

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 2006¹.

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 Representatives³ 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

²article: 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)).

³Non-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](#).

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

⁵importer: 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)).

⁶supplier 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)).

1 for use in the production process of his articles, he also has to fulfil downstream user
 2 requirements. If the substances are instead purchased outside of the EEA, the article
 3 producer has the role of importer of substances along with the related obligations, such as
 4 registration. Therefore, in general, companies are advised to identify their obligations by
 5 running the [Navigator](#) on the ECHA website. The Navigator helps industry to determine its
 6 obligations under REACH and find the appropriate guidance on how to fulfil these obligations.

7 **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 1.2. Structure of the guidance

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

4 1. Do I need this guidance? (see chapter 1)

5 2. Do I have an article? (see chapter 2)

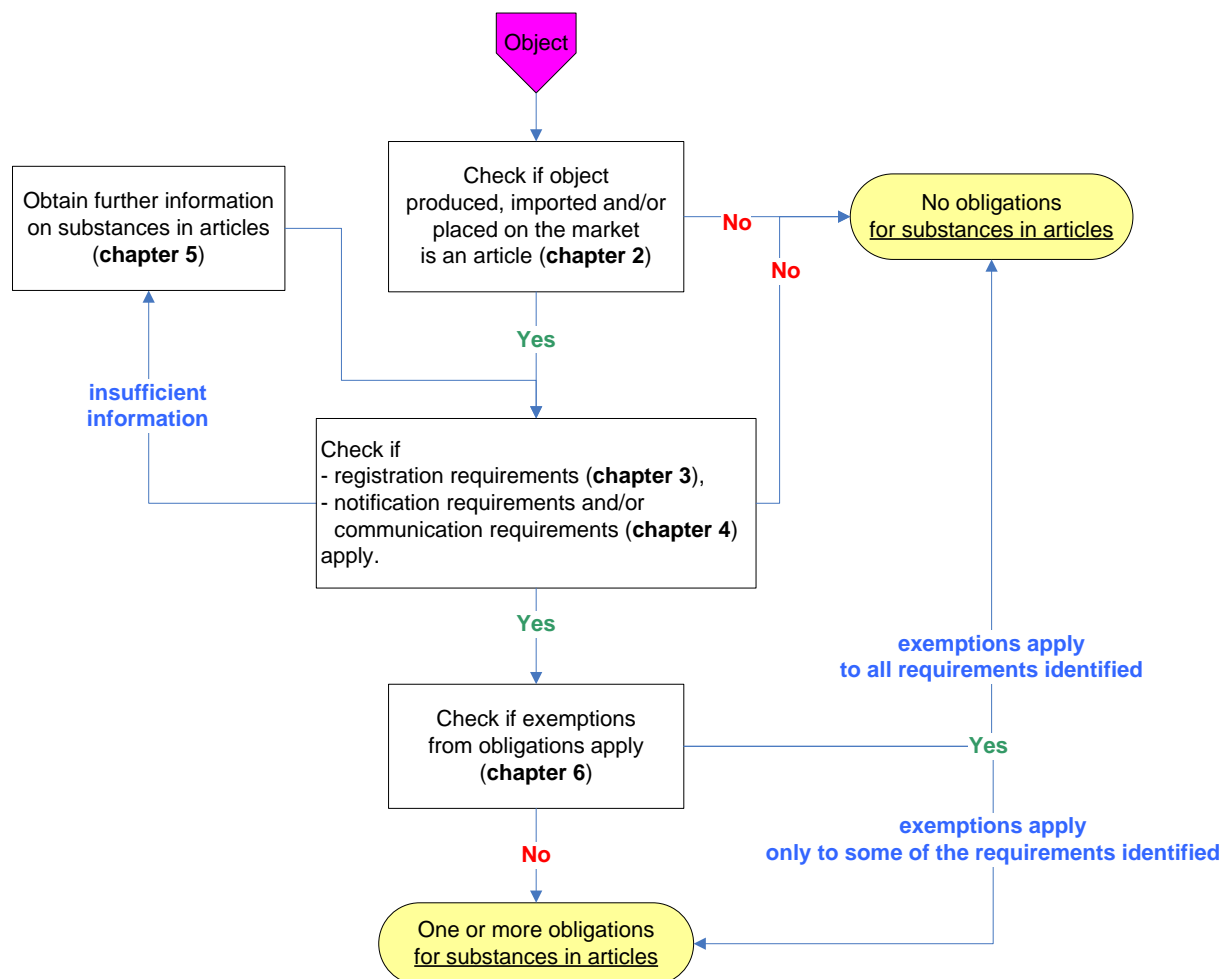
6 3. Is there an intended release of substances from my article and what are the
7 consequences of this (i.e. my obligations)? (see chapter 3)

8 4. Does the composition of my article lead to particular obligations? (see chapter 4)

9 5. How can I obtain further information on the substances in my article? (see chapter 5)

10 6. Can I benefit from any exemption from an obligation concerning substances in articles?
11 (see chapter 6)

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



15

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

18

1 1.3. Topics covered by other guidance documents

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

5 Substances being (an integral) part of imported articles cannot be subject to **authorisation**.
6 This means that in order to import articles into the EEA an authorisation cannot be required.
7 However, if an EEA-based producer of articles incorporates a substance as such or in a
8 mixture⁷ into these articles, that use of the substance may have to be authorised (if the
9 substance is listed in REACH Annex XIV). If such a substance is acquired from the EEA
10 market, the supplier has to give this information in Section 16 of the safety data sheet or via
11 information according to Article 32. If the article producer imports such substances himself,
12 he has to apply for authorisation in order to continue his use(s) of the substances. According
13 to article 3(24) of the REACH Regulation, the production of an article is considered as a use.
14 Details on the authorisation procedure and notifying the use of authorised substances can be
15 found in chapter 8 of the [Guidance for downstream users](#) and in the [Guidance on](#)
16 [authorisation application](#).

17 Furthermore, the content of substances in articles can be restricted or banned under the
18 **restrictions** procedure. Therefore, article producers and importers have to follow the
19 conditions outlined in Annex XVII of the REACH Regulation as amended⁸. Details on
20 compliance with restrictions under REACH are given in chapter 8 of the [Guidance for](#)
21 [downstream users](#). Please note that other legislation concerning restrictions limiting the use
22 of hazardous substances in articles still apply separately from REACH. Examples are the
23 General Products Safety Directive 2001/95/EEC and product specific legislation such as
24 Directive 2002/95/EC on the Restriction of the Use of Certain Hazardous Substances in
25 Electrical and Electronic Equipment (RoHS), Directive 88/378/EEC on toys or Directive
26 2000/53/EC on End of Life Vehicles (ELVs). A list of relevant legislation aside from REACH is
27 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](#).

1 2. DECIDING WHAT IS AN ARTICLE UNDER REACH

2 When determining if and which requirements apply, the first step is to check whether the
3 objects⁹ produced, imported and/or placed on the market are considered to be articles under
4 REACH or not.

5 An article is generally understood to be an object composed of one or more substances or
6 mixtures given a specific shape, surface or design. It may be produced from natural
7 materials, such as wood or wool, or from synthetic ones, such as polyvinyl chloride (PVC). It
8 may be very simple, like a wooden chair but can also be very complex, like a laptop
9 computer, consisting of many parts. Most of the commonly used objects in private
10 households and industries are articles, e.g. furniture, clothes, vehicles, books, toys, kitchen
11 equipment and electronic equipment. Buildings are not considered to be articles, so long as
12 they remain fixed to the land on which they stand¹⁰.

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

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

20 2.1. The function of an object

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

28 2.2. The shape, surface and design of an object

29 The shape, surface and design of an object represent its physical appearance and can be
30 understood as other than chemical characteristics. **Shape** means the three-dimensional form
31 of an object, like depth, width and height. **Surface** means the outermost layer of an object.
32 **Design** means the arrangement of the “elements of design” in such a way as to best
33 accomplish a particular purpose. For example, the design of a textile may be determined by
34 the twist of fibres in the yarn, the weave of threads in a fabric and the treatment of the surface
35 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.

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

5 **Example 1: Blasting grit**

6
7 Grit for abrasive blasting needs to be hard and have sharp edges to be applied as blasting
8 medium (e.g. for glass engraving or stone etching). The hardness and the cleavage
9 properties of the materials used as blasting grit, such as corundum or steel, depend on the
10 chemistry of these materials, and should not be confused with the shape, surface or design
11 of an object.
12

13 Furthermore it is to be noted that according to Article 3(3) of the REACH Regulation an article
14 is an object which during production is given a special shape, surface or design which
15 determines its function to a greater degree than its chemical composition. This implies that
16 the **shape, surface or design must be deliberately determined and given during a**
17 **production step**. In this sense, the “production step” of an article can also be understood to
18 include the assembly of the components (which can themselves be articles) of a complex
19 article (e.g. a laptop).

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

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

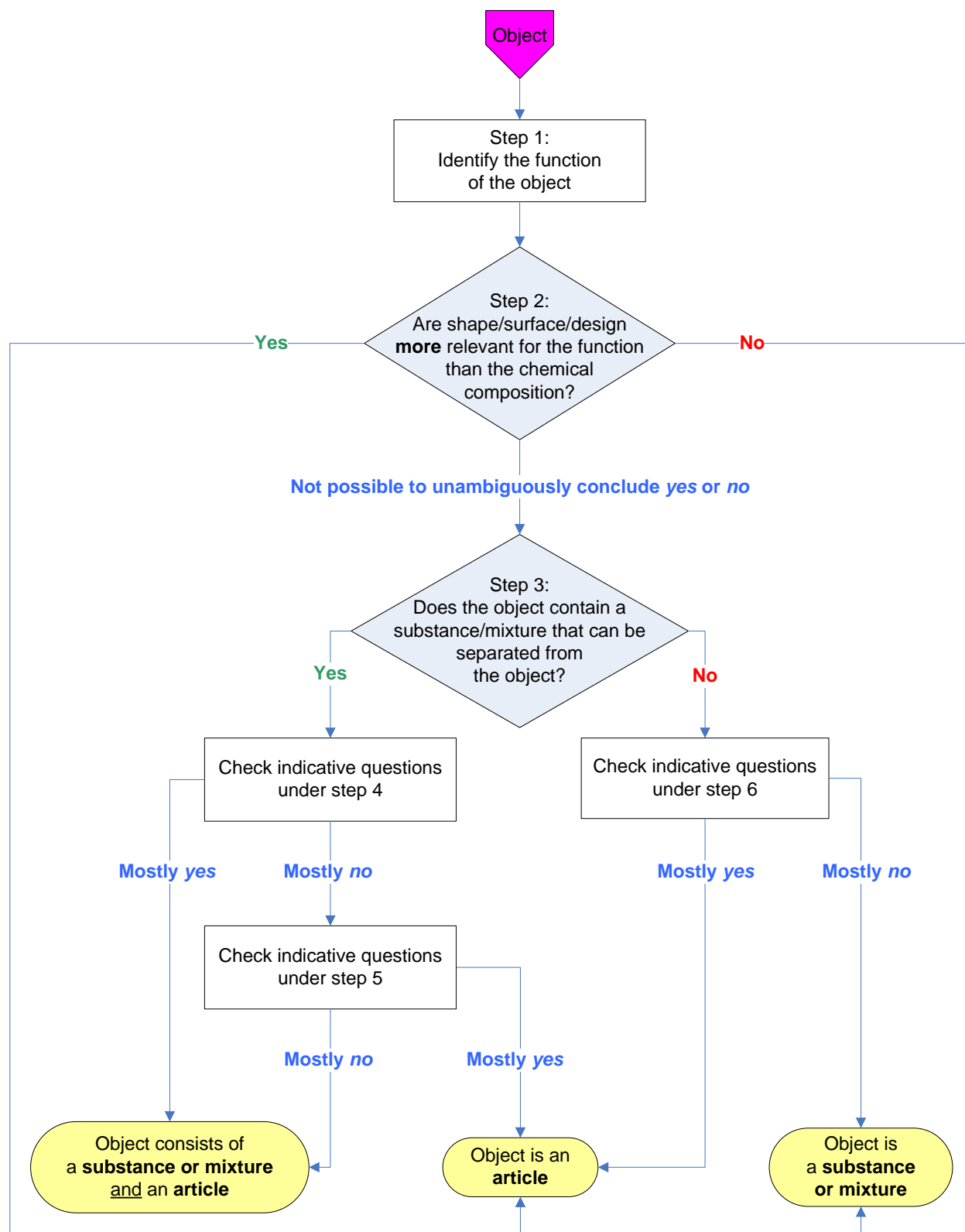
26 Therefore **a set of objects cannot be regarded as one article, but has to be regarded as**
27 **many articles, substances and/or mixtures.**

28 **2.3. Packaging**

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

1 2.4. Deciding whether an object is an article or not

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



3
4 **Figure 2: Decision-making on whether an object is an article or not**

5

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

2 **Step 2:** In many cases applying the REACH definition of an article is straightforward. The
3 decision on whether an object is an article or not can then directly be made by comparing the
4 importance of physical and chemical characteristics for achieving the object's function. **If you
5 can unambiguously conclude that the shape, surface or design of the object is more
6 relevant for the function than its chemical composition, the object is an article. If the
7 shape, surface or design is of equal or less importance than the chemical
8 composition, it is a substance or mixture.**

9 **Example 2: Wax crayon**

10 A wax crayon consists of paraffin wax and pigments and is used for colouring and drawing
11 on paper. As its shape/surface/design are not more relevant for the function of the crayon
12 (to bring pigment to paper) than its chemical composition, it is to be regarded as a mixture.
13
14

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

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

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

25 **Step 4:** For determining whether the chemical content of the object is an integral part thereof
26 (and therefore the object as a whole is an article as defined under REACH) or if it is a
27 substance/mixture for which the rest of the object functions as a container or carrier material,
28 the following indicative questions should be answered:

29 *Question 4a: If the substance/mixture were to be removed or separated from the object and
30 used independently from it, would the substance/mixture still be capable in
31 principle (though perhaps without convenience or sophistication) of carrying out
32 the function defined under step 1?*

33 *Question 4b: Does the object act mainly (i.e. according to the function defined under step 1)
34 as a container or carrier for release or controlled delivery of the
35 substance/mixture or its reaction products?*

36 *Question 4c: Is the substance/mixture consumed (i.e. used up e.g. due to a chemical or
37 physical modification) or eliminated (i.e. released from the object) during the
38 use phase of the object, thereby rendering the object useless and leading to the
39 end of its service life?*

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

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

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

9 **Example 3: Printer cartridge**

10 Answering the above indicative questions: 4a) if the toner/ink was moved from the
11 cartridge, it would still be possible to bring it to paper, although with a loss of quality and
12 convenience; 4b) the function of the cartridge is to hold the toner/ink in place inside a
13 printer and it controls the speed and mode of release; 4c) the cartridge is disposed of
14 without the toner/ink, which is consumed during the service life of the cartridge. The
15 answers to the questions allow the conclusion that a printer cartridge is a combination of an
16 article (functioning as container) and a substance/mixture.
17
18

19 **Step 5:** If the answers to the indicative questions under step 4 are mostly no, you should use
20 the following questions to cross-check whether the object as a whole should indeed be
21 considered as an article and not as a combination of an article (functioning as a container or
22 a carrier material) and a substance/mixture.

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

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

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

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

35 **Example 4: Thermometer**

36 Answering the above questions: 5a) the empty thermometer would fail to show the
37 temperature; thus the object would no longer be useful; 5b) the main function of the
38 thermometer is to show the temperature, this is not a delivery of a substance or mixture;
39 5c) the thermometer is normally disposed of together with its chemical content.
40 So answering these questions leads to the conclusion that a thermometer is an article
41 and the liquid within an integral part of it.
42
43

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

1 **Step 6:** According to the assessment made under step 3, the object does not contain a
2 substance or mixture that can be physically separated. Deciding whether the object fulfils the
3 REACH definition of an article or not may however still be difficult in certain cases. Common
4 examples are raw materials and semi-finished products that are further processed to final
5 articles, but other cases might exist. In these cases, where making a decision is difficult, you
6 may use the following indicative questions in order to better determine whether or not the
7 object is an article. These questions can only be used to support the evaluation of the
8 importance of the chemical composition versus the shape/surface/design in relation to the
9 function and thus facilitate the application of the article definition.

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

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

18 *Question 6c: When further processed, does the object undergo only “light processing”, i.e. no*
19 *gross changes in shape?*
20 *“Light processing”, such as drilling, surface grinding or coating, may improve or*
21 *modify an object’s shape, surface or design for carrying out a function and is*
22 *thus frequently applied to objects which are already articles. Thus, if only “light*
23 *processing” is applied, this is an indication that the object is an article.*
24 *Processes leading to gross changes in shape, meaning changes of depth, width*
25 *and height of an object, are not regarded as “light processing”. These can for*
26 *example be primary shaping processes (such as casting or sintering) or forming*
27 *processes (such as extrusion, forging or rolling). If the object preserves at least*
28 *one of its characteristic dimensions (depth, width and/or height) when further*
29 *processed, the process can be regarded as “light processing”.*

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

37 Not all questions may apply to all objects and the weight of evidence of the answers to the
38 questions may vary from case to case. However, in concluding whether the object is an
39 article or not, the answer to various of the relevant indicative questions should be considered
40 and not only the answer to one of them. **Predominantly answering with yes to the**
41 **questions indicates that the object is an article. Predominantly answering no to the**
42 **questions indicates that the object is a substance or mixture.** Appendix 2 illustrates how
43 to apply these indicative questions and gives examples from four different industry sectors.

44

1 2.5. Documentation

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

12 Checklists or other standardised tools developed by industry associations and other
13 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 article¹². **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 size¹³ 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).

1 conditions of use¹⁴ (this can be established by applying the criteria in section 3.1).

- 2 • The total amount of the substance present in all articles with intended release (i.e.
3 including the amounts that are not intended to be released) produced or imported by one
4 actor exceeds 1 tonne per year¹⁵.

5 Hence, in order to identify a possible obligation to register a substance in articles it needs to
6 be checked if the 1 tonne per year threshold is exceeded. For this the identity and the
7 tonnage of the actual substance do not always have to be known, as the 1 tonne per year
8 threshold can initially be compared to:

9 1. the total tonnage of *all articles with intended release* produced and/or imported, and to

10 2. the total tonnage of *all substances and mixtures intended to be released* incorporated in
11 these articles.

12 If any of these tonnage values is equal to or remains under 1 tonne per year, the volume of
13 *individual substances intended to be released* incorporated in these articles will definitely also
14 be below 1 tonne per year. Thus, registration of substances in these articles will clearly not
15 be required. However, if the need to register cannot be excluded on the basis of these
16 checks, the *individual substances intended to be released* will have to be identified, and
17 (unless you can benefit from an exemption from registration; see chapter 6) also their
18 respective tonnage.

19 The tonnage of a *substance intended to be released* contained in articles can be calculated
20 using either of the following equations:

21
$$Vol_{subs.} = Weight_{article} \cdot Number_{articles} \cdot Conc_{max\ mixture\ in\ article} \cdot Conc_{max\ subs.\ in\ mixture}$$

22
$$Vol_{subs.} = Vol_{articles} \cdot Conc_{max\ subs.\ in\ article}$$

23 $Vol_{subs.}$: volume of a *substance intended to be released* contained in articles [t/a].

24 $Weight_{article}$: weight of one article [t/article].

25 $Number_{articles}$: number of articles produced and/or imported per year [articles/a].

26 $Conc_{max\ mixture\ in\ article}$: maximum weight fraction of the *mixture intended to be released* in the
27 article; value between 0 and 1 (50% = 0.5, 25% = 0.25, 20% = 0.2, etc.).

28 $Conc_{max\ subs.\ in\ mixture}$: maximum weight fraction of the substance in the *mixture intended to be*
29 *released*; value between 0 and 1 (50% = 0.5, 25% = 0.25, 20% = 0.2,
etc.).

30 $Vol_{articles}$: volume of articles produced and/or imported per year [t/a].

31 $Conc_{max\ subs.\ in\ article}$: maximum weight fraction of the *substance intended to be released* in the
32 article; 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 up¹⁶.

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 \(ESIS\)](#)

- 1 • [Commission Staff Working Document SEC\(2007\)1635](#) on the implementation of the
2 “Community Strategy for Endocrine Disrupters”
- 3 • List of Chemicals for Priority Action of the [OSPAR Commission](#)
- 4 • [SIN List database](#) of the International Chemical Secretariat (ChemSec)
- 5 • [Trade Union Priority List](#) of the European Trade Union Confederation (ETUC)

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

10 **4.2. Notification according to Article 7(2)**

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

- 13 • The substance is included in the Candidate List for authorisation.
- 14 • The substance is present in articles produced and/or imported above a concentration of
15 0.1% (w/w).
- 16 • The total amount of the substance present in all articles produced and/or imported, which
17 contain more than 0.1% (w/w) of the substance, exceeds 1 tonne per actor per year.

18 The substance concentration threshold of 0.1% (w/w) applies to the article as produced or
19 imported. The same threshold applies to each article imported as a component of an
20 imported complex article as well as the imported complex article. Hence, importers must
21 collect information not only on the complex article but also on the component articles thereof.

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

25 The notification obligation rests on importers and producers of articles. Therefore, the (EU)
26 producer of a complex article does not need to notify the component articles that he uses,
27 because they have been notified upstream by the persons who imported or manufactured
28 them.

29 A notification is not required for a substance in articles which have been produced or
30 imported before the substance has been included on the Candidate List for authorisation¹⁷.
31 Furthermore, in certain cases an exemption from the obligation to notify applies (see chapter
32 6).

33 A notification of substances in articles shall be made at the latest 6 months after it has been
34 included on the Candidate List of Substances of Very High Concern for authorisation, but
35 only starting from 1 June 2011. This means that for substances included in the Candidate List

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.

1 before 1 December 2010, the notifications have to be submitted not later than 1 June 2011.
2 For substances included in the Candidate List on or after 1 December 2010, the notifications
3 have to be submitted no later than 6 months after the inclusion.

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

- 5 • the identity and contact details of the producer or importer of the articles
- 6 • the registration number for the substance, if available
- 7 • the identity of the SVHC (this information is available from the Candidate List and the
8 supporting documentation)
- 9 • the classification of the substance (this information is available from the Candidate List
10 and the supporting documentation)
- 11 • a brief description of the use(s) of the substance in the article(s) as specified in section
12 3.5 of Annex VI and of the uses of the article(s)
- 13 • the tonnage range of the substance contained in the articles, i.e. 1-10 tonnes, 10-100
14 tonnes, 100-1000 tonnes or ≥ 1000 tonnes.

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

18 **4.3. Obligations according to Article 33**

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

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

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

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

- 39 • There is no tonnage trigger for these obligations (i.e. they also apply below 1 tonne per
40 year).
- 41 • Packaging is always to be treated as article(s) separate from the contents of the
42 packaging. Therefore, the obligations to communicate information on substances in

1 articles also apply to packaging materials.

2 • The substance concentration threshold of 0.1% (w/w) applies to every article supplied, be
3 it a component article or a complex article. Article suppliers must provide information not
4 only on the complex articles but also on their component articles.

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

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

10

11 **4.3.1. Communicating information according to Article 33**

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

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

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

17 • what the hazards of the SVHC are for human health and the environment

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

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

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

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

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

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

39 • information on labels

- 1 • link to a website with up-to-date information
- 2 • standard communication formats developed by industry sector associations

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

6 **4.4. Determination of the concentration of a SVHC in complex** 7 **articles with component articles**

8 In order to calculate whether the concentration of an SVHC substance exceeds 0.1% (w/w) in
 9 a complex article (for the purposes of Article 7(2) or 33 obligations), firstly it needs to be
 10 known for each component article whether it contains above 0.1% (w/w) of the SVHC or not
 11 (if not yet available, this information can be obtained by different means as described in
 12 chapter 5).

13 To illustrate the cases that may arise when checking the 0.1% threshold for a complex article
 14 made up of more than one component article, the example of the laptop assembled from
 15 different component articles, such as transformer, motherboard, memory, processor, chassis,
 16 etc. is taken up:

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

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

- 21 1. find out the concentration of the SVHC in each component and the mass of each
 22 component containing the SVHC (whether above 0.1% (w/w) or below),
- 23 2. calculate the mass of the SVHC in each of these n components as follows,

$$24 \quad m_{SVHC \text{ in component}} = m_{\text{component}} \cdot Conc_{SVHC \text{ in component}} [\%] \cdot 0.01$$

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

$$27 \quad Conc_{SVHC \text{ in whole article}} [\%] = \frac{m_{SVHC \text{ in component A}} + m_{SVHC \text{ in component B}} + \dots + m_{SVHC \text{ in component n}}}{m_{\text{whole article}}} \cdot 100$$

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

31 The importer of a complex article may use the same method to calculate the concentration of
 32 an SVHC in the complex article.

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

2 *[Please note that this example has been removed from the guidance following the*
3 *judgement of the Court of Justice of 10 September 2015 in case C-106/14. New/update*
4 *examples will be re-inserted into the next version of this guidance after full*
5 *consultation]*

6

7 4.5. Determining the total amount of a SVHC on the Candidate List
8 in different articles

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

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

$$15 \text{Vol}_{\text{SVHC in one article type}} [t/a] = (\text{Conc}_{\text{SVHC in whole article}} [\%] \cdot 10^{-2}) \cdot (m_{\text{article}} [g/article] \cdot 10^{-6}) \cdot n_{\text{articles}} [\text{articles}/a]$$

16

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

$$20 \text{Vol}_{\text{SVHC in all article types}} [t/a] = \text{Vol}_{\text{SVHC in article type A}} [t/a] + \text{Vol}_{\text{SVHC in article type B}} [t/a] + \dots + \text{Vol}_{\text{SVHC in article type n}} [t/a]$$

21

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.

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

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

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.

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

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.

21

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.

1 Unlike suppliers of substances and mixtures, **suppliers of articles** do not always have to
2 provide standardised information to their customers. Only when the articles supplied contain
3 a substance included in the Candidate List of Substances of Very High Concern for
4 authorisation in a concentration above 0.1% (w/w), they must provide available and relevant
5 safety information according to Article 33, including, as a minimum, the name of that
6 substance.

7 **5.1.2. Requesting information up the supply chain**

8 Where the information received is not sufficient to check compliance with REACH, producers,
9 importers and suppliers of articles may consider obtaining the necessary information by pro-
10 active requests in the supply chain. The following points should be taken into consideration
11 when requesting information from other actors in the supply chain:

- 12 • It may be helpful to tell suppliers why the information is needed, which may be unknown,
13 particularly to non-EEA suppliers. For this, several [publications](#) are available on ECHA's
14 website, that explain the background and implications of REACH. Some of these
15 documents are available in different languages helping to overcome language barriers.
- 16 • To avoid requests having to be passed up complex supply chains via several distributors,
17 the producers of articles, formulators and manufacturers of substances could be identified
18 and addressed directly to obtain the information required.
- 19 • In many cases the exact composition of articles or mixtures is not needed to clarify
20 whether requirements for substances in articles have to be fulfilled. Certainty in particular
21 that no notification or communication obligations for substances in articles apply can also
22 be achieved by excluding or limiting the presence of substances that are on the
23 Candidate List of substances for authorisation. Suppliers could for example provide
24 certificates which guarantee that certain substances are not used in the manufacture of
25 their products or remain below certain concentrations in their products. A different
26 approach would be to include respective criteria in supply contracts excluding or limiting
27 the presence of certain substances in the products to be supplied.
- 28 • It is recommended that requests in the supply chain are targeted and aim at excluding or
29 limiting the presence of certain substances (e.g. those on the Candidate List for
30 authorisation) instead of asking for the exact composition of articles or mixtures, which is
31 more often confidential information.
- 32 • Substances intended to be released from articles are usually released as part of mixtures,
33 the concentration of which in the articles is more often known than the concentration of
34 the individual *substances intended to be released*. If the maximum content of the *mixture*
35 *intended to be released* in articles is known, critical levels for the concentration of
36 substances in the mixture, above which a registration of substances in those articles
37 might be required, can be calculated as shown in section 5.1.2.1. Information requests up
38 the supply chain should then be focused on substances exceeding the concentration
39 calculated to be critical.

40 Some industry sectors have developed information systems and tools that can be used to
41 obtain and communicate information on substances in articles within the supply chain in an
42 efficient manner. There may however be cases where supply chain communication will not
43 be successful. In these cases other means of obtaining information on substances in articles
44 may be used, such as a combination of branch knowledge, publicly available information
45 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.

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

$Conc_{\text{max subs. in mixture}}$: 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].

$Conc_{\text{max mixture in article}}$: 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.

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

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

1 the supplying company?

2 • Is there reason for concern over the validity of the declaration?

3 If yes, access to any documentation supporting the declaration should be requested.

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

8 • A scientific test report should include the following elements:

9 - Name and address the laboratory involved in the analysis

10 - Date of receipt of the sample and date of performance of the test

11 - Unique identification of the report (such as a serial number) and date of issue

12 - Clear identification and description of the sample and the substance(s)
13 for which testing was performed

14 - Sample preparation methods and analytical methods used,
15 including references to the standards used and any deviations from them

16 - The limit of detection (LOD) or limit of quantification (LOQ) of the test method

17 - Results of the test (with unit of measurement) including uncertainty of the test results

18 - Name and signature of the individual authorizing the report

19 • It should be checked whether the concentration of a substance obtained in the test is
20 really below the relevant limit (e.g. below the 0.1% threshold or the critical concentration
21 level for substances in a *mixture intended to be released*).

22 • The raw materials and processing of a product can change over time, leading to
23 alterations of the product batches supplied. Therefore it needs to be ensured that the test
24 documented in the report was conducted with the relevant type of product (i.e. the same
25 type as the products supplied).

26 • There should be some level of understanding of the methods used in the test. If the
27 presentation of the methods is not clear then an explanation should be sought from the
28 supplier to avoid confusion and possible non-compliance.

29 **5.2. Chemical analysis of substances in articles**

30 Substances contained in articles can be identified and their concentrations quantified by
31 applying analytical methods. If other approaches to obtaining information fail or become too
32 complicated, conducting chemical analysis may thus be an option to obtain information on the
33 composition of articles. This is particularly the case when an article consists of a
34 homogenous material, but also for complex, small articles, shredding and testing of a sample
35 might be a feasible approach.

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

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

3 Although chemical analyses may be helpful in certain situations, it is to be noted that they
4 may yield ambiguous results and/or be very costly and are thus not recommended as the
5 preferred instrument for obtaining information.

6 **5.2.1. Difficulties of chemical analyses**

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

- 9 • Articles may be very complex and composed of different parts and materials. It is
10 therefore difficult to create a sample for the analysis that represents the whole article.
- 11 • Substances that are included in the article matrix may have to be extracted from it¹⁸.
 - 12 - This may result in chemical reactions that could “create” substances which do not
13 exist in the article.
 - 14 - The extraction may not be exhaustive, thus the full content of substances in the matrix
15 may not be obtainable.
 - 16 • Various analytical methods are available to screen for the existence and identification of
17 different substances in a sample.
 - 18 - Measurements in most cases will identify the chemical constituents in the sample but
19 not necessarily “the substance” which were originally used to produce the article. Note
20 that substances may consist of several constituents (for more information please
21 consult the [Guidance on substance identification](#)).
 - 22 - Some methods may show the existence of certain elements (e.g. halogens) rather
23 than the existence of substances.
 - 24 - If a high number of different substances are contained, several analyses may be
25 needed to identify all substances, and it is particularly difficult to assign an appropriate
26 method if it is not clear what is being searched.
 - 27 - The quantification of substances requires additional measurements.

28 **5.2.2. Planning chemical analyses of substances in articles**

29 Chemical analyses have to be planned carefully taking into account what information can be
30 obtained with which methods. If an analysis is carried out, a strategy should be developed in
31 collaboration with experienced laboratories and based on available methods. The testing
32 strategy and interpretation of results should take into account any other available information
33 on the article which is being analysed e.g. from industry sector organisations, research
34 institutions and accredited chemical analysis laboratories. There are no formal requirements
35 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.

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

5 The following steps are proposed, when planning chemical analyses:

- 6 • Consult experts or sector information sources to narrow down which substances to look
7 for (e.g. for many articles it can be excluded that gaseous substances are contained
8 therein).
- 9 • Develop a strategy for testing as a tiered process, i.e. broad screenings, narrow
10 screenings and identification by e.g. semi-quantitative methods.
- 11 • Identify which part(s) of the article to analyse: liquids, gases or powders contained in the
12 article, extracts from the article matrix, article parts likely to contain a particular SVHC,
13 etc.
- 14 • 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 use¹⁹, 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

¹⁹The terms “normal conditions of use” and “reasonably foreseeable conditions of use” are explained in section 3.1.

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

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

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

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

22 **Note that it may be more difficult and costly to demonstrate “no exposure” than**
23 **making a notification.** Some key notions on exposure assessment are described in section
24 6.3.1, for further guidance on how demonstrating that no exposure occurs please consult
25 chapters R14 to R18 of the [Guidance on information requirements and chemical safety](#)
26 [assessment](#).

27 **6.3.1. Potential for release**

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

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

1 - The disposal technology.

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

9 **6.4. Exemption from registration and notification of substances** 10 **already registered for a use**

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

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

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

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

24 To ensure that the substance in question is the same as a substance that has already been
25 registered, comparing names, and EINECS or CAS numbers of both substances may not
26 always be sufficient. When deciding whether or not two substances can be regarded as the
27 same, the “criteria for checking if substances are the same” given in chapter 5 of the
28 [Guidance on substance identification](#) should be applied.

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

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

4 Substances will be registered throughout the phase-in scheme until 2018. Thus, a substance
5 may not yet have been registered at the time a producer or importer of an article checks if his
6 use has already been registered.

7 **6.4.1. Information sources to determine if a substance is already** 8 **registered for a use**

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

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

23 In case a substance requiring a safety data sheet has been registered in a quantity of 10 t/a
24 or more, recipients of this substance (on its own or in a mixture) are provided by their supplier
25 with the relevant **exposure scenarios** in an annex to the safety data sheet. If relevant to the
26 recipients of this substance, these exposure scenarios also cover the uses by which the
27 substance is incorporated in articles. Therefore the information contained in exposure
28 scenarios can be used by article producers to establish whether their use of the substance
29 has already been registered up the supply chain.

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

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

- 39 • A good way to identify manufacturers and importers of a substance who might have
40 registered it for a particular use, is to launch a corresponding request within the
41 Substance Information Exchange Forum for this substance (SIEF), provided that you
42 have pre-registered the substance and become a participant in that SIEF.
- 43 • You may also contact trade associations, who might have information on the registration
44 status of a particular substance and the uses the substance has been registered for.

- 1 • As a downstream user, a producer of articles has the right to make the use by which he
2 includes a substance (on its own or in a mixture) in his articles known to his supplier
3 requesting that his use becomes an identified use²⁰. The supplier has several options to
4 react to a use made known to him (further information is provided in chapter 8 of the
5 [Guidance for downstream users](#)). However, in the course of the dialogue initiated with the
6 supplier, the article producer may obtain the confirmation that the substance has been or
7 will be registered for his use.

8
9 The ECHA dissemination database for substance information, which can be accessed via the
10 ECHA website: <http://apps.echa.europa.eu/registered/registered-sub.aspx> contains
11 information on registered substances provided by companies in their registration dossiers. It
12 includes a variety of information on the substances which companies manufacture or import
13 and may include information on the uses of the substance, unless the companies have
14 claimed this information as confidential, including use of the substance in articles. However,
15 since the description of the use available here consists only of elements of the use descriptor
16 system, the information will normally not be sufficient to conclude on the sameness of two
17 uses for the purpose of establishing whether an exemption on the basis of Article 7(6)
18 applies.

19

20

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	
	<u>article</u> with an integral substance/mixture	combination of an <u>article</u> (functioning as a container or a carrier material) and a <u>substance/mixture</u>
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

1 **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 <u>article</u> and a <u>substance /mixture</u>	combination of an <u>article</u> and a <u>substance /mixture</u>	combination of an <u>article</u> and a <u>substance /mixture</u>	see table 5

2

1 **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 <u>article</u> and a <u>substance/mixture</u>	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.

1 **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	<u>article</u> with an integral substance/mixture	<u>article</u> with an integral substance/mixture	<u>article</u> with an integral substance/mixture

1 **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 <u>article</u> and a <u>substance/mixture</u>	combination of an <u>article</u> and a <u>substance/mixture</u>	combination of an <u>article</u> and a <u>substance/mixture</u>

2

²²This 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.

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

Object	Wax tape for skis (example for adhesive tapes that deliver substances/mixtures onto a surface, whereas the carrier material serves only as a release liner and aid to easy application; the adhesive layer may change its shape upon application)	Adhesive tape for fixing carpets (example for adhesive tapes that do not deliver substances/mixtures onto a surface, and consist of adhesive layer(s) and a backing or internal reinforcement)
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 <u>article</u> and a <u>substance/mixture</u>	see table 8

2

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.

1 **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	<u>article</u> with an integral substance/mixture

1 **APPENDIX 2: EXAMPLES OF SETTING THE BORDERLINE** 2 **IN THE SEQUENCE OF PROCESSING** 3 **NATURAL OR SYNTHETIC MATERIALS INTO** 4 **FINAL ARTICLES**

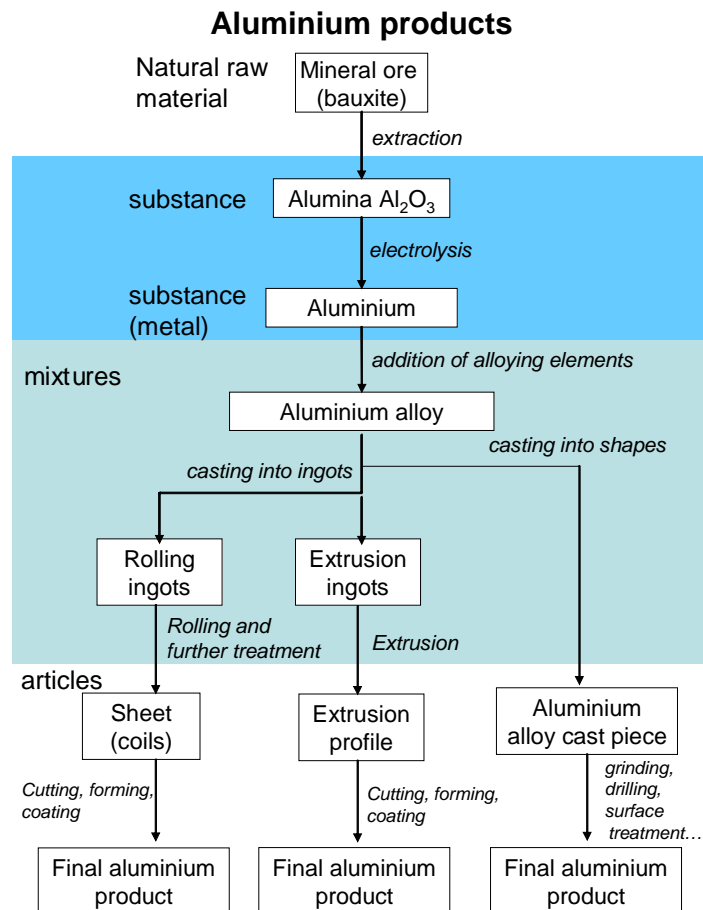
5 In section 2.3 the main guidance text contains explanations and indicative questions to
6 support the evaluation of the importance of the chemical composition of objects versus their
7 shape/surface/design in relation to the function. The indicative questions 6a to 6d can be
8 used to determine the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

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

19 In the following, guidance on where and how to set the borderline during the refinement of
20 raw materials and production of various final articles is given for four sectors: metals, textile
21 (in cooperation with non-woven industry), paper and plastic. The examples are intended to
22 illustrate the decision making process and it should be stressed that if in doubt, a careful
23 examination in line with the indicative questions should be conducted. In line with this, the
24 following examples should be applied with care taking into account the exceptions indicated
25 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.



6

7

Figure 3: Transition from bauxite to final aluminium products

The transition point from mixture²⁴ 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.

11

²⁴ formerly termed "preparation" as in the figure.

1 **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

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

7 Below the two ways of processing aluminium ingots shown in figure 3 are discussed with
8 regard to the borderline between mixture and article status.

1 Aluminium alloy - rolling ingots - coils

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

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

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

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

27 Aluminium alloy - extrusion ingots - extrusion profiles

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

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

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

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

1 **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. 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

2 Raw material types similar to the aluminium alloy cast piece are: castings (e.g. centrifugal,
3 die, investment, sand, etc.), continuous cast shapes (e.g. bars, billets, blooms, rounds,
4 slabs). A case-by-case consideration should normally be done to make the final decision on a
5 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.

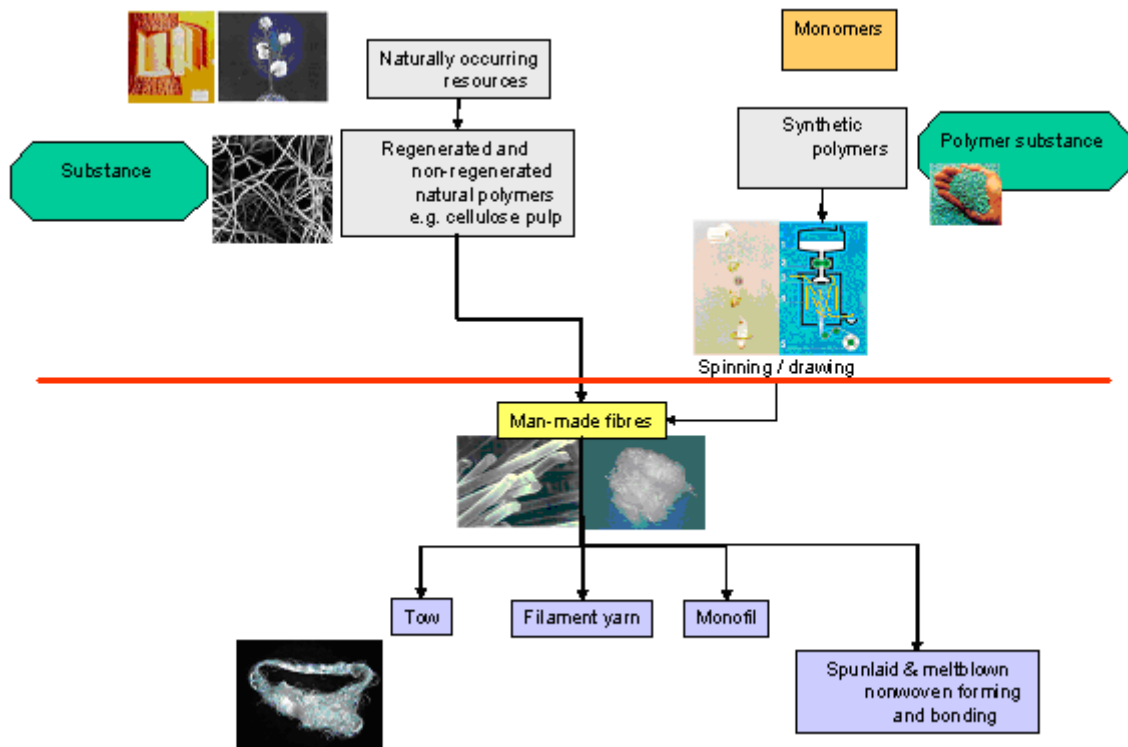


Figure 4: Transition from raw materials to final textile/non-woven products

1 **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

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

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

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

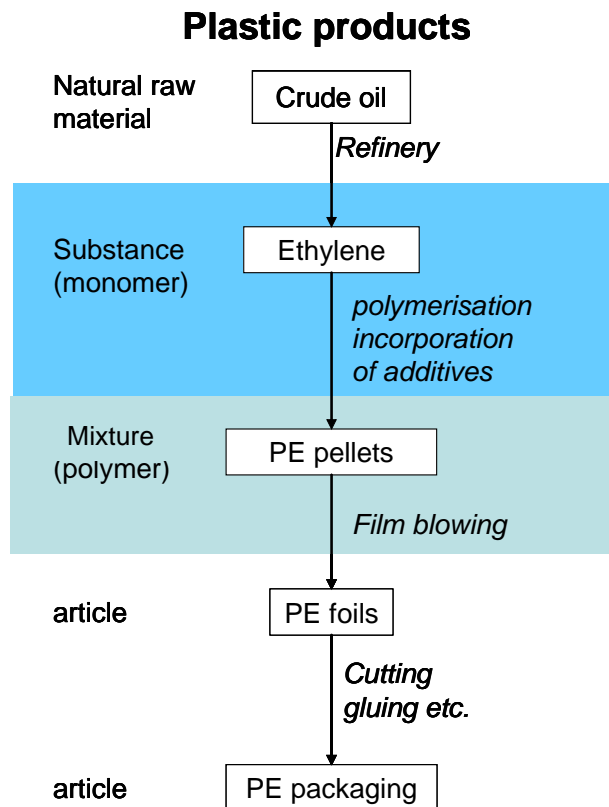
12 The type of extrusion/drawing determines the diameter of the fibre and therefore it is the
13 processing step that deliberately forms the shape of the fibre. Further properties like strength,
14 elongation and shrink are given to the fibres in this step as well. The man-made fibres are
15 ‘assembled’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

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

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

1 3) Polymer processing

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



7
8 **Figure 5:** Transition from crude oil to plastic products
9

1 **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

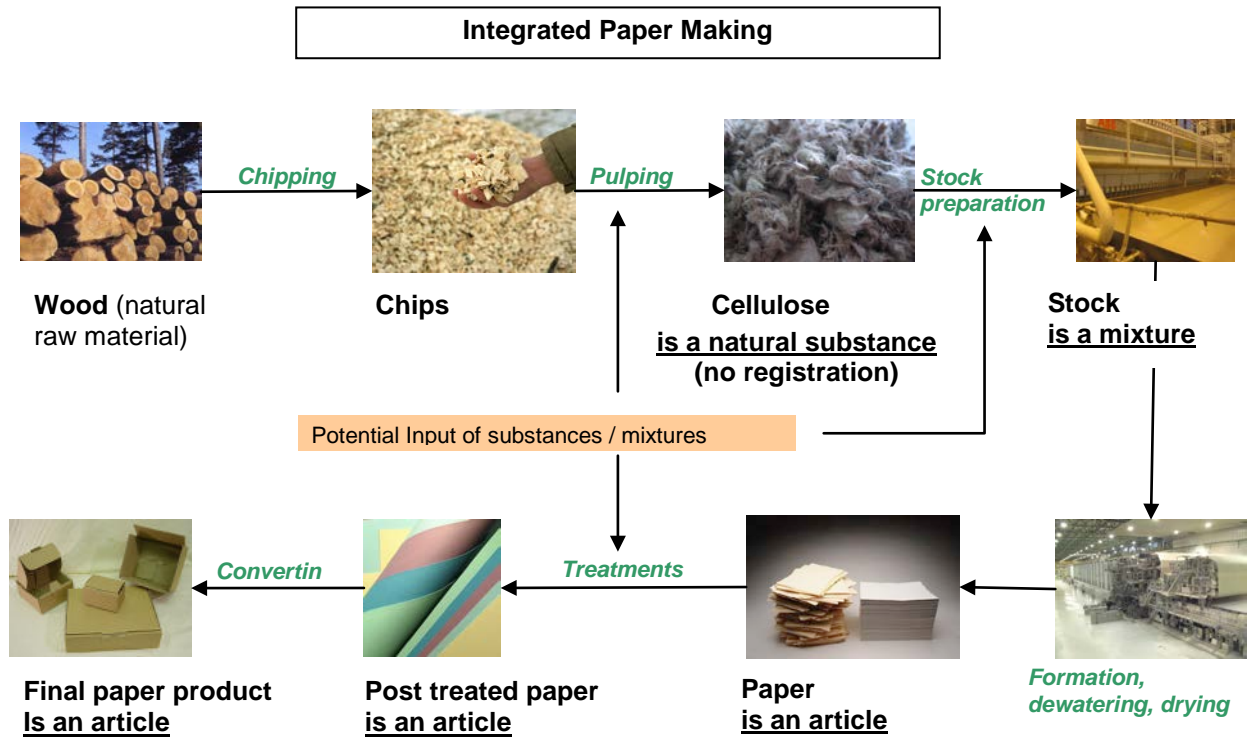
2 Whereas the polymer pellets do not have an end use function yet, the converted materials
3 are likely to have one. In the example, the PE foil can directly be used for packaging and can
4 also be used and modified in further processing.

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

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

1 **4) Paper processing**

2 The transition point from mixture to article is between the stock and the dried paper.



3
4 **Figure 6:** Illustrative example of the general transition point from wood to paper articles
5

1 **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

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

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

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

10

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.

1 **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) Xi;R38 (Skin Irrit. 2; H315) R43 (Skin Sens. 1; H317) N;R50/53 (Aquatic Acute 1; H400 - Aquatic Chronic 1; H410)	800

2 **Information on amount of substance used**

3 The quantity of D-limonene in the scented toys can be calculated as the amount in each toy
4 (800 mg/kg × 0.002 kg/toy = 1.6 mg/toy) multiplied by the amount of toys imported annually
5 (1,000,000 toys/a). The annual amount of D-limonene in the toys imported is 1.6 kg/a, which
6 is below 1 t/a.

7 It can also be calculated how many toys the importer can import before reaching the
8 threshold of
9 1 t/a for D-limonene:

$$10 \quad \text{Number}_{\text{max articles}} = \frac{1/a}{\text{Conc}_{\text{subs. (w/article)}}} = \frac{1/a}{1.6 \text{ mg/toy}} = \frac{1/a}{1.6 \cdot 10^{-9} \text{ t/toy}} = 625 \cdot 10^6 \text{ toys/a}$$

11 $\text{Number}_{\text{max articles}}$: maximum number of articles that can be produced and imported per year
12 without triggering registration obligations.

13 $\text{Conc}_{\text{subs. (w/article)}}$: content of the substance in one article.

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

16 **Illustration of the decision process**17 **Example: Toy with lemon scent (D-limonene)**18 **Are you the first EU producer or importer of the object?**

19 YES.

20 **Is your object an article?** (consult chapter 2)21 YES. The company imports toys which are articles, because the shape determines their
22 function.
2324 **Is there an intended release of substances from the article?** (consult chapter 3)25 Substances are released during the use of the article. The release is an additional quality of
26 the toy and the release is therefore intended, otherwise the article would not smell.27 **Does the article contain a SVHC included in the Candidate List?**
28 (consult chapters 4 and 5)29 As the importer has no information except the results from the chemical analysis he could
30 do the following:31 1) Collect information on sector knowledge and typical content of substances in this type of
32 article, standards like the toys directive etc. He would compare that information with the

1 Candidate List for authorisation and may have doubts whether he can exclude the presence
2 of SVHC. He does not find information on the fragrances intended to be released.

3 2) Check the supply chain requesting if any of the substances on the Candidate List is
4 included in the article or the substances/mixtures used to produce the article or receive
5 confirmation that SVHC are not present in the article. Check the supply chain and ask if the
6 supplier of the fragrance substances can be identified. If yes, the importer of toys may try to
7 obtain a safety data sheet.

8 3) Plan and perform screening for substances on the Candidate List by analytical methods if
9 no information is obtained from the suppliers and content of SVHC is likely (see results
10 above).

11 4) Check if identified substances are listed on the Candidate List (The emission test
12 revealed the presence of compounds classified with R50/53 (Aquatic Acute 1; H400 -
13 Aquatic Chronic 1; H410) and R51/53 (Aquatic Chronic 2; H411). These compounds may
14 potentially fulfil the criteria as PBT/vPvB substances, and thus be identified as SVHC).

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

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

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

20 **Identify each substance intended to be released from the article.**

21 A total of 11 fragrance compounds were identified to be contained in the toy. During the
22 emission test various compounds were detected and some of the detected compounds
23 were identified with a CAS number and classification.

24 The output from the analysis was the substance name only. The C&L inventory to be
25 established should be consulted in order to obtain a CAS number and classification.

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

28 **Substances exempted from registration?**

29 NO.

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

31 The substance has not been registered.

32 **Determine the amount of each substance intended to be released (all such articles in
33 a company should be considered and summed up)**

34 Based on the chemical analysis, the content of D-limonene intended to be released is
35 determined to be 800 mg/kg in the inner part of the toy. The content of D-limonene in the toy
36 is 1.6 mg as the weight of the inner part was 2 g.

37 **Total amount > 1 t/a?**

38 It is assumed that this toy is the only article containing D-limonene and imported by the
39 company. The annual amount of D-limonene is calculated to be 1.6 kg/a, which is below 1
40 t/a.

41 **Registration of D-limonene in the toys is not required.**
42

43

44

1 Comments on the case

2 The importer may import toys with several other fragrances, which also have to be examined.
3 Each individual substance to be released has to be identified.

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

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

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

1 **2) Clothes**

2 *[Please note that this example has been removed from the guidance following the*
3 *judgement of the Court of Justice of 10 September 2015 in case C-106/14. New/update*
4 *examples will be re-inserted into the next version of this guidance after full*
5 *consultation]*

6 **3) Automotive tyres**

7 *[Please note that this example has been removed from the guidance following the*
8 *judgement of the Court of Justice of 10 September 2015 in case C-106/14. New/update*
9 *examples will be re-inserted into the next version of this guidance after full*
10 *consultation]*

1 **4) Inflatable sleeping mattress**

2 *[Please note that this example has been removed from the guidance following the*
3 *judgement of the Court of Justice of 10 September 2015 in case C-106/14. New/update*
4 *examples will be re-inserted into the next version of this guidance after full*
5 *consultation]*

1 APPENDIX 4: INFORMATION SOURCES ON SUBSTANCES 2 IN ARTICLES

3 The non-exhaustive list below contains examples of available information sources on
4 substances in articles. They provide various information, e.g. which substances to expect in
5 certain types of articles, which substances can be ruled out of being present in certain
6 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_processes/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 jewellery, hobby products for children, headphones and hearing protection aids, artificial nails and nail hardeners, etc.
Different Eco-labels: EU Eco-label "Flower" Nordic Eco-label Blue Angel Eco-label Austrian Eco-label Thai Green Label	http://www.eco-label.com , http://www.ecolabel.eu http://www.svanen.nu http://www.blauer-engel.de http://www.umweltzeichen.at http://www.tei.or.th/greenlabel	Eco-label requirements limiting and excluding the use of certain substances in consumer goods.
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 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)	http://ec.europa.eu/environment/waste/elv_index.htm	Requirements regarding the substances in materials and components of vehicles and end-of life vehicles.
International Dismantling Information System (IDIS)	http://www.idis2.com	The IDIS was developed by the automotive industry to meet the legal obligations of the ELV Directive and provide information to dismantling companies about the content of the banned heavy metals in car components.

1 APPENDIX 5: METHODS FOR THE SAMPLING AND 2 ANALYSIS OF SUBSTANCES IN ARTICLES

3 The non-exhaustive list below contains examples of sampling methods and analytical
4 methods for substances in articles, and in particular methods for the determination of
5 substances released from articles. Please note that the division of the list into different parts
6 based on different types of article is not strict. More methods for different sectors and
7 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. Other analysis methods include: - NAA (neutron activation analysis) - AAS (atomic absorption spectros.) - 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”	http://www.din.de	Methods to determine the condensable emissions from leather parts in cars.
Standard ISO 6452 “Determination of fogging characteristics of trim materials in the interior of automobiles”	http://www.iso.org	
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. 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 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. 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 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.

1 **APPENDIX 6: OTHER LEGISLATION RESTRICTING THE**
 2 **USE OF SUBSTANCES IN ARTICLES**

Instrument	Coverage	Conditions	Notes
(Biocides) Directive 98/8/EC	Biocidal products	<ul style="list-style-type: none"> Substances included in Annex I may be used as active substances in biocidal products, Annex I may contain substance specific conditions Authorisation of biocidal products at national level 	<ul style="list-style-type: none"> The use of certain biocides is restricted by Regulation (EC) No 1907/2006 Restrictions on non-active substances should be under Regulation (EC) No 1907/2006
Directive 94/62/EC	Packaging and packaging waste	<ul style="list-style-type: none"> Concentration limits for heavy metal content in packaging materials 	
Directive 76/768/EEC	Cosmetics	<ul style="list-style-type: none"> Lists of banned and permitted substances for use in cosmetic products 	
Regulation (EC) No 842/2006	Greenhouse gases	<ul style="list-style-type: none"> Restrictions on fluorinated greenhouse gases 	
(RoHS ²⁵) Directive 2002/95/EC	Electrical and electronic equipment falling under categories set in Annex IA to (WEEE ²⁶) Directive 2002/96/EC	<ul style="list-style-type: none"> New equipment may not contain Pb, Hg, Cd, Cr(VI), PBB, PBDE Exemptions listed in an Annex 	
Amendment 2006/690/EC	The use of Pb in crystal glass in specific materials and components used in electrical and electronic equipment	<ul style="list-style-type: none"> Exemptions for applications of Pb in crystal glass 	
Amendment 2006/691/EC	Exemptions for applications of Pb and Cd in electrical and electronic equipment	<ul style="list-style-type: none"> Exemptions granted based on a review process 	
Amendment 2006/692/EC	Exemptions for applications of Cr(VI) in electrical and electronic equipment	<ul style="list-style-type: none"> Exempted until 1/07/2007 	

²⁵ Restriction of Hazardous Substances

²⁶ Waste Electrical and Electronic Equipment

Instrument	Coverage	Conditions	Notes
Directive 89/106/EEC Directive 89/686/EEC Directive 93/42/EEC Directive 98/79/EC Directive 90/385/EEC	Construction products Personal protective equipment Medical devices In vitro diagnostic medical devices Active implantable medical devices	<ul style="list-style-type: none"> Contain general provisions on the materials from which the products covered can be made, especially specifying that they should not affect health of users and not release toxic gases Directive 90/385/EEC also has a provision on bioavailability of substances in the devices 	
Directive 2006/66/EC	Batteries and accumulators		
(ELV ²⁷) Directive 2000/53/EC	Vehicles and end-of life vehicles	<ul style="list-style-type: none"> The use of Pb, Hg, Cd and Cr(VI) is prohibited in vehicles and their components 	
(GPS ²⁸) Directive 2001/95/EEC	All consumer products or aspects of those products that are not covered by specific European safety legislation	<ul style="list-style-type: none"> A number of measures, including published standards and codes of good practice may be taken into account in assessing safety 	<ul style="list-style-type: none"> Products must provide levels of safety that consumers can reasonably expect
(Toys) Directive 88/378/EEC	Toys as defined in Article 1	<ul style="list-style-type: none"> Limit values for bioavailability of metals resulting from the use of toys 	<ul style="list-style-type: none"> Use of certain substances in toys restricted by Regulation (EC) No 1907/2006
Directive 93/11/EEC	Elastomer or rubber teats and soothers	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> In Annex I groups of materials and articles are listed which shall be subject to specific directives 	<ul style="list-style-type: none"> 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

²⁷ End-of-Life Vehicles

²⁸ General Product Safety

Instrument	Coverage	Conditions	Notes
Directive 2002/72/EC	Plastic materials and articles intended to come into contact with foodstuffs	<ul style="list-style-type: none"> • Positive lists with authorised substances which excludes all others from use in a certain application • Annex II ‘monomers and other starting substances’ • Information on impurities in substances and constituents of mixtures • Overall and specific migration limits 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Contains list of permitted substances 	

1 APPENDIX 7: PARTS OF THE REACH REGULATION OF 2 PARTICULAR RELEVANCE

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

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

19 The REACH Regulation as well as the Regulations amending it can be accessed through the
20 website of [ECHA](#).

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