>Directive 98/79/EC<br>Directive 90/385/EEC | Construction products<br>Personal protective equipment<br>Medical devices<br>In vitro diagnostic medical devices<br>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<br>• Directive 90/385/EEC also has a provision on bioavailability of substances in the devices | |
| Directive 2006/66/EC | Batteries and accumulators | | |
| (ELV[31]) 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[32]) 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 |

[31] End-of-Life Vehicles
[32] 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<br>• Annex II 'monomers and other starting substances'<br>• Information on impurities in substances and constituents of mixtures<br>• 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 | |

# APPENDIX 7: PARTS OF THE REACH REGULATION OF PARTICULAR RELEVANCE

The following parts of the REACH Regulation are of particular relevance for producers, importers and suppliers of articles:

- **Article 3(3)** provides the definition of an article for the purpose of the REACH Regulation.
- **Article 7** defines under which circumstances article producers and importers have to register or notify substances in articles.
- **Articles 23 and 28** specify the deadlines for pre-registration and registration of phase-in substances.
- **Articles 29 and 30** create the data sharing obligations of registrants and the obligation to participate in Substance Information Exchange Fora (SIEF).
- **Articles 57 and 59** contain the criteria for substances of very high concern (SVHC) and the procedure for inclusion of substances in the Candidate List of Substances of Very High Concern for authorisation.
- **Article 33** defines the duty of article suppliers to communicate information on SVHC in their articles to recipients and consumers.
- **Annex XVII** lists conditions of restrictions, which may pertain to certain substances in articles.

The REACH Regulation as well as the Regulations amending it can be accessed through the website of ECHA.

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