

Guidance on requirements for substances in articles

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Version 4.0



LEGAL NOTE

This document aims to assist users in complying with their obligations under the REACH Regulation. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

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Version 4.0**

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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 Council of 18 December 2006¹ and its amendments as of 31 August 2011.

¹ 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).

Document History

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Version 1	First edition	May 2008
Version 2.0	Second edition - revised structure and updated content	April 2011
Version 3.0	Fast-track update to make “quick” corrections to the parts with references to the 0.1% limit that are no longer consistent with the conclusions of the judgement of the Court of Justice of 10 September 2015 in case C-106/14. Reformatted to current ECHA corporate image. Updated reference to toy safety directive (Directive 2009/48/EC).	December 2015
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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 for use in the production process of his articles, he also has to fulfil downstream user requirements.

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

³ Non-EEA producers of articles may appoint 'Only Representatives' to fulfil all REACH obligations of the importers of their articles in the EEA. The role and obligations of an Only Representative are explained in detail in chapter 2 of the [Guidance on registration](#).

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

⁵ importer: means any natural or legal person established within the Community who is responsible for import (Article 3(11)); import: means the physical introduction into the customs territory of the Community (Article 3(10)).

⁶ supplier of an article: means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market (Article 3(33)), including retailers (Article 3(14)).

If the substances are instead purchased outside of the EEA, the article producer has the role of importer of substances along with the related obligations, such as registration. Therefore, in general, companies are advised to identify their obligations by running the [Navigator](#) on the ECHA website. The Navigator helps industry to determine its obligations under REACH and find the appropriate guidance on how to fulfil these obligations.

Table 1: Obligations described in the present guidance

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

1.2 Structure of the guidance

The present document is structured to facilitate your work on how to identify and fulfil your obligations under the REACH Regulation for substances contained in your articles. Each chapter provides guidance for answering one of the following questions. The structure of the guidance and questions below are ordered by the frequency of the obligations, i.e. the most frequently applicable obligation first, which is useful from a practical point of view.

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

The flowchart below (figure 1) gives an overview of the major steps involved in identifying your obligations for substances in articles and directs the reader of the guidance to the corresponding chapters.

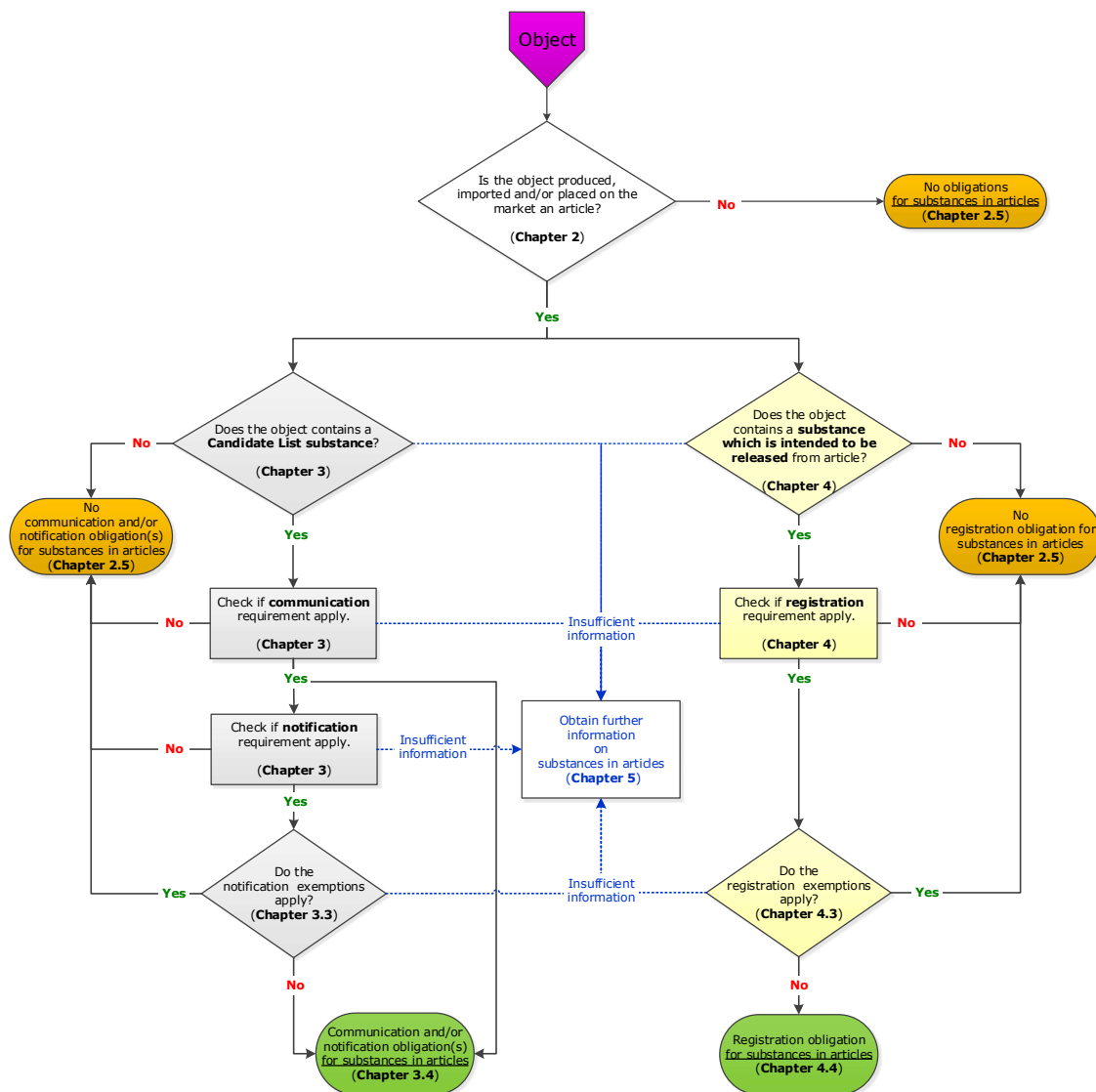


Figure 1: General process for identifying obligations for substances in articles according to Articles 7 and 33

1.3 Topics covered by other guidance documents

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

Restrictions may also affect importers of articles. The figure 2 below represents the main REACH processes that may affect producers and importers of articles. It also identifies the main lists of substances available on ECHA's website relevant to these actors.

The risk management option analysis (RMOA) and the identification of substances of very high concern (SVHCs) processes are further explained in Chapter 3.1, as well as the function of the

following lists of substances: the Public Activities Coordination Tool (PACT), the Registry of Intentions (RoI) and the Candidate List.

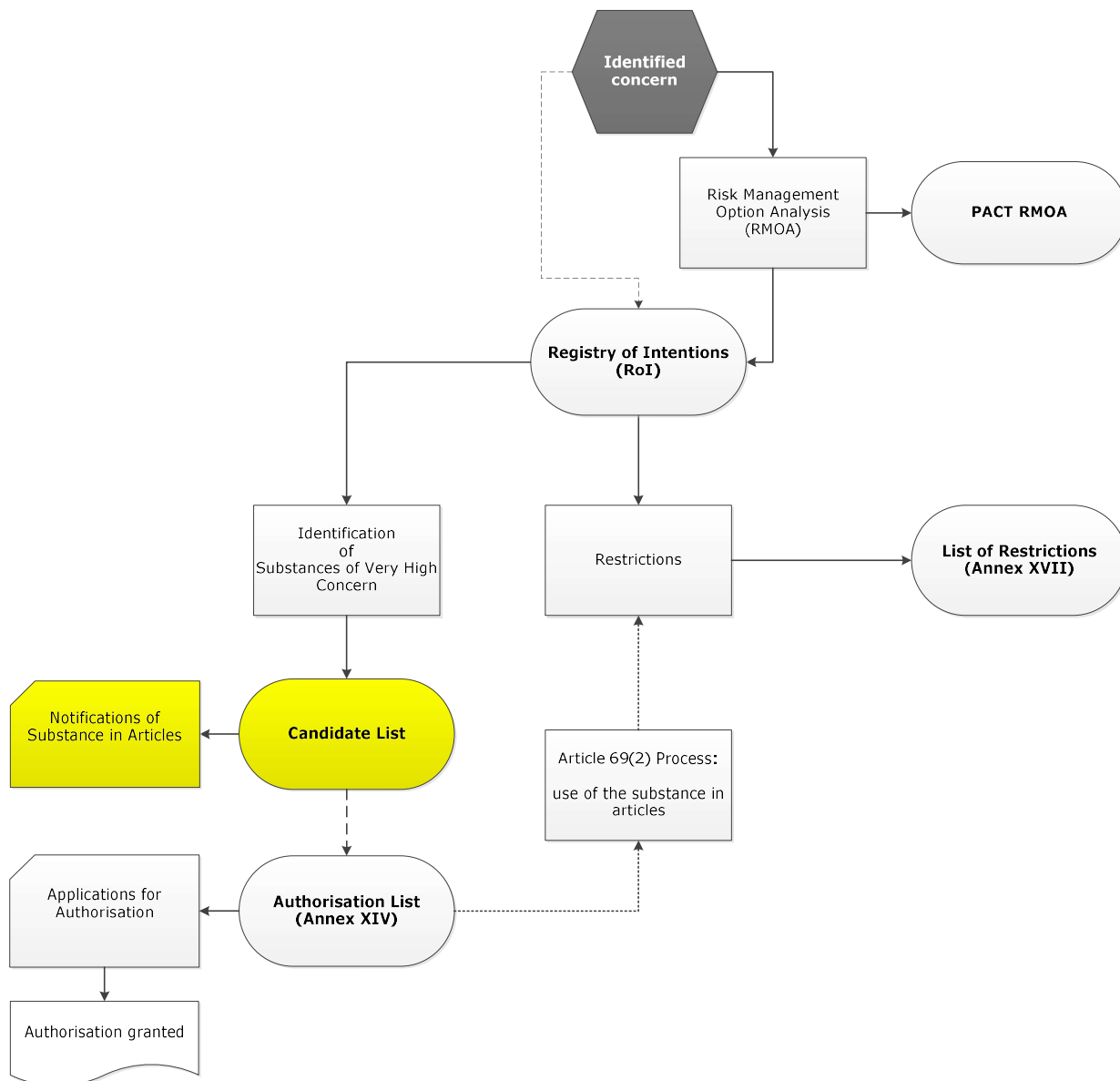


Figure 2: REACH processes that may affect producers and importers of articles and the relevant lists of substances that are important to these actors.

A Candidate List substance, which was subsequently placed in Annex XIV (authorisation list) of REACH, cannot be placed on the market or used after a given date (sunset date), unless an authorisation is granted for a specific use, or the use is exempted from authorisation. Any EEA-based producer of articles that incorporates such a substance into the produced articles, either as such or in a mixture, needs to check if such a use will require authorisation after the sunset date.

The EEA-supplier of a Candidate List substance, which is subject to authorisation, must communicate this information in section 15.1 of the safety data sheet (SDS)⁷ or via communication according to Article 32 of REACH. The producer of an article, as a downstream user may use a substance subject to authorisation provided that the use is in accordance with the conditions of an authorisation granted to an actor further up the supply chain. In such cases, the authorisation number has also to be included on the label and in Section 2 of the safety data sheet. The producer of the article can also decide to apply for an authorisation for his own use.⁸ This decision should be made as soon as the substance is included in Annex XIV to ensure that an adequate quality authorisation application can be developed in time. If the article producer imports such substances himself, he has to apply for authorisation in order to continue his use(s) of the substances. Details on the authorisation procedure and notifying the use of authorised substances can be found in chapter 8 of the [Guidance for downstream users](#) and in the [Guidance on application for authorisation](#).⁹

Authorisation is not required if the substance is imported into the EEA as an integral part of the imported articles.

The content of substances in articles can be restricted or banned under the **restrictions** procedure.¹⁰ Article producers and importers have the obligation to comply with the restrictions and conditions set out in Annex XVII of the REACH Regulation¹¹. You can consult the list of restrictions in Annex XVII on the ECHA website.¹²

Details on compliance with restrictions under REACH are given in chapter 8 of the [Guidance for downstream users](#). Suppliers must include information on whether a substance they supply, as such or in mixtures, is subject to restriction in Section 15.1 of the safety data sheet or in other information supplied to you according to Article 32 of REACH. If a restriction is imposed, the supplier must provide an updated safety data sheet or other information without delay.

After the sunset date for a Candidate List substance on the authorisation list (Annex XIV of REACH), ECHA assesses whether the risks for the uses of that substance in articles are adequately controlled. If they are not, then ECHA prepares an Annex XV dossier proposing a restriction for those uses. Such a proposal may result in a restriction for the incorporation of that substance into articles, including imported articles.¹³

Please note that other legislation concerning restrictions on the use of hazardous substances in articles still apply separately from REACH. Examples include product specific legislation such as Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), Directive 2009/48/EC on the safety of toys or Directive 2000/53/EC on end-of life vehicles (ELVs). A non-exhaustive list of relevant legislation aside

⁷ Please refer to subchapter 3.15 of the *Guidance on the compilation of safety data sheets* at <http://echa.europa.eu/guidance-documents/guidance-on-reach>.

⁸ For more information, please refer to the *Develop an application strategy* webpage at <http://echa.europa.eu/applying-for-authorisation/develop-an-application-strategy>.

⁹ Please refer also to *How to apply for authorisation* webpage at <http://echa.europa.eu/applying-for-authorisation>.

¹⁰ The general procedure is set out in Articles 79 to 73 of REACH. For more information, please refer to the dedicated page on the ECHA website: <http://echa.europa.eu/addressing-chemicals-of-concern/restriction/>.

¹¹ 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](#).

¹² Available at echa.europa.eu/addressing-chemicals-of-concern/restrictions/list-of-restrictions.

¹³ For more information, please refer to the dedicated page on the ECHA website: <http://echa.europa.eu/addressing-chemicals-of-concern/restriction/echas-activities-on-restrictions>

from REACH is provided in Appendix 9 of this guidance.

1.4 Practical examples in the guidance

The main text of the guidance and appendixes 1 to 5 contain several examples to illustrate specific issues explained in the text or how to proceed when checking different legal requirements related with the substance in articles provisions only. These examples do not intend to be exhaustive. Overarching examples are included in appendix 5 to the guidance. The table below summarises the specific coverage of each example included in the guidance.

Table 2: List of practical examples in the guidance and their coverage

Chapter/ Appendix	Example	Coverage
Chapter 2.2	Example 1: Blasting grit	To show that physical properties that result from the chemistry of the material(s) the object is made of should not be confused with the physical form (shape, surface or design) of the object.
Chapter 2.3	Example 2: Wax crayon	To give a simple case on how to distinguish a mixture from an article, taking into account the function of the object.
Chapter 2.3	Example 3: Printer cartridge	To illustrate the application of a first tier of indicative questions (step 4 of the flowchart in figure 2) to decide whether an object is a combination of a substance/mixture and an article.
Chapter 2.3	Example 4: Thermometer	To illustrate the application of a second tier of indicative questions (step 5 of the flowchart in figure 2) to decide whether a substance/mixture is an integral part of an article or a combination of that substance/mixture and an article.
Chapter 4.1	Example 5: Intended release of substances from articles – panty hose with lotion	To show a case of an article with a substance which is intended to be release under normal or reasonably foreseeable conditions of use.

Chapter 4.2	Example 6: Calculation of tonnage of a substance intended to be released – scented t-shirt	To show how to calculate the tonnage of a substance intended to be released from an article.
Chapter 4.2.1	Example 7: Critical concentration level for substance in a mixture intended to be released – smelling toy	To show how to calculate the critical concentration level for a substance in a mixture intended to be released.
Appendix 1	Several examples (listed in Table 3 in appendix 1)	To show borderline cases of substances/mixtures in containers or carrier materials.
Appendix 2	1) Aluminium processing as an example of metal processing	To show cases of setting the borderline in the sequence of processing natural or synthetic materials into final articles.
	2) Textile and non-woven processing	
	3) Polymer processing	
	4) Paper processing	
Appendix 3	Example 1: Article made directly from a substance or a mixture - plastic garden chair	To illustrate how the concentration of a Candidate List substance should be determined in an article made directly from a substance or a mixture.
	Example 2: A substance or a mixture is combined with an existing article and becomes an article itself - insulated electric wire	To illustrate how the concentration of a Candidate List substance should be determined when an article is produced by incorporating a mixture containing that substance to an article and the substance or mixture thereby becomes an integral part of that article.

	<p>Example 3: A substance or a mixture is incorporated into an article becoming thereby an integral part of the final article - printed t-shirt</p>	<p>To illustrate how the concentration of a Candidate List substance should be determined when an article is produced by incorporating a mixture containing that substance to an article and the substance or mixture thereby becomes an integral part of that article.</p>
	<p>Example 4: A substance or a mixture is incorporated into an article becoming thereby an integral part of the article - adhesive tape</p>	<p>To illustrate how the concentration of a Candidate List substance should be determined when an article is produced by incorporating a mixture containing that substance to an article and the substance or mixture thereby becomes an integral part of that article.</p>
	<p>Example 5: Two or more articles mechanically assembled together - upholstered sofa</p>	<p>To illustrate how the concentration of Candidate List substance(s) should be determined in an object made of two or more articles mechanically (i.e. without the addition of any substance or mixture) assembled together.</p>
	<p>Example 6: Joining two or more articles together using a substance or a mixture - aircraft skin fuselage panel</p>	<p>To illustrate how the concentration of Candidate List substance(s) should be determined in an object made of two or more articles joined together by using substance(s)/mixture(s).</p>
Appendix 4	<p>Example 1: Calculation of the total amount of a Candidate List substance in separated articles - non-stick Kitchenware (frying, grill and sauce pans)</p>	<p>To illustrate how the Candidate List substance tonnage must be calculated in separate articles imported/produced containing that same substance.</p>
	<p>Example 2: Calculation of the total amount of a Candidate List substance in an assembled object - multi-socket power strip</p>	<p>To illustrate how the same Candidate List substance tonnage must be calculated where present in articles assembled or joined together into an imported/produced final assembled object</p>

Appendix 5	Example 1: Approach to identify which articles may contain certain Candidate List substances - outdoor jacket	To illustrate a practical approach on how to identify which articles may contain certain Candidate List substances
	Example 2: Articles joined or assembled together into an object - printed circuit board	To illustrate practical hints on how to identify and differentiate all articles joined or assembled together in an object
Appendix 6	Case 1: Scented children's toys: toy with lemon scent (D-limonene)	To give cases for checking if requirements under Article 7 and Article 33 apply, by using the overall approach shown in the flowchart in figure 1: Case 1 - intended release of substance/mixture from articles Cases 2 to 4 – Candidate List substances in articles
	Case 2: Articles for clothing and jewellery articles	
	Case 3: Inflatable air chamber of a sleeping mattress	
	Case 4: Bicycle	

1

2 In most of the examples throughout the guidance no specific substances are used due to the
3 dynamic nature of the "regulatory status" of a substance as shortly explained in the previous
4 subchapter. Any supplier of articles, including producers and importers of articles should also
5 check if there are other REACH requirements applicable to the production of the article or to the
6 imported articles containing Candidate List substances. For example, the producers of articles
7 should check if the use of a Candidate List substance placed on the authorisation list is subject
8 to authorisation for their use of the substance or mixture containing the substance. If that use is
9 not covered by an authorisation from their supplier, they need either to apply for an
10 authorisation or cease the use of the substance to produce the article after the sunset date. The
11 importers of articles should always check if restrictions apply to imported articles containing the
12 Candidate List substance. These issues are not illustrated in the examples provided in this
13 guidance.

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2 DECIDING WHAT IS AN ARTICLE UNDER REACH

When determining if and which requirements apply, the first step is to check whether the objects¹⁴ produced, imported and/or placed on the market are considered to be articles under REACH or not.

An article is generally understood to be an object composed of one or more substances or mixtures given a specific shape, surface or design. It may be produced from natural materials, such as wood or wool, or from synthetic ones, such as polyvinyl chloride (PVC). Objects may be simple, like a paper sheet, but can also be very complex, like a laptop computer, consisting of many articles. Most of the commonly used objects in private households and industries are or incorporate articles, e.g. furniture, clothes, vehicles, books, toys, kitchen equipment and electronic equipment. Buildings are not considered to be articles, so long as they remain fixed to the land on which they stand¹⁵.

Article 3(3) of the REACH Regulation defines an article as *"an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition"*

In order to determine whether or not an object fulfils the definition of an article under REACH, the object's function and its characteristics (shape, surface or design) given by the production process need to be assessed.

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

2.1 The function of an object

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

2.2 The shape, surface and design of an object

The shape, surface and design of an object represent its physical form and can be understood as other than chemical characteristics. **Shape** means the three-dimensional form of an object, like depth, width and height. **Surface** means the outermost layer of an object. **Design** means the arrangement or combination of the "elements of design" in such a way as to best accomplish a particular purpose of the object, taking into account amongst others the safety, utility/convenience, durability, and quality. For example, the design of a textile fabric may be determined by the twist of fibres in the yarn, the weave of threads in the fabric and the treatment of the surface of the textile fabric.¹⁶

¹⁴ The term "object" can in principle refer to any product in the supply chain.

¹⁵ The same applies to other immovable (large) structures such as bridges, as well as smaller structures such as piers or garden pavillons, etc., which are fixed to the land.

¹⁶ The textile fabric has a specific design due to the twist of the fibres in the yarn or the weave of the threads. Then, the fabric is an article consisting of two or more articles; the yarns (threads) are used as component articles and the fibres are articles used as components in a yarn (thread). The fibres, the yarns (threads) and the fabric have different functions.

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

Example 1: Blasting grit

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

Furthermore it is to be noted that according to Article 3(3) of the REACH Regulation an article is an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition. This implies that the **shape, surface or design must be deliberately determined and given during a production step**. The formation of certain shapes and surfaces of solid materials (e.g. pellets, crystals, powder, etc.) determined solely by the chemistry of raw materials and other conditions during the chemical production process do not fulfil the article definition, if their function is defined to a greater degree by the chemical composition. Articles that are assembled or joined together remain articles, as long as they keep a special shape, surface or design, which defines them to a greater degree than the chemical composition, or as long as they do not become waste.

2.3 Deciding whether an object is an article or not

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

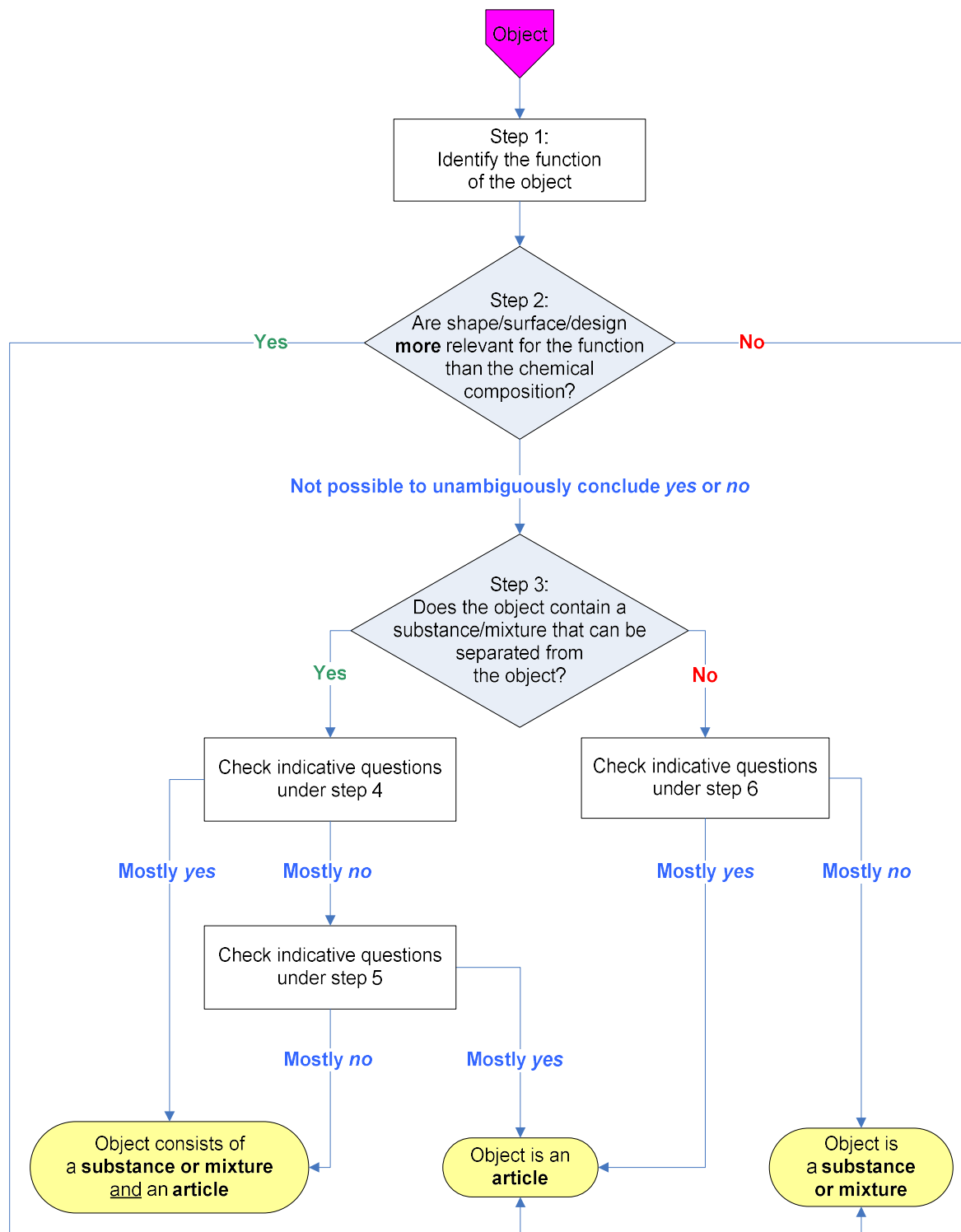


Figure 2: Decision-making on whether an object is an article or not

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

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

Example 2: Wax crayon

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

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

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

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

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

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

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

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

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

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

Example 3: Printer cartridge

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

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

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

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

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

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

Example 4: Thermometer

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

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

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

Question 6a: Does the object have a function other than being further processed?

If the object predominantly has other functions (i.e. end-use functions), then this may be an indication that it is an article according to the definition of REACH.

Question 6b: Does the seller place the object on the market and/or is the customer mainly interested in acquiring the object because of its shape/surface/design (and less because of its chemical composition)?

If the object is mainly put on the market or acquired because of its shape/surface/design, this is an indication that the object is an article.

Question 6c: When further processed, does the object undergo only "light processing", i.e. no gross changes in shape?

"Light processing", such as drilling, surface grinding or coating, may improve or modify an object's shape, surface or design for carrying out a function and is thus frequently applied to objects which are already articles. Thus, if only "light processing" is applied, this is an indication that the object is an article.

Processes leading to gross changes in shape, meaning changes of depth, width and height of an object, are not regarded as "light processing". These can for example be primary shaping processes (such as casting or sintering) or forming processes (such as extrusion, forging or rolling). If the object preserves at least one of its characteristic dimensions (depth, width and/or height) when further processed, the process can be regarded as "light processing".

Question 6d: When further processed, does the chemical composition of the object remain the same?

A change of the chemical composition in the next processing steps may indicate the object being a mixture. However, some treatments of an object which is an article may result in a change in its overall chemical composition, but not in the status of the object being an article. Examples are printing onto the surface, painting, applying coatings, dyeing etc.

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

This step 6 was developed to assess mostly objects which are further processed (e.g. semi-finished articles). For objects that do not contain a substance or mixture that can

be physically separated and that are not produced or manufactured to be further processed but rather to perform specific function(s) during their end-use (e.g. carbon electrodes for the manufacture of aluminium, grinding wheels made only of an abrasive material), the answer to indicative questions 6a and 6b may not be very helpful to reach a final conclusion. In such cases, a deeper assessment is needed by taking into account specific considerations applicable to the particular object under assessment.

2.4 Packaging

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

2.5 Documentation

From Article 36(1)¹⁷ of the REACH Regulation, it follows that article producers, who are considered downstream users under REACH, if they use a substance or mixture in the production of their articles, have to keep available all the information they require to carry out their REACH obligations. But even if it has been identified that no obligations under REACH apply, these companies should consider documenting the results of their compliance assessment. This includes documenting information requests made to their suppliers of substances, mixtures or articles, information received from those suppliers, including certificates and other relevant information provided by them, the decision-making on whether certain products are articles, substances or mixtures as well as the checking if specific requirements apply for these, based amongst others on the information received from the suppliers. Documenting this is recommended to **producers and importers of articles** in general, as it facilitates demonstrating REACH compliance towards customers and (inspecting/enforcing) authorities.

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

¹⁷ "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 CANDIDATE LIST SUBSTANCES OF VERY HIGH CONCERN IN ARTICLES

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.

3.1 Candidate List substances

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 1A or 1B
- persistent, bioaccumulative and toxic (PBT) substances or very persistent and very bioaccumulative (vPvB) substances
- substances identified on a case-by-case basis for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern, e.g. 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. Interested parties can get advance notice of substances intended to be proposed as SVHCs for Candidate List inclusion via the so-called '[Registry of Intentions \(RoI\)](#)' list on ECHA's website. The early warning provided by the RoI also gives interested parties time to prepare for commenting during the public consultation, which comes after the proposal for SVHC identification has been submitted by ECHA (at the request of the Commission) or a Member State.

Before submitting an intention to prepare an Annex XV dossier on SVHC identification, ECHA or Member State Competent Authorities (MSCAs) often prepare a risk management option analysis (RMOA). The RMOA is a voluntary process, i.e. not part of the processes as defined in the legislation, which promotes early discussion on substances which may require further regulatory action.¹⁸ The substances for which an RMOA is under development or has been completed are communicated through the [Public Activities Coordination Tool \(PACT\)](#) on ECHA's website. PACT includes also information on substances for which there is an on-going informal hazard assessment for PBT/vPvB properties or endocrine disruptor properties or for which one has been completed. The substance inclusion in PACT does not mean that a substance has the suspected properties or that there is need for regulatory risk management actions until an RMOA conclusion is

¹⁸ For more information On RMOA, please refer to the dedicated page on the ECHA website: <http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/rmoa>

published on that list. This advance notice in PACT allows e.g. stakeholders and the general public to know which substances are under examination by ECHA or MSCAs for possible SVHC identification. If the RMOA concludes that the most appropriate regulatory risk management action is SVHC identification, an intention for that will be included on RoI. Therefore, the PACT and the RoI facilitate a timely preparation for complying with possible obligations that could result when a substance is eventually put on the Candidate List. Therefore article producers, importers and suppliers are advised to regularly check the PACT and the RoI on ECHA's website.

It is important to note that the legal obligations described in this chapter only apply to the substances included in the [Candidate List](#). Other sources of information such as those mentioned above provided here are just meant to help companies in identifying substances that are under authorities' scrutiny and might be included in the Candidate List.

3.2 Communication and notification of Candidate List substances in articles

The identification of a substance as an SVHC and its inclusion in the Candidate List trigger communication and notification obligations for the importers and producers of an article that contains such a substance under certain circumstances. It can also trigger communication obligations down the supply chain to other suppliers of articles such as distributors. These requirements aim at ensuring the safe use of chemicals in produced and imported articles and ultimately contributing to the reduction of the risks for human health and the environment.

3.2.1 Communication of information down the supply chain

The aim of Article 33 is to ensure that sufficient information is communicated down the supply chain to allow the safe use of articles by end-users including consumers. The information flow along the supply chain enables all operators to take, at their stage, the appropriate risk management measures to guarantee the safe use of articles containing CL substances. The information also allows the operators in the supply chain and consumers to make informed purchase choices on the articles they buy.

A supplier of articles containing a SVHC included on the Candidate List for authorisation in a concentration above 0.1% (w/w) has to provide relevant safety information about this substance available to him to the recipients of these articles (Article 33(1)). If no particular information is necessary to allow safe use of the article containing a substance from the Candidate List, as a minimum the name of the substance in question has to be communicated to the recipients. The information is to be provided to the recipients automatically, i.e. as soon as the substance has been included on the Candidate List for authorisation.¹⁹ Note that the term "recipients" refers to industrial or professional users and distributors, but not to consumers.

Upon request of a consumer, the same supplier of articles has to provide relevant safety information about the Candidate List substance available to him also to this consumer (Article 33(2)). If no particular information is necessary to allow safe use of the article, as a minimum the name of the substance in question has to be communicated to the

¹⁹ The relevant date is the date of the supply of the articles after the substance has been included on the Candidate List.

consumer. The consumer has to be provided with this information within 45 calendar days of the request and free of charge. It is also to be noted that a retailer supplying articles, for example, does not comply with this obligation just by referring the consumer to his own supplier, or the producer of the articles.

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

- The substance concentration threshold of 0.1% (w/w) applies to every article supplied. This threshold applies to each article of an object made up of more than one article, which were joined or assembled together;
- There is no tonnage trigger for these obligations;
- The obligations apply to articles after the substance is included in the Candidate List and are supplied after the inclusion. Thus, the date of supply of the article is the relevant date.

The practical examples in Appendix 3 show how to determine the concentration of Candidate List substances in articles, in order to apply the 0.1% w/w concentration threshold, which triggers the communication obligations. The 0.1% w/w concentration threshold of a Candidate List substance in articles is also a condition for the notification obligation under Article 7(2) as explained in the next subchapter.

3.2.2 Notification of Candidate List substances in articles

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

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

The substance concentration threshold of 0.1% (w/w) applies to each article as produced or imported. This threshold applies to each article of an imported object made up of more than one article, which were joined or assembled together.

In case of import, importers of an object which comprises one or more articles are importers of these articles and must collect information for each one of them. The notification obligation rests on importers and producers of articles. Therefore, the (EU) producer of an object made up of more than one article that has been supplied to him in the EU does not need to notify the substance(s) present in the articles that he uses, because they must have been notified upstream by the persons who imported or produced them.

Since it is the substance in the article that is notified, and not the article, a separate notification is required for each Candidate List substance in the same article if the conditions listed above are fulfilled. If several articles contain the same Candidate List substance, one notification for this substance is sufficient.²⁰

²⁰ For practical reasons, articles which are identical should also be grouped (see Appendix 4).

A notification is not required for a substance in articles which have been produced or imported before the substance has been included on the Candidate List for authorisation²¹. Furthermore, in certain cases an exemption from the obligation to notify applies (see subchapter 3.3).

The calculation of the total amount in tonnes of the same Candidate List substance in all articles produced or imported requires 3 steps:

1. Determine if the Candidate List substance in question is present above the 0.1% w/w concentration threshold for each article produced or imported (see subchapter 3.2.1);

2. Calculate the amount in tonnes of that Candidate List substance in each article produced or imported per year where it is present above the 0.1% w/w concentration threshold;

3. Calculate the total amount in tonnes for all articles by summing up the amounts calculated for each article accordingly to point 2 above.

If the total amount of the Candidate List substance present in all articles produced and/or imported, which contain more than 0.1% w/w of that substance as calculated in step 3 above, exceeds 1 tonne per actor per year, the producer and/or importer has the obligation of submitting a notification of substances in articles to ECHA for that Candidate List substance (see chapter 3.4.2).

Appendix 4 includes practical examples on how to determine the total tonnage of a Candidate List substance in all articles imported or produced.

Depending on the information available and the processes involved in the production of the article, the calculation of the total amount of the Candidate List substance present in all articles produced and/or imported may not be straightforward. In this case, you may choose to notify to ECHA even in cases where you are uncertain if the tonnage is at or above 1 t/a. The production or the import of those articles may vary from one year to the other, depending on the market conditions. In this case, you are encouraged to update your notification at least where the changes are significant.

3.3 Exemptions from notification

There are no exemptions from the obligations to communicate information on substances in articles according to Article 33 (see subchapter 3.2.1).

Two specific exemptions are applicable to the notification of substance in articles obligation: (a) exemption based on “exclusion of exposure” and (b) exemption for substances already registered for a use. The latter is also applicable to the registration obligation for substances intended to be released from articles (see chapter 4 and in particular subchapter 4.3).

Note that you do not need to check these specific exemptions, if you do not wish to do so. **It might require more resources and and be more difficult to properly assess**

²¹ This is due to fact that the notification obligation is linked not only to the presence of a Candidate List substance in articles above certain concentrations and in certain quantities, 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.

and document exclusion of exposure or to find out if the use is already registered, than to prepare and submit the substance in articles notification.

The following subchapters explain how to check if you are covered by an exemption from substance in articles notification obligation.

3.3.1 Exemption of substances already registered for a use

According to Article 7(6) a notification of a substance in articles is not required, if the substance has already been registered for that use (i.e. the process by which the substance is included in the articles).²² This refers to any registration of that use of the substance in the same supply chain or any other supply chain.

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

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

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

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

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

²² According to the same Article, this exemption is also applicable to registration obligation for substances intended to be released from articles (see subchapter 4.3.3). Therefore, in the text below where mentioned "notifier" or "notify" can also be read as "registrant of a substance intended to be released from articles" or "register".

use in question has to be described more in detail than just by using elements of the use descriptor system. To come to a conclusion on whether the substance is considered as registered “for that use” or not, the potential registrant or notifier has to compare the description of his use with those uses already registered for the substance. The conclusion obtained and the considerations that led to it should be well documented in order to be able to demonstrate REACH compliance towards authorities, when required.

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

3.3.2.1 Information sources to determine if a substance is already registered for a use

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

A safety data sheet (SDS) contains information on uses of the substance or mixture as far as they are known by the supplier. As a downstream user, an EU producer of articles receives an SDS for the Candidate List substance or for a mixture containing that substance. The producer of the articles has also a right to communicate to his supplier(s) of the substance or mixture his specific use(s) (i.e. the process by which the substance is included in the articles) with the aim that his use becomes an identified use and covered by the registration.

In case a substance requiring a SDS 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 SDS. If relevant to the recipients of this substance, these exposure scenarios also cover the uses by which the substance is incorporated in articles. Therefore the information contained in exposure scenarios can be used by article producers to establish whether their use of the substance has already been registered up the supply chain. If the article producer uses a mixture containing the registered substance in the production of his articles, he may only receive the SDS of the mixture. The SDS of the mixture may not contain exposure scenarios in annex, but the formulator of the mixture has incorporated the relevant information concerning the (safe) use in it.²³

Detailed information on communication of uses of chemical substances in the supply chain can be found in chapters 1 and 3 of the “[Guidance for downstream users](#)”.

It may be possible, depending on the detailedness of the use descriptions in the SDS, to conclude that a particular use of this substance as such or in a mixture has already been registered. However, in case of doubt, confirmation of the sameness of both uses (i.e. the use of the substance in the articles and one of the uses registered) should be sought by the article producer from the suppliers of the substance or mixture. Alternatively you could identify (e.g. through the registration number in the SDS) and ask a manufacturer

²³ Further information on this issue may be found in chapters 7 of the “[Guidance for downstream users](#)”.

or importer of that substance for the uses he has registered this substance for, or whether he has registered it for your particular use.

Article producers that produce a complex object out of component articles, which have been supplied to them and who do not incorporate a substance into it, will receive information on the component articles from their suppliers under Article 33(1) REACH. They can rely on the fact that any notification of registration obligations have been fulfilled by the article producers who incorporated substances into the component articles.

The importers of articles may not benefit from safety data sheets to obtain information that allows them to conclude on whether the substance incorporated in the imported articles is considered as registered "for that use" or not. They can obtain this information in different ways:

- A good way to identify manufacturers and importers of a substance who might have registered it for a particular use, is to launch a corresponding request to the relevant Substance Information Exchange Forum for this substance (SIEF), or to contact directly registrants which may be identified in the available information on ECHA's dissemination portal or by searching on the internet.
- They may also contact trade associations, who might have information on the registration status of a particular substance and the uses the substance has been registered for.

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

3.3.2 Exemption based on "exclusion of exposure"

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 use²⁴, including disposal²⁵.

Note that it may require more resources and be more difficult to demonstrate "no exposure" than making a notification.

Exposure to a substance in an article is possible even if the substance is not intentionally released from the article as it may migrate unintentionally. 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.** Humans may be exposed to substances released from

²⁴ The terms "normal conditions of use" and "reasonably foreseeable conditions of use" are explained in section 4.1.

²⁵ The term "disposal" here also covers the waste stage. This stage, as part of the life cycle of a substance, needs to be considered in the exposure assessment to demonstrate "exclusion of exposure".

articles by inhaling gases or particles (inhalation route), by contact with the skin (dermal route), or by swallowing (ingestion/oral route). Substances can be released into the different environmental compartments (water, air, soil and sediments). All exposure routes at all life cycle stages have to be considered (service life of the article and waste stage) when assessing the 'exclusion of exposure'.

A justification of the exemption that demonstrates exclusion of exposure should be documented so that it can be presented to enforcement authorities on request. Such a justification needs to show that no exposure to humans or the environment takes place during the article service life and the waste stage²⁶ and could include for example one or more of the following elements:

- If the substance is contained in the article by technical means: a reasoning why the article is unlikely to be opened or to break leading to a release of the substance, in particular during the waste stage.
- If the substance is embedded in the matrix of the article: a description of the stability of the article matrix and the bonds between the substance and the matrix during the different life cycle stages of the article.
- A proof that the substance remains fully immobile inside the article and does not migrate out of it (e.g. due to the inherent physicochemical properties of the substance, or a special coating of the article).
- A proof that the amounts of substance released from the article are contained by technical means or directly destroyed (e.g. during thermal treatment of waste).

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

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

For further guidance on how demonstrating that no exposure occurs please consult chapters R14 to R18 of the [Guidance on information requirements and chemical safety assessment](#).

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

- Physicochemical properties of **the substance**, like vapour pressure, water solubility, stability in contact with air, water, etc.
- Structure and chemistry of **the article matrix** including physicochemical parameters and the way in which the substance is incorporated in it (chemically bonded or not).
- **The conditions of use and disposal** of the article, such as:

²⁶ Examples of releases that therefore lead to exposure are listed in subchapter 4.1, with the exception of a release in an accident, when exemplifying cases where a release of substances from an article is not considered to be an intended release.

- Location of use (indoor or outdoor use, private homes, workplace, etc.).
- Physical conditions at place of use (temperature, ventilation, etc.).
- Whether or not articles are part of a comprehensive waste collection scheme.
- The disposal technology.

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

3.4 What information to communicate and to notify

3.4.1 Communicating information according to Article 33

In order for an article importer or producer to determine **what information he must communicate** according to Article 33, he has to consider:

- all the life-cycle stages of the article (e.g. transport, uses) from the production stage until final disposal,
- what the potential routes of exposure are during each of these life-cycle stages and/or specific uses or use conditions (e.g. processing of a semi-finished article, installation of the article, maintenance)
- what the hazards of the SVHC in the Candidate List are for human health and the environment
- what types of exposure control / personal protection measures are likely to be appropriate during each of the life-cycle stages in order for the handling of the article to be considered safe
- how the article can be properly disposed when it reaches its end of service life.

These considerations are required in order to identify any risks arising from the Candidate List substance in the article, and thus determine which information has to be provided to the user, in addition to the name of the Candidate List substance, in order for him to control these risks. This means that the obligatory additional information depends on what a user needs to know to be able to use the article safely and not on how available this safety information is. Providing only the name of the substance is unlikely to be sufficient to allow safe use of the article in many cases. Any downstream supplier must pass the information that has been provided to him on down the supply chain or, upon request, to consumers,.

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

The most appropriate **format for provision of information** may also vary, depending on the content and the addressee of the information. Standard answering letters might

be a suitable medium to inform consumers, whereas a professional or industrial user might be better informed through separate use instructions.

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

- modification of existing documents, such as instructions for use and packaging
- information on labels
- link to a website with up-to-date information
- standard communication formats developed by industry sector associations
- IT systems or tools available to facilitate communication throughout the supply chain

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

3.4.2 Notifying information to ECHA according to Article 7(2)

Note that you need to notify when you start importing or producing articles fulfilling the conditions for the notification obligation or the total tonnage per year becomes higher than the 1t/a threshold.

A Substance in Articles notification shall be made no later than 6 months after the substance has been included in the Candidate List.

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

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

More detailed information is given on how to provide this information within the notification in the Manual - How to prepare a substance in articles notification, available on the ECHA website.

Once a notification has been submitted, notifiers are strongly encouraged to keep their notification up-to-date. The notification can be updated in case the notified information changes, e.g. change in tonnage range, production/import of different articles containing the same Candidate List substance.

4 SUBSTANCES INTENDED TO BE RELEASED FROM ARTICLES

4.1 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 of use 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 article²⁷. **Reasonably foreseeable conditions of use** mean conditions of use that can be anticipated as likely to occur because of the function and physical form 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.

²⁷ Examples of the exclusion of specific conditions of use are 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 size²⁸ 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 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.
- A release in an accident.
Example: release of substances from a thermometer that drops and breaks.

²⁸ 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).

4.2 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 conditions of use²⁹ (this can be established by applying the criteria in section 3.1).
- The total amount of the substance present in all articles with intended release (i.e. including the amounts that are not intended to be released) produced or imported by one actor exceeds 1 tonne per year³⁰.

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

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

If any of these tonnage values is equal to or remains under 1 tonne per year, the quantity of *individual substances intended to be released* incorporated in these articles will definitely also be below 1 tonne per year. Thus, registration of substances in these articles will clearly not be required. However, if the need to register cannot be excluded on the basis of these checks, the *individual substances intended to be released* will have to be identified, and (unless you can benefit from an exemption from registration; see subchapter 4.3) also their respective tonnage.

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

$$m_{\text{subs.}} = \text{Weight}_{\text{article}} \cdot \text{Number}_{\text{articles}} \cdot \text{Conc}_{\text{max mixture in article}} \cdot \text{Conc}_{\text{max subs. in mixture}} \quad (1)$$

$$m_{\text{subs.}} = m_{\text{articles}} \cdot \text{Conc}_{\text{max subs. in article}}$$

$m_{\text{subs.}}$: tonnage of a *substance intended to be released* contained in articles [t/a].

$\text{Weight}_{\text{article}}$: weight of one article [t/article].

$\text{Number}_{\text{articles}}$: number of articles produced and/or imported per year [articles/a].

$\text{Conc}_{\text{max mixture in article}}$: 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.).

²⁹ Both of the conditions must be met, i.e. the intention to be released and the normal or reasonable foreseeable conditions of use.

³⁰ 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 2.2.6.3 of the [Guidance on registration](#).

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

m_{articles}: tonnage of articles produced and/or imported per year [t/a].

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

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.

The tonnage of the fragrance substance intended to be released is calculated using equation (5) in the text above.

$$m_{\text{subs}} = m_{\text{articles}} \cdot \text{Conc}_{\text{maxsubs in article}} = 100 \text{ t/a} \cdot 0.05 = 5 \text{ t/a}$$

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 up³¹.

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

³¹ 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.

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.

4.2.1 Critical concentration level for substances in a *mixture intended to be released*

Substances intended to be released from articles are usually released as part of mixtures, the concentration of which in the articles is more often known than the concentration of the individual substances intended to be released. If the maximum content of the mixture intended to be released in articles is known, critical levels for the concentration of substances in the mixture, above which a registration of substances in those articles might be required, can be calculated as shown below.

The concentration limit for a substance in a *mixture intended to be released from articles*, above which registration is necessary, can be calculated if the maximum concentration of the mixture incorporated in articles and the total production and/or import quantities of these articles are 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.

$$Conc_{\text{max subs. in mixture}} = \frac{1/t_a}{m_{\text{articles}} \cdot Conc_{\text{max mixture in article}}} \quad (6)$$

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

m_{articles} : tonnage of articles produced and/or imported per year [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 7: Critical concentration level for substance in the mixture intended to be released

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

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

The concentration limit for a substance in the mixture of fragrances *intended to be released from the toys*, above which registration is necessary, can be calculated using equation (6) in the text above.

$$Conc_{\text{max subs. in mixture of fragrances}} = \frac{1/a}{m_{\text{toys (articles)}} \cdot Conc_{\text{max mixture in toy (article)}}} = \frac{1/a}{30/a \cdot 0.15} = 0.22 = 22\%$$

Conclusion: This means that registration is not necessary for substances contained in the fragrance mixture in a concentration of a maximum of 22% w/w. 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% w/w is exceeded for any of the substances contained in the fragrance mixture.

4.3 Exemptions from registration

Obligation to register substances intended to be released from articles identified as described in subchapters 4.2 do not apply in certain cases. This subchapter explains what you have to check to establish if you are covered by an exemption from registration of substances intended to be released in articles.

4.3.1 General exemption of substances

A number of substances are exempted in general (i.e. whether on their own, in mixtures or in articles) from registration³² as sufficient information is known about these substances or registration 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 under Article 7 would therefore not be required.

4.3.2 Exemption of recovered substances

The REACH Regulation exempts substances which are recovered in the EEA from

³² As mentioned in subchapter 3.4, this exemption is also applicable to notification obligation. Therefore, in the text where mentioned "registration" can also be read as "notification".

1 registration³³, provided a number of conditions are met (Article 2(7)(d)). Producers of
2 articles made of recovered substances can therefore in principle benefit from this
3 exemption. The conditions set by REACH which have to be respected in order to benefit
4 from this exemption are described in section 1.6.4.5 of the [Guidance on registration](#).

5 **4.3.3 Exemption of substances already registered for a use**

6 According to Article 7(6) a registration of a substance in articles is not required if the
7 substance has already been registered for that use

8 For further information on this specific exemption applicable to the registration obligation
9 for substances intended to be released in articles refer to subchapter 3.4.1.

11 **4.4 Registration of substances in articles**

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

³³ As mentioned in subchapter 3.4, this exemption is also applicable to notification obligation for Candidate List substances. Therefore, in the text where mentioned "registration" can also be read as "notification".

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 level of effort for a company in obtaining this information will largely depend on whether it has a quality management system or an alternative means of ensuring traceability of raw materials and articles compositions in place or not. Quality management systems can include e.g. article 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. Other approaches to obtain the necessary information include procurement and contract specifications, suppliers declarations on articles and materials compositions, (IT) tools to transfer information and manage communication in the supply chains, risk assessment, and product design and development. If such routines and tools are already in place, less effort will be needed to obtain the required information on substances in articles, whether this is done through communication in the supply chain or by means of chemical analyses.

5.1 Information via the supply chain

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

5.1.1 Standardised information from suppliers in the EEA

Information needed to identify and comply with requirements for substances in articles can often be derived from standardised information that is obtained from suppliers based in the EEA. **Suppliers of substances or mixtures**, for instance, have to provide their customers with safety data sheets, or, where a safety data sheet is not required, with available and relevant safety information and details on regulatory requirements (need for authorisation, restrictions imposed) according to Article 32. This obligation also applies when the substance or mixture is supplied in a container or on a carrier material.

In case a substance requiring a safety data sheet has been registered in a quantity of 10 t/a or more, recipients of this substance (on its own or in a mixture) are provided by their supplier with the relevant exposure scenarios in an annex to the safety data sheet.

Exposure scenarios describe how a substance is used during its life cycle and recommend how to control exposure of humans and the environment. These exposure scenarios cover the incorporation of the substance in articles and the resulting life cycle stages of the substance, including the service life of the articles and the waste life cycle stage.

Therefore the information contained in exposure scenarios can be useful particularly for article producers when preparing the information to be provided to customers as required by Article 33.

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

5.1.2 Requesting information up the supply chain

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

- It may be helpful to tell suppliers why the information is needed, which may be unknown, particularly to non-EEA suppliers. For this, several [publications](#) are available on ECHA's website, that explain the background and implications of REACH. Some of these documents are available in different languages helping to overcome language barriers.
- Certain IT systems and tools facilitate the communication and transfer of standardised information in complex supply chains and prevents interruptions in the information flow. They may also allow to specify the required information for specific regulatory purposes and to identify and address directly the producers of articles, formulators and manufacturers of substances.
- In many cases the exact composition of articles or mixtures is not needed to clarify whether requirements for substances in articles have to be fulfilled. Certainty in particular that no notification or communication obligations for substances in articles apply can also be achieved by excluding or limiting the presence of substances that are on the Candidate List of substances for authorisation. Suppliers could for example provide certificates which guarantee that certain substances are not used in the manufacture of their products or remain below certain concentrations in their products. A different approach would be to include respective criteria in supply contracts excluding or limiting the presence of certain substances in the products to be supplied.
- It is recommended that requests in the supply chain are targeted and aim at excluding or limiting the presence of certain substances (e.g. those on the Candidate List for authorisation) instead of asking for the exact composition of articles or mixtures, which is more often confidential information.
- Information requests up the supply chain for substances intended to be released from articles when released as part of mixtures, should be focused on substances exceeding the concentration calculated to be critical as shown in subchapter 4.2.1. The main reason for this result from the fact that the concentration of the *mixture intended to be released* in the articles is more often known than the concentration of the individual *substances intended to be released*.

Several sector-specific and more general information systems and tools have been recently developed or adapted to support the management of complex supply chains. They can be used to obtain and communicate information on substances in articles within the supply chain in an efficient manner. There may however be cases where supply chain

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

5.1.2.1 Evaluation of information received from suppliers

When information is requested up the supply chain, suppliers often provide **declarations of compliance** for their products, which may also be integrated in IT systems or tools. 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 articles supplied?
- Who is making the declaration, and does the signer have the authority to sign on behalf of the supplying company?
- Is there reason for concern over the validity of the declaration?
If yes, access to any documentation supporting the declaration should be requested.

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

- A scientific test report should include the following elements:
 - Name and address the laboratory involved in the analysis
 - Date of receipt of the sample and date of performance of the test
 - Unique identification of the report (such as a serial number) and date of issue
 - Clear identification and description of the sample and the substance(s) for which testing was performed
 - Sample preparation methods and analytical methods used, including references to the standards used and any deviations from them
 - The limit of detection (LOD) or limit of quantification (LOQ) of the test method
 - Results of the test (with unit of measurement) including uncertainty of the test results
 - Name and signature of the individual authorizing the report
- It should be checked whether the concentration of a substance obtained in the test is really below the relevant limit (e.g. below the 0.1% threshold or the critical concentration level for substances in a *mixture intended to be released*).
- The raw materials and processing of a product can change over time, leading to alterations of the product batches supplied. Therefore it needs to be ensured that the test documented in the report was conducted with the relevant type of product (i.e. the same type as the products supplied).

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

5.2 Chemical analysis of substances in articles

Substances contained in articles can be identified and their concentrations quantified by applying analytical methods. If other approaches to obtaining information fail or become too complicated, conducting chemical analysis may thus be an option to obtain information on the composition of articles.

For certain articles (e.g. toys, shoes) it is even common practice to perform chemical analyses of materials used in the production or of final products. Such analyses performed routinely for checking of compliance with other legislation or product quality control can also serve to obtain information needed for compliance with REACH.

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

5.2.1 Difficulties of chemical analyses

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

- It may be challenging to create a representative sample for the analysis of an article.
- Substances that are included in the article matrix may have to be extracted from it³⁴.
 - This may result in chemical reactions that could “create” substances which do not exist in the article.
 - The extraction may not be exhaustive, thus the full content of substances in the matrix may not be obtainable.
- Various analytical methods are available to screen for the existence and identification of different substances in a sample.
 - Measurements in most cases will identify the chemical constituents in the sample but not necessarily “the substance” which were originally used to produce the article. Note that substances may consist of several constituents (for more information please consult the [Guidance on substance identification](#)).
 - Some methods may show the existence of certain elements (e.g. halogens) rather than the existence of substances.
 - If a high number of different substances are contained, several analyses may be needed to identify all substances, and it is particularly difficult to assign an appropriate method if it is not clear what is being searched.

³⁴ 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.

- The quantification of substances requires additional measurements.

5.2.2 Planning chemical analyses of substances in articles

Chemical analyses have to be planned carefully taking into account what information can be obtained with which methods. If an analysis is carried out, a strategy should be developed in collaboration with experienced laboratories and based on available methods. The testing strategy and interpretation of results should take into account any other available information on the article which is being analysed e.g. from industry sector organisations, research institutions and accredited chemical analysis laboratories. There are no formal requirements on which methods and laboratories to use; it is up to each company to judge the appropriateness of methods and laboratories. However, whenever possible and appropriate, existing standard methods and appropriate accredited laboratories should be used. Examples of standard methods for sampling and analysis of substances in articles can be found in appendix 5.

The following steps are proposed, when planning chemical analyses:

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

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
thermometer with liquid	x	
printer ribbon		x
wet cleaning wipe		x
wax tape for skis		x
adhesive tape for fixing carpets	x	
battery	x	
desiccant bag		x
detector tube	x	
candle		x

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

Object	Spray can with paint	Printer cartridge		Thermometer with liquid
Function	Bring paint onto surface	Bring toner/ink onto paper		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.		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).		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.		NO , the liquid and the container are disposed of together.

Object	Spray can with paint	Printer cartridge		Thermometer with liquid
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>		see table 5

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

Object	Battery	Desiccant bag	Detector tube ³⁵
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.

³⁵ 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.

Object	Battery	Desiccant bag	Detector tube ³⁵
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

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 ³⁶ 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

³⁶ This is regarded as true, although in reality a significant part of the cleaning agent may not actually be consumed, as its *function* is to be released as far as practical.

1 **Table 7: Applying indicative questions to pressure sensitive adhesive tapes³⁷**

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

³⁷ Terms used in the table are defined according to EN 12481:

Backing: flexible material such as fabric, foil or paper which can be coated with a pressure sensitive adhesive.

Reinforcement: a material which strengthens the backing and/or the adhesive.

Release liner: a removable material which protects the adhesive face or faces.

Substrate: a surface or material to which the tape is applied.

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

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

Appendix 2. Examples of setting the borderline in the sequence of processing natural or synthetic materials into final articles

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

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

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

1) Aluminium processing as an example of metal processing

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

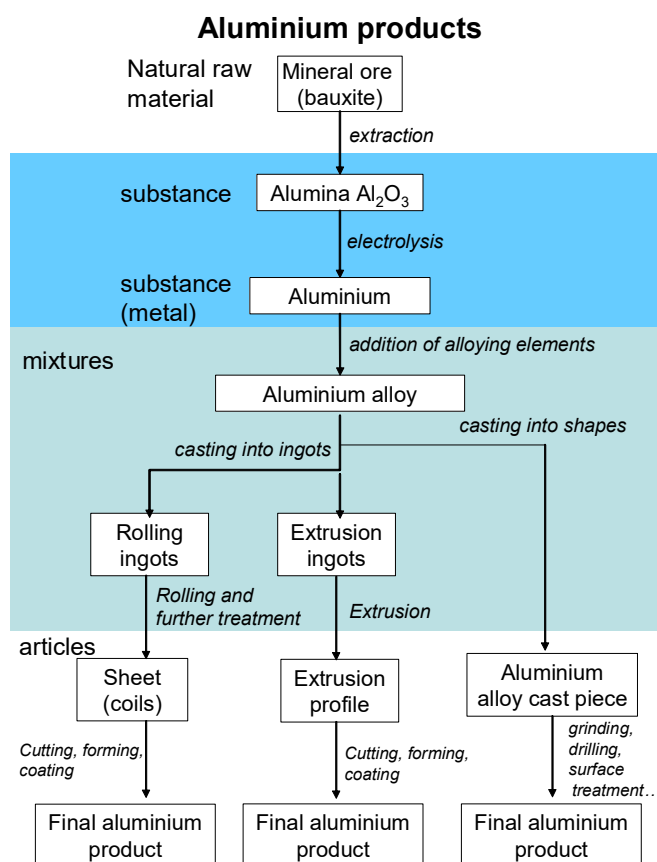


Figure 3: Transition from bauxite to final aluminium products

The transition point from mixture³⁸ 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.

³⁸ formerly termed "preparation" as in the figure.

Table 9: Applying indicative questions to different stages of aluminium processing (part 1)

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

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

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

Aluminium alloy – rolling ingots – coils

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

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

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

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

Aluminium alloy – extrusion ingots – extrusion profiles

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

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

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

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

9

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

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

the final decision on a material's status.

2) Textile and non-woven processing

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

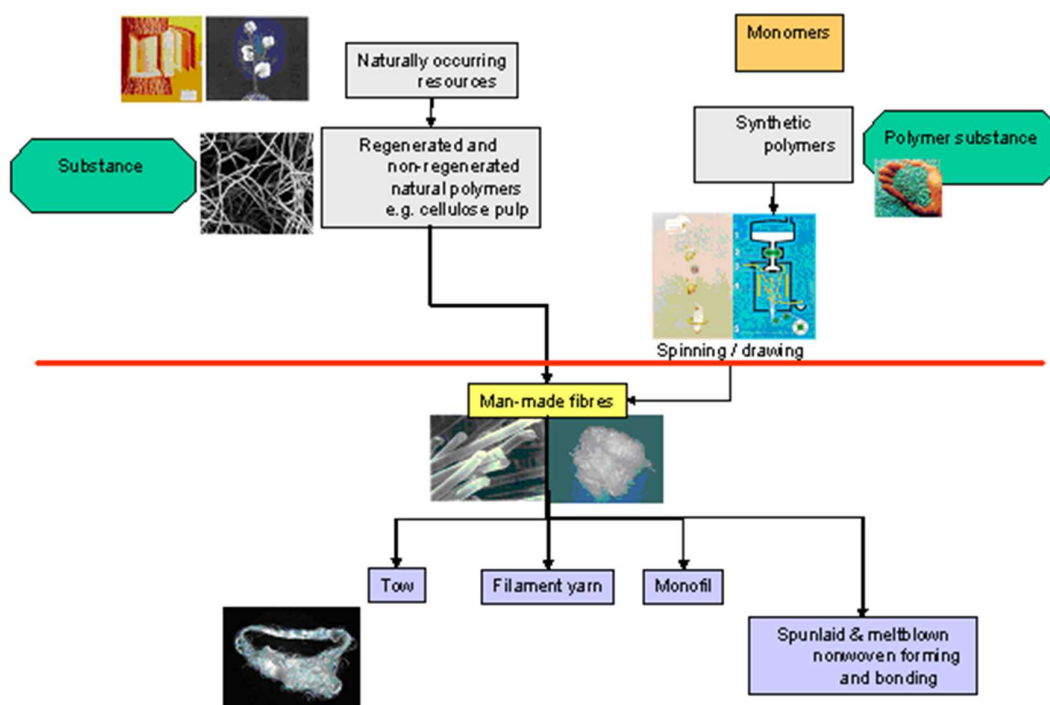


Figure 4: Transition from raw materials to final textile/non-woven products

Table 11: Applying indicative questions to different stages of textile/non-woven processing

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

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

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

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

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

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

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

14

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3) Polymer processing

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

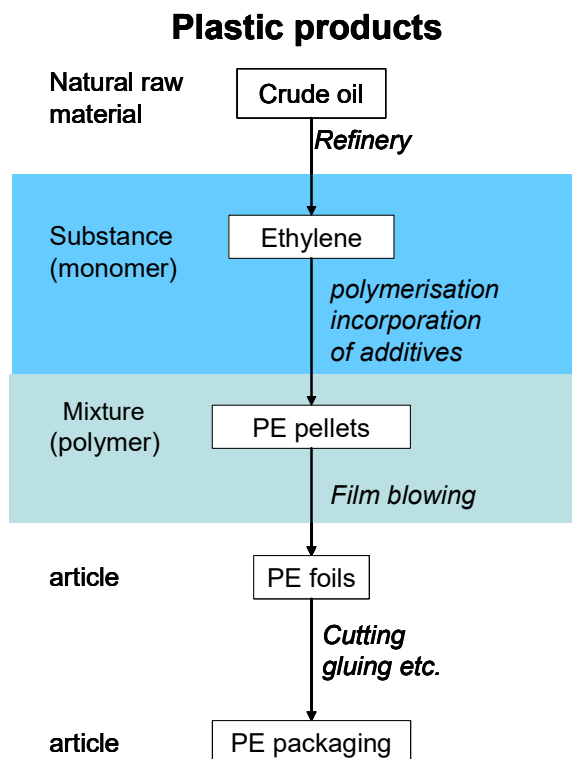


Figure 5: Transition from crude oil to plastic products

Table 12: Applying indicative questions to different stages of polymer processing

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

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

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

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

4) Paper processing

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

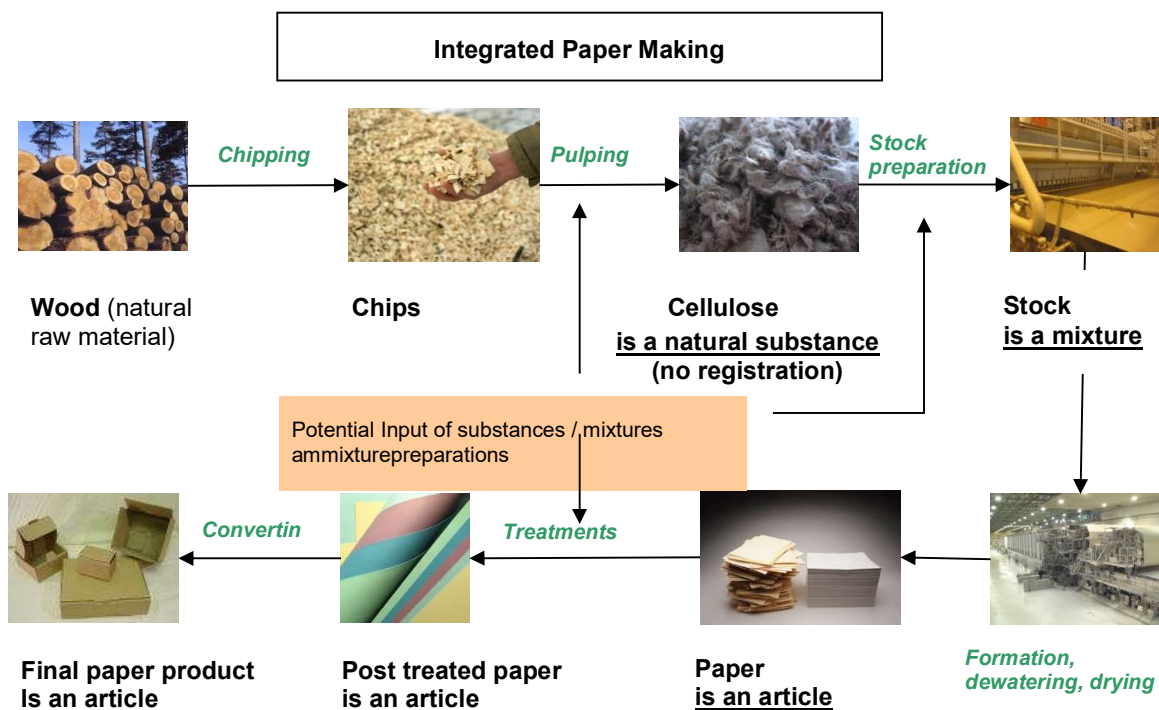


Figure 6: Illustrative example of the general transition point from wood to paper articles

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,
3 e.g. packaging of filling material. Although it is further processed to better fulfil a specific
4 purpose, the paper already has a function apart from being raw material for further
5 processing.
- 6 The dewatered paper is the first stage of the raw material, which does have a specific
7 shape, surface and design. Any previous production stages of the raw material can
8 therefore not represent an article status.
- 9 The further treatment of paper may change the overall shape of paper significantly.
10 However, the design is not changed.

11

12

Appendix 3. Examples on how to determine the concentration of a Candidate List substance in articles

The examples below show how to determine the concentration of a Candidate List substance in weight by weight in articles of different complexities. This determination is essential to assess if the article produced or imported contains that substance above the 0.1% w/w concentration threshold. This threshold triggers the communication obligation down the supply chain under Article 33 of REACH. It is also a condition for the substance in article notification obligation under Article 7(2).

Examples 1 show how a Candidate List substance concentration can be determined when an article is produced directly from a substance or a mixture.

Example 1: Article made directly from a substance or a mixture - Plastic garden chair

The article is a garden chair injection moulded during production, in one piece, and has a total weight of 3.0 kg. It is made from a mixture of polyethylene and a Candidate List substance used as a pigment. The concentration of this pigment in the mixture – and hence in the garden chair – is 0.12% w/w, i.e. above the 0.1% w/w concentration threshold.



Supply chain communication:

The EU producer or the importer has to communicate down the supply chain or to consumers upon request the presence of the Candidate List substance in the garden chair, as well as any information to allow its safe use (see subchapter 3.2.1). Any actor in the supply chain receiving this information from the producer or importer and supplying the garden chairs must pass on that information to the next actor in the supply chain or to consumers upon request.

Comments on the example:

An EU producer of garden chairs can rely on the fact that their chemical suppliers have a (legal) obligation to provide them with information and an established communication tool to do so: the supplier of the polyethylene pellets has to provide the producer of

chairs information on the concentration of the Candidate List substance in a safety data sheet (SDS).

Importers of the chairs should request information from their non-EU suppliers on the concentration of the Candidate List substance in the imported articles.

Example 2 shows how a Candidate List substance concentration is determined when an article is produced directly from a substance or a mixture in combination with an existing article (e.g. the insulator tube formed directly by extrusion in the copper electric wire in an insulated wire; the screw driver with a handle formed by moulding plastics directly onto the metal part).

Example 2: A substance or a mixture is combined with an existing article and becomes an article itself: insulated electric wire

An insulated electric wire consists of a core of copper wire (article) covered with an insulating PVC tube. The insulating PVC tube is produced, e.g. through extrusion over the copper core wire. The insulating PVC tube (insulator tube) has a function on its own and fulfils the definition of an article. The insulated electric wire contains two articles joined together: the insulator tube and the copper wire core.

The PVC mixture used in the coating contains 40% w/w of a Candidate List substance used as a plasticizer – and hence in the insulator - is 40% w/w, i.e. above the 0.1% w/w concentration threshold.

The copper wire does not contain any Candidate List substances above the 0.1% w/w threshold.



Supply chain communication

The EU producer or the importer has to communicate down the supply chain and to consumers upon request, the presence of Candidate List substance in the insulator tube in an insulated electric wire, as well as any information to allow its safe use (see subchapter 3.2.1). Any actor in the supply chain receiving this information from the

producer or importer and supplying the insulated electric wires must pass on that information to the next actor in the supply chain or to consumers upon request.

Comments on the example:

1. EU producers of the insulated electric wires can rely on the fact that their chemical suppliers have a (legal) obligation to provide them with information and an established communication tool to do so: a supplier of the PVC mixture has to provide the producer of insulated wires with information on the concentration of the Candidate List substance in a safety data sheet (SDS).

Importers of the insulated wires should request information from their non-EU suppliers on the Candidate List substance in the imported articles (including the insulator tubes) .

2. In the case the insulated electric wire is produced by pulling a PVC sheathing (insulator tube produced separately) over the inner copper wire, the importers and the EU producers have the same obligations as described above. However, the EU producer of the insulated electric wire receives information on the presence of the Candidate List substance on the insulator tubes (articles) and on their safe use from his supplier(s).

A substance or a mixture containing this substance can be incorporated into an existing article or several articles (e.g. coatings, paints, adhesives and sealants) and the substance becomes an integral part of the article(s). In such cases, the concentration of the substance incorporated during production into the article is determined in relation to the total weight of the article.

In these cases, the concentration of the Candidate List substance, after incorporating a substance or a mixture containing this substance into the article, is determined using the following equation:

$$Conc_{subst. in article} = Conc_{subst. in mixture} \times Conc_{mixture in article} \quad (1)^{39}$$

where,

$Conc_{subst. in article}$ is the concentration (% w/w) of the Candidate List substance in the article;

$Conc_{subst. in mixture}$ is the concentration (% w/w) of the Candidate List substance in the mixture⁴⁰;

$Conc_{mixture in article}$ is the concentration (% w/w) of the mixture in the article.

³⁹ Please note that the terms $Conc_{subst. in article}$, $Conc_{subst. in mixture}$ and $Conc_{mixture in article}$ in % w/w in equation (1) should be understood as meaning the weight fractions: values between 0 and 1 (50% = 0.5, 25% = 0.25, 20% = 0.2, etc.).

⁴⁰ Please note that the term $Conc_{subst. in mixture}$ in equation (1) can be used for mixtures where the weight loss of the mixture during incorporation in the article is negligible or in the dry form after incorporation in the article. If there is a significant evaporation of the solvent or other components from the mixture during its incorporation in the article, the term $Conc_{subst. in mixture}$ must be corrected by a factor to take into account the weight decrease of the mixture. The same term in equation 1 also assumes that the evaporation or transformation of the Candidate List substance is negligible. If that is not the case, another correction factor must be applied to take this into account.

The examples 3 and 4 show how the concentration of a Candidate List substance is determined in an article produced by incorporating a substance or mixture into an article.

Example 3: A substance or a mixture is incorporated into an article becoming thereby an integral part of the article - printed t-shirt

A printed t-shirt was produced by incorporating paints to make the print in an existing unprinted t-shirt fabric. One of the paints used contains a Candidate List substance used as pigment at a concentration of 2% w/w. The non-volatile substances content (solids) of that paint is 67% w/w. The printed t-shirt weighs 150g and contains 3g of the paint containing the Candidate List substance. The concentration of that substance should be determined in relation to the total weight of the printed t-shirt.



The concentration (% w/w) of the Candidate List substance in the printed t-shirt ($Conc_{subst. \text{ in } t\text{-shirt}}$) can be calculated using the equation (1) in the text above.

- The concentration of the Candidate List substance in the paint ($Conc_{subst. \text{ in } paint}$) needs to be corrected by a factor of 100/67 due to the (semi-)volatile substances contained in the paint which evaporate during the incorporation of the paint in the unprinted t-shirt fabric. Thus, $Conc_{subst. \text{ in } paint} = (100/67) \times 2\% = 3\% \text{ w/w}$.

- The concentration of the paint in the printed t-shirt is calculated as follows:
 $Conc_{paint \text{ in } t\text{-shirt}} = 0.003\text{kg}/0.150\text{kg} = 2\% \text{ w/w}$.

Therefore,

$$Conc_{subst. \text{ in } t\text{-shirt}} = Conc_{subst. \text{ in } paint} \times Conc_{paint \text{ in } t\text{-shirt}} = (3\%) \times (2\%) = 0.06\% \text{ w/w}^{41}$$

The Candidate List substance concentration in the printed t-shirt is 0.06% w/w, which is not above the 0.1% w/w concentration threshold.

Supply chain communication

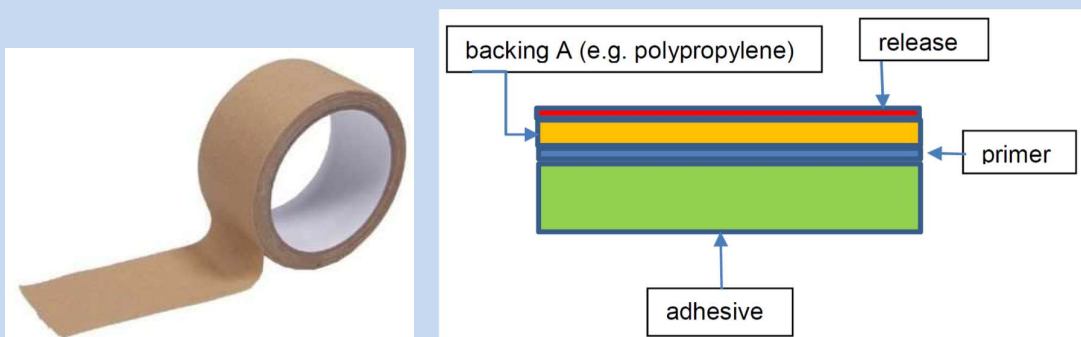
The EU producer or the importer of the printed t-shirts do not need to communicate, down the supply chain or to consumers upon request, the presence of the Candidate List substance.

⁴¹ When applying equation (1), 3%, 2% and 0.06% must be understood as meaning 0.03, 0.02, 0.0006, respectively.

Example 4: A substance or a mixture is incorporated onto an article becoming thereby an integral part of the article - adhesive tape

An adhesive tape B (article) is produced by incorporating in an article - backing A (polymer foil) - an adhesive (mixture), a primer (mixture) and a release system (mixture). All these mixtures are integral parts of the adhesive tape B and cannot be separated from the adhesive tape B without destroying it.

Adhesive tapes are used by workers and consumers in several applications, in particular for joining or protecting articles or materials. The adhesive tape does not have the same function of the backing foil.



Backing A:

The backing A is polypropylene foil made by extruding polypropylene with a Candidate List substance 1, used as stabilizer. The concentration of that substance in the backing A (article) is 0.5% w/w, that is above the 0.1% w/w concentration threshold.

Supply chain communication:

The producer or the importer of the backing A is the supplier of the producer of the adhesive tape B. Therefore, this backing A supplier is required to communicate, to the producer of the adhesive tape B, the presence of the Candidate List substance 1 in backing A, as well as any information to allow its safe use (see subchapter 3.2.1), in particular by workers.

Adhesive tape B (incorporating the primer, adhesive and release system mixtures into the backing A):

The producer of the final adhesive tape B incorporates, onto one of the surfaces of the backing A, a primer mixture which promotes adhesion between this surface and the adhesive (mixture) applied next. A release system (mixture) is also incorporated onto the other surface of the backing A.

The backing A weights 20 g/m². The primer, adhesive and release system mixtures weight in total 60 g/m², while the release system weights specifically 10 g/m², in the adhesive tape B. The total weight of the adhesive tape B is therefore 80 g/m². The release system in the adhesive tape B contains a Candidate List substance 2 at a concentration of 3% w/w.

The total concentration of the Candidate List substance 2 in the adhesive tape B ($Conc_{subst.2 \text{ in adhesive tape B}}$) is calculated using equation (1) in the text above:

- the concentration of the release system in the adhesive tape B ($Conc_{release \text{ system in adhesive tape B}}$) is 0.125% w/w [= (10 g/m²)/(80 g/m²)]

- the concentration of the Candidate List substance 2 in the release system ($Conc_{subst.2 \text{ in release system}}$) is 3% w/w

thus,

$$Conc_{subst.2 \text{ in adhesive tape B}} = Conc_{subst.2 \text{ in release system}} \times Conc_{release \text{ system in adhesive tape B}} = (3\%) \times (0.125\%) \approx 0.004\% \text{ w/w}$$

The concentration of the Candidate List substance 2 in adhesive tape B is 0.004% w/w. This concentration is below the 0.1% w/w concentration threshold.

The backing A containing the Candidate List 1 becomes an integral part of the adhesive tape B during its production.

Supply chain communication:

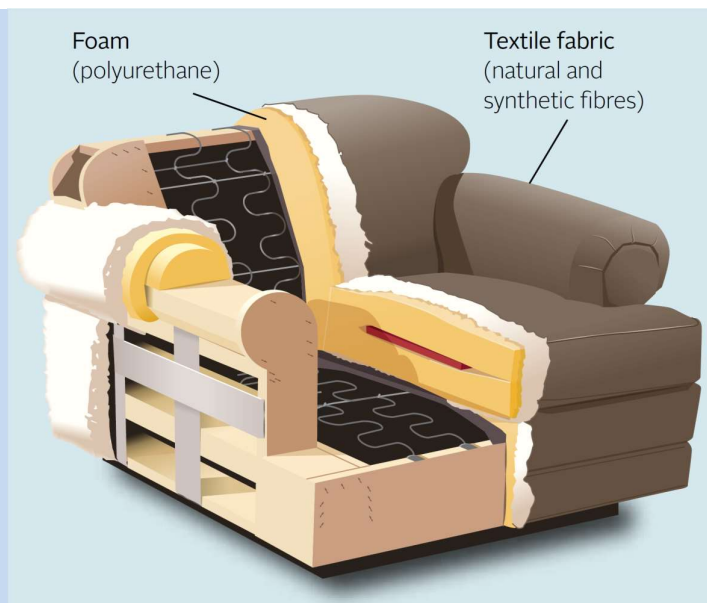
The EU producer or the importer of the adhesive tape B has to communicate down the supply chain, the presence of the Candidate List substances 1 in the backing A of the adhesive tape B, specifying where it is present, as well as any information to allow its safe use (see subchapter 3.2.1). Any actor in the supply chain receiving this information from the producer or importer and supplying the adhesive tapes must pass on that information to the next actor in the supply chain or to consumers upon request.

Regarding the Candidate List substance 2 present in the release system of the adhesive tape B, the EU producer or importer does not need to communicate any information down the supply chain, because its concentration in this article is below the 0.1% w/w concentration threshold.

Two or more articles can be “mechanically” assembled together (i.e. without the addition of any substance or mixture). In these cases, the concentration of the Candidate List substance must be determined for each article as shown in example 5.

Example 5: Two or more articles “mechanically” assembled together - upholstered sofa

An upholstered sofa is assembled from several articles,. Most common sofas are made of a combination of articles such as the frame, the springs, the cushions, the yarns and the fabric. In this example, we only consider the cushions foam blocks and the textile fabrics as articles containing Candidate List substances above 0.1% w/w threshold. Nevertheless, the producer or the importer of the upholstered sofa should check for each article assembled or joined into the sofa if it contains Candidate List substances.



The sofa covering is cut from textile fabric that contains 0.17% w/w of a Candidate List substance 1. The cushion foam blocks used in the production of the sofa were cut from a bigger polyurethane foam block, which is an article that contains 0.2 % w/w of a Candidate List substance 2.

Supply chain communication

Both the fabric and the cushion foam blocks are already articles before being assembled into the upholstered sofa. Cutting the fabric and the foam blocks into pieces with different sizes does not change their status as articles. In both cases, the concentrations of the Candidate List substances are above the 0.1% w/w concentration threshold. Therefore, the producer, the importer or any other downstream supplier of the sofas has to communicate down the supply chain or to consumers upon request the presence of Candidate List substance 2 in the cushions and of Candidate List substance 1 in the textile fabrics, as well as any other information to ensure the safe use of the upholstered sofa containing these articles (see subchapter 3.2.1).

An EU producer of the upholstered sofa can rely on the fact that the suppliers of the textile fabric and the foam blocks, including producers and/or importers, have a (legal) obligation to provide them with information, according to Article 33(1) of the REACH Regulation, on the presence of the Candidate List substance 1 in the textile fabric and on the presence of the Candidate List substance 2 in the polyurethane foam blocks and information on how to use them safely in the production of the sofa.

The importer or importers of any of these articles (textile fabric, foam blocks or upholstered sofa) need to request the information from their non-EU suppliers. They should receive information on the Candidate List substances concentration and safe use of the textile fabrics and foam blocks to be used in the production of the sofa from their non-EU suppliers and/or on the safe use of upholstered sofa containing these articles during the service life of the sofa in the case of importing the assembled sofa.

Two or more articles may be joined together with the addition of substance(s) or mixture(s), e.g. by welding or using adhesives. In these cases, the concentration of the Candidate List substance is determined in each article even if they cannot be separated without destroying the final product. This also applies to cases where an article used as a component undergoes changes in shape, surface or design during the production of the final article, but keeps its status as article. However, this will not apply where the article used as component loses the shape, surface or design of its own to such an extent that it can no longer be identified as an article when integrated into the final product.

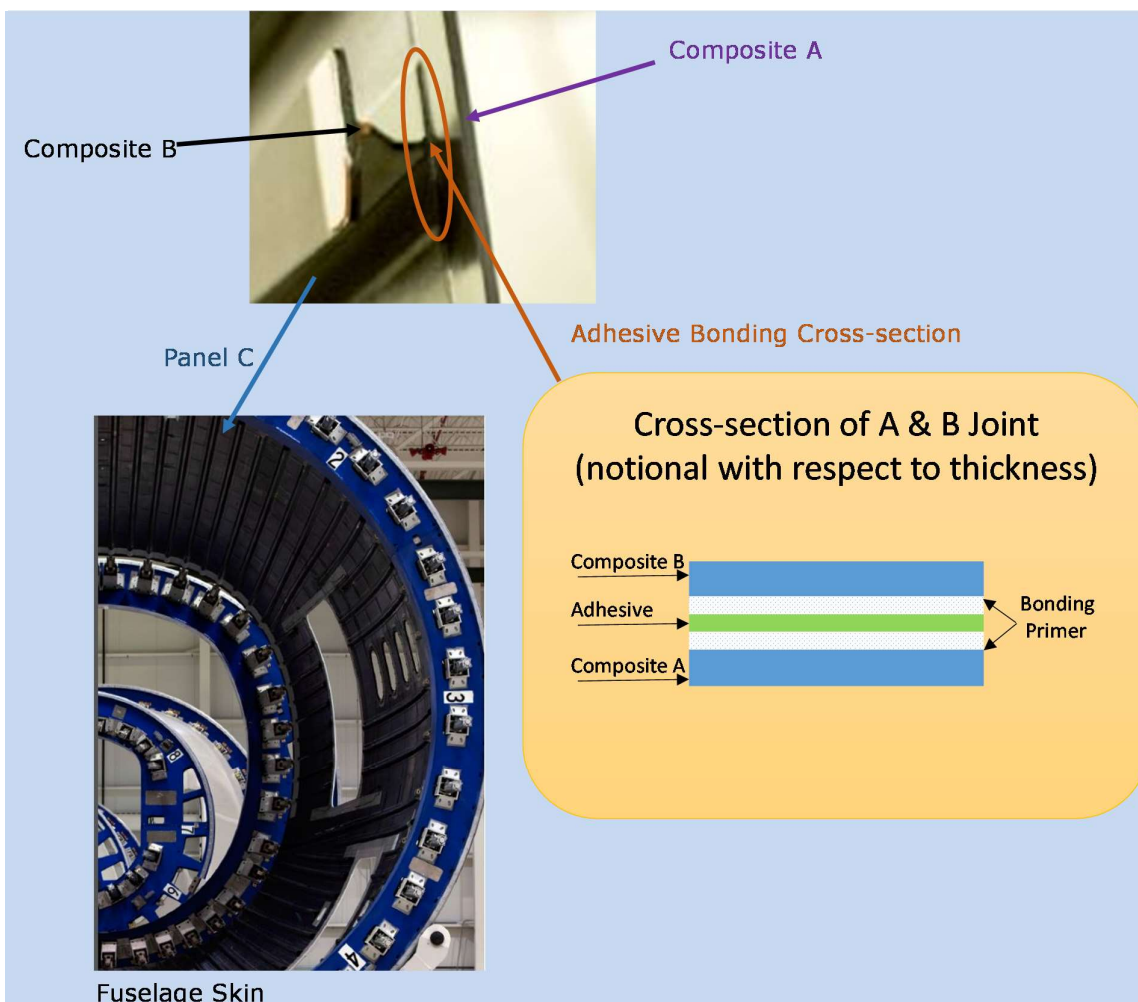
If an article is produced by joining two or more articles by using a mixture containing a Candidate List substance, its concentration needs to be determined in the final article. The concentration is determined in relation to the total weight of the articles and the mixture(s) incorporated.

Example 8 aims at illustrating the approach to follow to determine the concentration of Candidate List substances when article is produced by joining two or more articles by using a mixture containing a Candidate List substance.

Example 6: Joining two or more articles together using a substance or a mixture - aircraft skin fuselage panel

Important note: This example is not meant to discuss whether a given object should be regarded as an article or not. The reader is therefore invited to consider that certain objects as "articles" for the purpose of this example (refer to chapter 2 of this guidance to understand how to conclude that the objects are articles).

An aircraft skin fuselage panel (panel C) is produced by joining together two different carbon composites (A and B) - adhesive bonding of two carbon composites - by using a primer (mixture) and a structural adhesive (mixture).



1

2 The primer and the adhesive resin are mixtures used to join the composite A to
3 composite B. The primer and the resin undergo curing during this process. The function
4 of composites A and B is to be constituents of the skin fuselage panel C. The function of
5 composite panel C, made by joining composites A and B using the primer and the resin
6 R3 mixtures, is to be a fuselage panel in the fuselage skin of an aircraft.

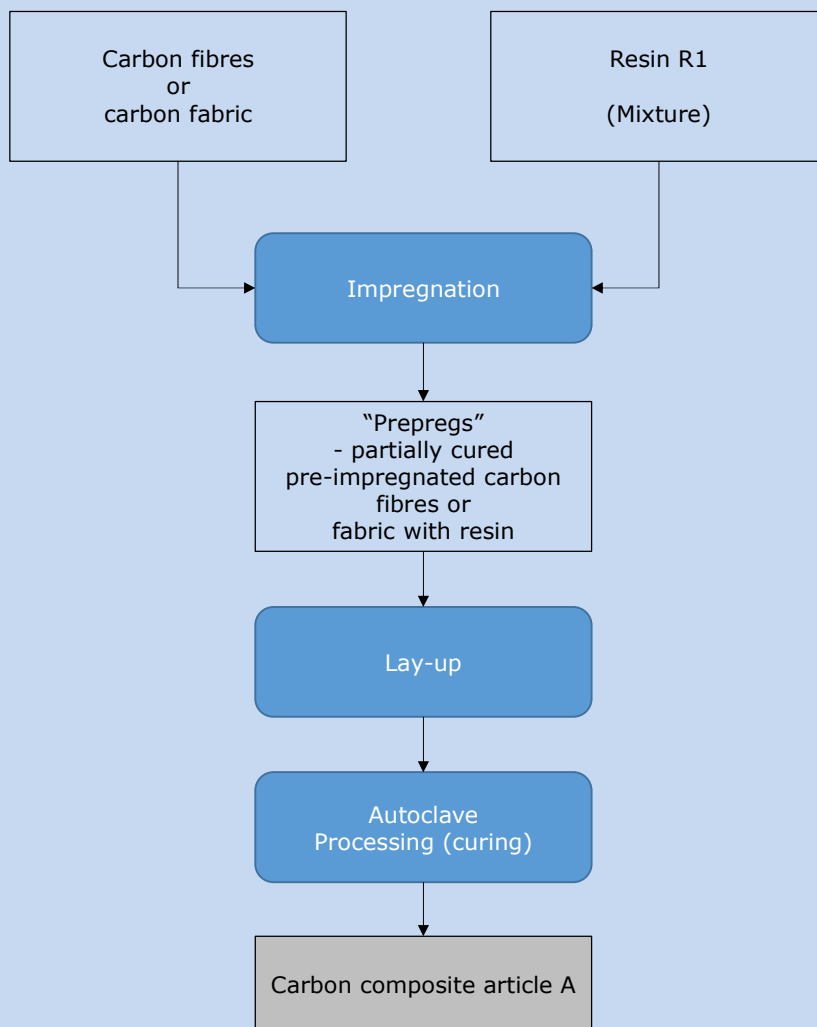
7 **How to calculate the percentage of Candidate List substances in the article(s):**

8 **Carbon composite A:**

9 The carbon composite A is produced from "Prepreg" sheets, as follows:

- 10 1. The "Prepreg" (or pre-impregnated) sheets are made by combining carbon fibers
11 or carbon fabric with a resin mixture R1 (e.g. epoxy resin + curing
12 agent(s)/hardener(s)/accelerator(s) + flame retardant(s)). This process is called
13 impregnation and the resin is partially cured to improve handling of the
14 "Prepreg" sheets. The resin R1 contains a Candidate List substance 1.
- 15 2. The "Prepreg" sheets are then cut into pieces, arranged and layered on a tool in
16 the so-called lay-up process and then cured under pressure (e.g. in an
17 autoclave) between 120 to 180 °C depending upon the resin system.

3. In the final carbon composite A, the several layers of "Prepreg" sheets are consolidated in the curing process - in which the carbon fibers/fabric and the resin are chemically bonded.



As detailed above, the resin mixture R1 is used to bind the carbon fibers or the carbon fabric together in the resin matrix during the "Prepreg" sheet production and finally it becomes an integral part of the carbon composite A. Thus, the concentration (% w/w) of the Candidate List substance 1 in the composite A can be calculated using the equation (1) in the text above, given that:

- the concentration of the Candidate List substance 1 in the resin mixture R1, after curing, is 5% w/w; and
- the concentration of the resin mixture R1 in composite A is 30% w/w after curing; then

$$Conc_{subst.1 \text{ in composite article A}} = Conc_{subst.1 \text{ in resin R1}} \times Conc_{Resin R1 \text{ in composite article A}} = (5\%) \times (30\%) = 1.5\% \text{ w/w}$$

Thus, in this example, the concentration of the Candidate List substance 1 in carbon composite A is 1.5% w/w that is above 0.1% w/w concentration threshold.

Supply chain communication

The producer or the importer of the carbon composite A supplies directly the producer of the skin fuselage panel C. Therefore, the producer or the importer of composite A must communicate to the producer of the skin fuselage panel C, the presence of the Candidate List substance 1 in the composite A, as well as any information to allow its safe use (see subchapter 3.2.1), in particular by workers.

Carbon composite B:

The carbon composite B is produced as the carbon composite A described above, using a resin R2. The carbon composite B contains a Candidate List substance 2 (from a resin mixture R2) at a concentration of 0.3% w/w that is above 0.1% w/w concentration threshold.

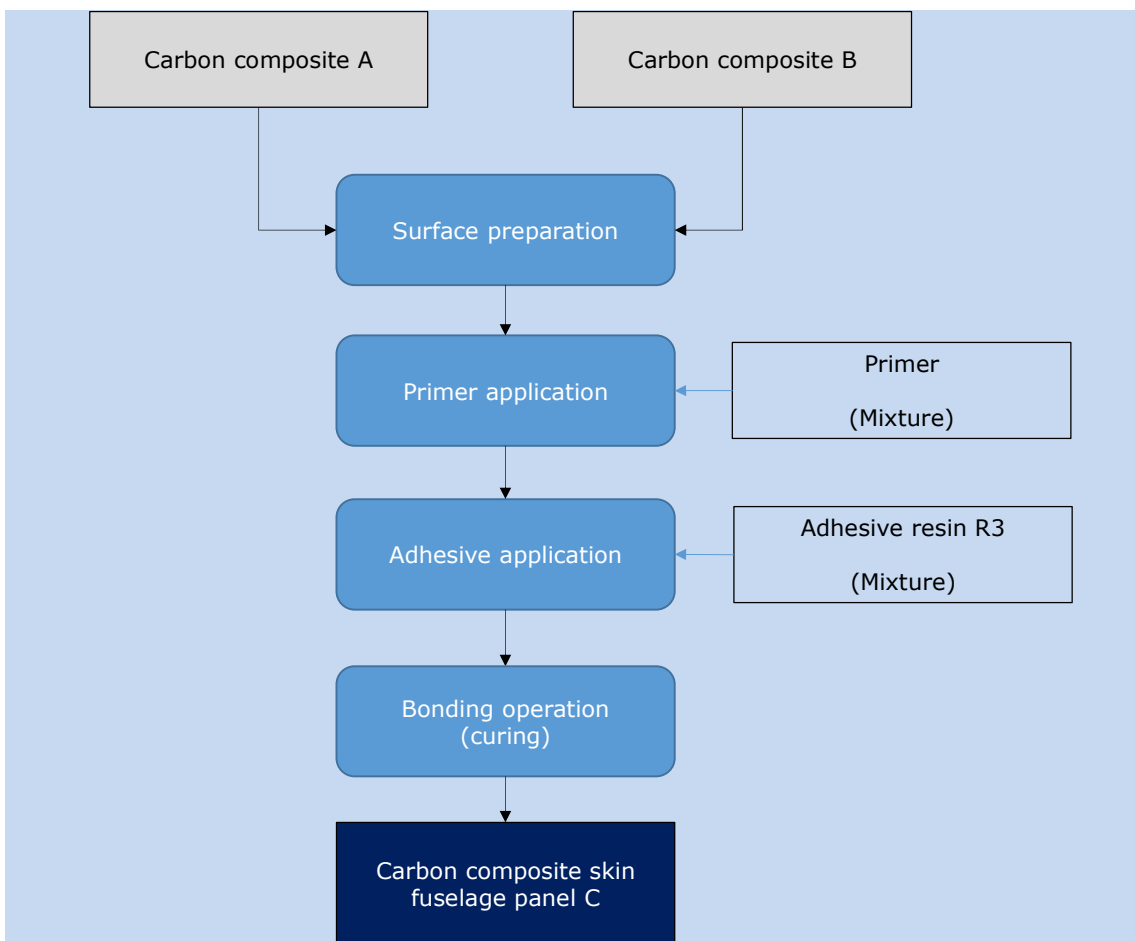
The producer or the importer of the carbon composite B supplies directly this article to the producer of the skin fuselage panel C.

Supply chain communication

The producer or the importer of the carbon composite B have the same communication obligations as those described above for the producer or importer of the carbon composite A.

Composite panel C (adhesive bonding of carbon composites A and B):

The producer of the skin fuselage panel C applies to the surface of each carbon composite (A and B) a primer mixture which promotes adhesion between the surfaces of the composites and the adhesive, and then a structural adhesive – an adhesive resin mixture R3 – to bond composite A to composite B. The resin mixture R3 contains the Candidate List substance 3. The bonding between both carbon composites is performed at approximately 120 to 180 °C, where the primer mixture and the adhesive resin R3 undergo curing. These mixtures after curing become integrated in the final carbon composite skin fuselage panel C.



The carbon composite A weights 40 kg, the carbon composite B weights 20 kg. After curing, the final weight of the primer in the panel C is 0.5 kg and of the adhesive mixture R3 is 2.5 kg for bonding composites A and B. The total weight of panel C is therefore 63 kg. The adhesive resin R3 weight percentage in Panel C ($Conc_{resin\ R3\ in\ panel\ C}$) is $(2.5\text{kg}/63\text{kg}) \times 100 = 4\%$ w/w. The adhesive resin R3 used to produce this panel, after curing, contains 8% w/w of a Candidate List substance 3 ($Conc_{subst\ 3\ in\ resin\ R3}$).

The adhesive mixture R3 containing the Candidate List substance 3 is applied to composite A and composite B to join them together. The concentration of the Candidate List substance 3 in panel C is, thus, calculated based on the concentration of the Candidate List substance 3 in the mixture R3 and the total amount of the mixture R3 incorporated in relation to the overall weight of the composites A and B and the primer and R3 mixtures (total weight of panel C).

The total concentration of the Candidate List substance 3 in Panel C is calculated using equation (1) in the text above:

$$Conc_{subst\ 3\ in\ panel\ C} = Conc_{subst\ 3\ in\ resin\ R3} \times Conc_{resin\ R3\ in\ panel\ C} = (8\%) \times (4\%) \approx 0.3\% \text{ w/w}$$

Thus, the concentration of the Candidate List substance 3 in panel C is 0.3% w/w (assuming that it does not undergo transformation during curing). This concentration is above the 0.1% w/w concentration threshold.

The carbon composites A and B are integrated in the skin fuselage panel C after being chemically joined to each other.

Supply chain communication

The EU producer or the importer of the final panel C, intended to be handled and installed by workers, has to communicate down the supply chain, the presence of the Candidate List substances 1, 2 and 3 in the article, specifying the article/material where they are present with sufficient specificity to allow safe use of the article, as well as any other information to allow its safe use (see subchapter 3.2.1).

Comments on the example:

1. The carbon fibres or the carbon fabric still retain their status as articles after being integrated in the resin matrix during the production of carbon composites A and B.

2. Supposing that composite B contains the Candidate List substance 2 at a concentration of 0.08% w/w, which is below 0.1% w/w threshold, then a EU producer or importer of the composite B does not have communication and notification obligations under REACH. The same applies to an EU producer or importer of panel C regarding the joined composite B in panel C.

3. Suppose that composite A contains the Candidate List substance 1 at a concentration of 1.5% w/w, composite B contains the same substance at 0.08 % w/w and the adhesive resin R3 after curing contains also that substance at 8% w/w. The producer of panel C needs to communicate in its supply chain the presence of the Candidate List substance 1 in the panel C (overall concentration including the quantity of the substance in composite B: $[(40\text{kg} \times 1.5\%) + (2.5\text{kg} \times 8\%)] / 63\text{kg} = 1.3\% \text{ w/w}$) and its component articles, specifying the article(s)/material(s) where the substance is present with sufficient specificity to allow safe use of the article, as well as any other information to allow its safe use including disposal. The sufficient specificity here can be understood as meaning the A part and the joining integral part where the resin R3 was incorporated in panel C as well as the whole panel C. It is also recommended, whenever possible, to provide the specific concentration of the Candidate List substance 1 in those specific parts of the fuselage panel C as well as the overall concentration of the substance in Panel C (obtained by calculating the total quantity of the substance in composites A and B and resin R3 in relation to the total weight of panel C).

4. Any downstream supplier of panel C must pass on down the supply chain the information that has been provided to him.

Appendix 4. Examples on how to determine the total amount of a Candidate List substance from different articles

The practical examples below show how to determine the total tonnage of a Candidate List substance in articles as produced or imported following the steps indicated in subchapter 3.2.2 of this guidance. This calculation covers all articles of the same producer or importer where the substance is present above the 0.1% w/w concentration threshold, in order to apply the 1 t/a trigger limit for submitting a notification of substances in articles to ECHA.

The terms "article type" and "same article" are not defined under REACH and are introduced below only for practical reasons, in particular for grouping articles to facilitate the calculation of the total amount of a Candidate List substance present in all articles produced and imported by a producer/importer. The term "article type" is used below to refer to the same articles, which only differ slightly e.g. in composition,⁴² colour,⁴³ physical properties, design, shape/dimensions, etc., but not on the main material, function, use, and gross changes on composition, physical properties, shape, design, etc. Some examples are given below:

- plastic film bags made of polyethylene with different colours and sizes are same articles (same type), and are different from plastic shower curtains made of polyester (different article type from the plastic film bags);
- Copper wires with different slightly different diameters are same articles (same type) and different from single-core fibre optics, therefore the copper wires and the single-core fibre-optics are different article types;
- Glass dinner and soup plates are same articles (same article type), while ceramic dinner and soup plates (same article type) are different from glass plates and therefore they are different article types.

For notifications concerning the same articles containing the same Candidate List substance, these articles should be grouped together for practical reasons, whenever possible, and the required information (see chapter 3.4.2) will be provided only once in the notification. In this case you should decide which articles are similar enough to be described together.⁴⁴ This can be done based on all the following conditions:

- the articles have the same use/function; and
- the Candidate List substance has the same technical function; and
- the Candidate List substance is located in the same (integral) part/material of the article; and
- the use conditions of the articles can be expected to be similar.

⁴² If the pigment or dye providing a specific colour to articles contains the Candidate List substance, then the colour indicator conjugated with composition differences could not be used or only be used with caution to consider articles as identical. Furthermore, articles with different colours typically have different chemical compositions and thus could differ with regard to presence of Candidate List substances.

⁴³ The concentration of a Candidate List substance in different articles must be approximately the same in order to group those articles under the same article type.

⁴⁴ For more information, please refer to the Appendix 4 and the manual *How to prepare a Substance in Articles Notification* available at <http://echa.europa.eu/manuals>

The calculation of the total amount in tonnes of the same Candidate List substance in all articles produced or imported, by the same actor, requires 3 steps (see subchapter 3.2.1):

1. Determine if the Candidate List substance in question is present above the 0.1% w/w concentration threshold for each article (type) produced or imported (see subchapter 3.2.1);

If the information available to the producer and/or importer can be in terms of the weight of the Candidate List substance in an article type, then its concentration in the particular article (either isolated or incorporated as a component of another article) must be determined to verify whether it is above the 0.1% w/w concentration threshold using the following equation:

$$Conc_{SVHC \text{ in article type}} [\%] = \frac{m_{SVHC \text{ in article type}} [kg]}{m_{\text{article type}} [kg / \text{article}]} \quad (2)^{45}$$

Where,

$Conc_{SVHC \text{ in article type}}$ is the concentration (% w/w) of the Candidate List substance in the article type;

$m_{SVHC \text{ in article type}}$ is the mass (in kilogram) of the Candidate List substance in the article type;

$m_{\text{article type}}$ is the mass (in kilogram) of each article of that type.

If the result of the calculation (or information provided directly) shows that the concentration in the specific article type is **below** 0.1% w/w, then the particular article type need **not** be considered in the following calculation of total tonnage.

2. Calculate the amount in tonnes of that Candidate List substance in each article (type) produced or imported per year where it is present above the 0.1% w/w concentration threshold;

To calculate the total amount, in tonnes, of the Candidate List substance in each of the different article types produced and/or imported per year ($m_{SVHC \text{ in article type } i}$) with a concentration of the Candidate List substance above 0.1% (w/w) use the following equation:

$$m_{SVHC \text{ in article type } i} [t / a] = \left(Conc_{SVHC \text{ in article type } i} [\%] \right) \times \left(\frac{m_{\text{article type } i} [kg / \text{article}]}{1000} \right) \times n_{\text{articles type } i} [\text{articles} / a] \quad (3)^{45,46}$$

⁴⁵ Please note that the term $Conc_{SVHC \text{ in article type}}$ and $Conc_{SVHC \text{ in article type } i}$ in % w/w in equations (2) and (3), respectively, should be understood as meaning the weight fractions: values between 0 and 1 (50% = 0.5, 25% = 0.25, 20% = 0.2, etc.).

⁴⁶ The equation assumes that the concentration of the Candidate List substance and the mass of the articles are the same. In certain situations, average values could be used.

Where, i is the article type A, B, ... n, which means for each different article type imported and/or produced containing the Candidate List substance above 0.1% w/w;

$Conc_{SVHC}$ in article type i is the concentration (% w/w) of the Candidate List substance in the article type i ;

$m_{article\ type\ i}$ is the mass (in kilogram) of each article of type i ;

$n_{article\ type\ i}$ is the number of articles of type i produced and/or imported per year.

3. Calculate the total amount in tonnes for all articles by summing up the amounts calculated for each article (type) accordingly to point 2 above.

The total amount, in tonnes, of the SVHC in all relevant articles produced and/or imported (m_{SVHC} in article type i , where i is A, B, ... n), which each contain more than 0.1% (w/w) of the substance, is obtained by summing up the amounts, in tonnes per year, calculated for each relevant article type (m_{SVHC} in article type A, m_{SVHC} in article type B, ... , m_{SVHC} in article type n):

$$m_{SVHC\ in\ all\ article\ types} [t/a] = m_{SVHC\ in\ article\ type\ A} [t/a] + m_{SVHC\ in\ article\ type\ B} [t/a] + \dots + m_{SVHC\ in\ article\ type\ n} [t/a] \quad (4)$$

Example 1: Calculation of the total amount of a Candidate List substance in separate articles - non-stick Kitchenware (frying, grill and sauce pans)

A company based in the European Union imports kitchenware from outside the EU. The company imports 300 000 frying pans, 150 000 grill pans and 450 000 sauce pans per year. Each frying, grill and sauce pan comprises the pan body (article) and a handle or grip (article) fixed to it through two screws (articles). The sauce pans also include lids. Only the pan bodies with the non-stick layer, comprising a base and a flared side wall, contain the **same** Candidate List substance.



The total weight of the each frying and grill pan body is 1 kg and the total weight of each sauce pan body is 1.5 kg. Each pan body with the non-stick layer contains the following quantities of a Candidate List substance: 2.3g in the frying pan body, 3.0g in the grill pan body and 1.8g in the sauce pan body.

The calculation of the total amount in tonnes of the same Candidate List substance in all pan bodies imported per year follows the 3 steps explained above.

1. Determination of the concentration of the Candidate List substance for each pan body produced or imported using equation (2) in the introductory text above.

• frying pan body:

$$Conc_{SVHC \text{ in frying pan body}} [\%] = (m_{SVHC \text{ in frying pan body}} [kg] / m_{frying \text{ pan body}} [kg / article]) \times 100$$

$$Conc_{SVHC \text{ in frying pan body}} [\%] = (0.0023 / 1) \times 100 = 0.23$$

0.23% w/w of the Candidate List substance per frying pan body;

• grill pan body:

$$Conc_{SVHC \text{ in grill pan body}} [\%] = (0.0030 / 1) \times 100 = 0.30$$

0.3% w/w of the Candidate List substance per grill pan body;

• sauce pan body:

$$Conc_{SVHC \text{ in grill pan body}} [\%] = (0.0018 / 1.5) \times 100 = 0.12$$

0.12% w/w of the Candidate List substance per sauce pan body.

The concentration of the Candidate List substance is greater than 0.1% w/w in all different pan bodies imported.

2. Calculation of the amount in tonnes of that Candidate List substance in each pan body type imported per year where it is present above the 0.1% w/w concentration threshold using equation (3) in the introductory text above.

• frying pan body:

$$m_{SVHC \text{ in frying pan bodies}} [t / a] = (Conc_{SVHC \text{ in frying pan body}} [\%]) \times \left(\frac{m_{frying \text{ pan body}} [kg / frying \text{ pan body}]}{1000} \right) \times (n_{frying \text{ pan bodies}} [frying \text{ pan bodies} / a])$$

$$m_{SVHC \text{ in frying pan bodies}} [t / a] = (0.23 \%) \times \left(\frac{1}{1000} \right) \times (300000) \approx 0.7^{47}$$

The total amount of the Candidate List substance in all frying pan bodies imported is 0.69 t/a;

⁴⁷ In this equation 0.23% must be understood as 0.23/100=0.0023. The same applies below when applying equation (3) in the introductory text.

- grill pan body:

$$m_{SVHC \text{ in grill pan bodies}} [t/a] = (0.30\%) \times \left(\frac{1}{1000} \right) \times (150000) \approx 0.5$$

The total amount of the Candidate List substance in all grill pan bodies imported is 0.45 t/a;

- sauce pan body:

$$m_{SVHC \text{ in sauce pan bodies}} [t/a] = \left(\frac{0.12}{100} \right) \times \left(\frac{1.5}{1000} \right) \times (450000) \approx 0.8$$

The total amount of the Candidate List substance in all sauce pan bodies imported is 0.81 t/a.

3. Summing up the amounts calculated for each pan body type using equation (4) in the introductory text above.

$$m_{SVHC \text{ in all pan bodies}} [t/a] = m_{SVHC \text{ in frying pan bodies}} [t/a] + m_{SVHC \text{ in grill pan bodies}} [t/a] + m_{SVHC \text{ in sauce pan bodies}} [t/a]$$

$$m_{SVHC \text{ in all pan bodies}} [t/a] = 0.7 t/a + 0.5 t/a + 0.8 t/a = 2 t/a$$

Summing up the values obtained for each pan body type calculated in the previous step, the total amount of the Candidate List substance in all pan bodies imported per year, which contain more than 0.1% (w/w) of that substance, is 2 t/a, which is above the 1 t/a threshold.

Conclusion: Since the total amount of the Candidate List substance imported in all pan bodies is 2 t/a, i.e. over the one tonne per year threshold, then the company has to submit a notification to ECHA for the Candidate List substance in the non-stick frying, grill and sauce pan bodies. (For possible exemptions please see subchapter 3.3). Furthermore, the company has to communicate down the supply chain, the presence of the Candidate List substance for each type of pan body included in each type of pan, as well as any information to allow its safe use (see subchapter 3.2.1).

Comments on the example:

1. The same duties apply to a company which produces in the European Union the non-stick frying, grill and sauce pan bodies.

2. If the EU producer of the assembled pans is not the same as the producer of the pan bodies, he can rely on the fact that the suppliers of pan bodies have a (legal) obligation to provide him with information, according to Article 33(1) of REACH Regulation, on the presence of the Candidate List substance in the pan bodies, including on how to use them safely during assembling of the pans by workers. The producer of the assembled pans is not required to notify ECHA of the presence of this Candidate List substance in the pans bodies, given that the producers or importers of the pan bodies have already done so. However, if confirmation of a notification previously submitted cannot be obtained from his EU suppliers, the producer of the assembled pans may prepare and submit a notification to ECHA for that substance in the pans bodies.

3. Any actor in the supply chain receiving the information mentioned above from the producer or importer and supplying the non-stick pan bodies or the assembled pans, should pass on that information to the next actor in the supply chain or to consumers

upon request. This means that any downstream supplier must pass on down the supply chain the information that has been provided to him.

Example 2: Calculation of the total amount of a Candidate List substance in articles assembled or joined together in a finished product - Multi-socket power strip

A company based in the European Union imports 300 000 multi-socket power strips per year. Each multi-socket power strip weights 0.5 kg and is produced by assembling or joining together many articles. Its main features are the 3 socket outlets in the upper part of the casing, a power switch and a 2 meter long extension cord with a plug at the other extremity of the cord.



The importer receives from the non-EU supplier information for all articles assembled or joined together in the a multi-socket power strip containing Candidate List substances above the 0.1% w/w concentration threshold. The information provided by the non-EU supplier is summarised in the table below:

Product / article name		material	article weight /kg	Candidate List substance	Concentration of the Candidate List substance % w/w
Housing	Upper casing with 3 sockets	ABS plastic	0.065	Candidate List substance 1	1
	Lower casing	ABS plastic	0.050	Candidate List substance 1	1
	Insulators in insulated wires in the casing ⁴⁸	PVC plastic	0.0010	Candidate List substance 2	40
	Actuator casing in the illuminated power switch	Polycarbonate plastic	0.010	Candidate List substance 1	3

⁴⁸ Assuming the insulated wires were produced as described in example 2 in Appendix 3.

Plug	Plug body/casing	phenolic plastic	0.037	Candidate List substance 1	3
				Candidate List substance 2	2
Power cable (extension cord)	Insulators in insulated electric wires ⁴⁸	PVC plastic	0.0050	Candidate List substance 2	40
	Cable sleeve	PVC plastic	0.055	Candidate List substance 2	20

The importer, after receiving the information contained in the table above, knows which articles incorporated in the multi-socket power strips contain the Candidate List substances 1 and 2 above the 0.1% w/w concentration threshold. Then, he can skip the step 1 explained above in the introductory text.

Following the step 2 explained in the text, the importer needs to calculate the amount of the Candidate List substances 1 or 2 in tonnes per year in the different articles contained in the 300 000 multi-socket power strips imported annually, which contain those substances above the 0.1% w/w concentration threshold, using equation (3) in the introductory text above. Please note that (since each power strip contains just one housing, one plug and one power cable) the number of each type of article is equal to the number of power strips imported (i.e. 300 000). The results are shown in the table below under the column "Total volume of Candidate List substance in articles".

Candidate List substance	Article name		Concentration of the Candidate List substance / % w/w	Article weight /kg	Total volume of Candidate List substance in articles / t/a	
Candidate List substance 1	Housing	Upper casing with 3 sockets	1	0.065	0.20	
		Lower casing	1	0.050	0.15	
		Actuator casing in the illuminated power switch	3	0.010	0.09	
	Plug	Plug body/casing	3	0.037	0.33	
Total					0.8	
Candidate List substance 2	Housing	Insulators in insulated wires in the casing	40	0.0010	0.12	
	Plug	Plug body/casing	2	0.037	0.22	
	Power cable (extension cord)	Insulators in insulated electric wires	40	0.0050	0.60	
		Cable sleeve	20	0.055	3.3	
		Total	4.2			

The importer needs now to determine the total amount of the Candidate List substances 1 or 2 in all articles, assembled or joined together in the power strips, which contain more than 0.1% w/w of those substances. This is done by following the step 3 described above in the text using equation (4) in the introductory text above, i.e. summing up the values obtained for each article type shown in the table above for each Candidate List substance. The results obtained are the following:

$$m_{SVHC_1 \text{ in all articles}} [t/a] = 0.20t/a + 0.15t/a + 0.09t/a + 0.33t/a = 0.8t/a$$

$$m_{SVHC_2 \text{ in all articles}} [t/a] = 0.12t/a + 0.22t/a + 0.60t/a + 3.3t/a = 4.2t/a$$

Conclusion:

The total amount of the Candidate List substance 1 in all articles, which contain more than 0.1% w/w of that substance, incorporated in the imported power strips is 0.8 t/a, i.e. below the one tonne per year threshold. Hence, the importer does not have to submit a notification to ECHA for this substance. The Candidate List substance 2 is contained in a total quantity of 4.2 t/a in all articles assembled or joined together in the imported multi-socket power strips, which contain more than 0.1% w/w of this substance. This quantity is over the one tonne per year threshold. Hence, the importer has to submit a notification to ECHA for that substance in each of those articles. This may not be necessary when exemptions apply as explained in subchapter 3.3.

The importer has also to communicate down the supply chain or to consumers upon request, the presence of the Candidate List substance 1 and 2 for each type of article incorporated into the imported multi-socket power strips, with sufficient specificity to allow safe use of the multi-socket power strips, as well as any other information to allow its safe use including disposal (see subchapter 3.2.1).

Comments on the example:

1. In the notification to be submitted to ECHA for the Candidate List substance 2, the insulators in the insulated electric wires in the casing or in the power cable can be grouped together because they are same articles as explained in the introductory text above, even if having different diameters/thicknesses, code colours, being bundled in cables together with the copper core, or integrated in different products/articles in the multi-socket power strip.

2. A company which produces or assembles multi-socket power strips (within the EU), using the same articles listed in the tables above, receives information from his supplier according to Article 33(1) of REACH Regulation, on the presence of the Candidate List substances 1 and/or 2, as well as on how to use them safely when assembling or joining them into the power strips by workers. The producer of the multi-socket power strips is in principle a recipient of articles used as components and he may not receive the exact concentrations of the Candidate List substances in those articles and therefore he may not be able to calculate the total tonnage of the Candidate List substances in the articles that he joins or assembles together in the multi-socket power strips. In principle, this information is not necessary because the producer of the multi-socket power strips is not required to notify ECHA of the presence of the Candidate List substance 2 in any of the articles listed in the tables above, given that the producers or importers of those articles have already done so. However, the producer may need to do so if he produces himself any of those articles containing the Candidate List substance 2 in a quantity higher than 1 t/a (e.g. the cable sleeve). Additionally, if a confirmation of a notification previously submitted cannot be obtained from its EU suppliers for the Candidate List substance 2 in

1 some or all articles, the producer of the assembled multi-socket power strip may also
2 prepare and submit a notification to ECHA for that substance.

3 The communication obligations down the supply chain also apply to the EU producer of
4 the multi-socket power strips, in the same terms described above for the importer.

5
6 3. Any downstream supplier of the multi-socket power strips must pass on down the
7 supply chain or to consumers upon request, the information that has been provided to
8 him by the importer or the producer.
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Appendix 5. Practical hints on how to apply the requirements for Candidate List substances

This subchapter intends to provide practical approaches and hints to address issues that may arise when applying the REACH requirements to cases where many articles are joined or assembled together. The assessment of the Candidate List substances in articles requirements must always be done case-by-case .

Determination of the presence and concentration of Candidate List substances in all articles joined or assembled together in a final product can be demanding where the number of articles is high, in particular for importers. It is also noted that the identification and differentiation of all articles may be challenging in these cases.

It is the responsibility of the article producers and importers, as well as of other suppliers of articles, to use the best approach adapted to each individual case when applying the requirements under the REACH regulation for Candidate List substances in articles for articles joined or assembled together. It is recommended always to document the approaches applied and basic considerations so that each duty holder is able to justify his conclusions towards customers and national enforcing authorities.

Approach to identify which articles may contain certain Candidate List substances

The idea behind this approach is to link the possible presence of certain Candidate List substances in articles through the materials used to produce those articles. This approach can be used to focus the work of suppliers of articles, in particular EU importers and producers of articles. There are some public sources (see Appendix 7) that give information on which substances might be contained in a specific material. These information sources can help the actors to identify which Candidate List substances are more likely to be present in an article containing these materials.

The following steps may be followed in this approach:

Step 1. Find the SVHCs included in the Candidate List or that may be added to that list.

For this step, please refer to subchapter 3.1 of this guidance.

Step 2. Find the composition of the articles and the materials used in the production of those articles.

This basic information should be requested from the supplier(s) of the article(s). The identification of the materials the articles concerned are made from may be done at different levels of granularity depending on the information gathered from the article suppliers or by other means. The materials identified may be divided into material groups (e.g. plastics, metals, textiles, etc.) and sub-groups (e.g. for plastic materials: polyolefines, epoxy resins, thermoplastics, etc.; for textiles: synthetic fibres, natural fibres, etc.).

Step 3. Checking which Candidate List substances are likely to be used in the materials the articles concerned are made of.

After identifying the materials the articles concerned contain in the previous step, in this step it is assessed which articles are likely to contain Candidate List substances – based on the materials used – and then which substances they may contain. In this assessment, (EU or non-EU) suppliers of articles look for indications from available information, including information on ECHA's dissemination portal, that certain substances are not

contained in a material (e.g. due to the physical state of the substance) or which are likely to be contained in the material due to an intended use or as impurities resulting from the production process.

Information useful to perform the assessment could include:

- technical function(s) of a substance that is needed to achieve a specific material quality or functionality;
- specific substances which have been reported to be present in (e.g. identified in analytical measurements) or absent from a material (e.g. based on sector knowledge or physical chemical properties of the material and the Candidate List substance);
- materials and substances' main uses (e.g. using use descriptors sector of use category (SU), chemical product categories (PC) and/or article category (AC) or more specific information available);
- typical concentration ranges of a substance in a material;
- regulatory status of a substance (i.e. restricted in REACH Annex XVII or under authorisation or regulated in specific product legislation, such as the Toys Directive).

Knowledge of which materials are used in a particular article category can be combined with knowledge of which Candidate List substances might be used in such materials. For example, knowing that an article is mainly produced using specific plastics and also knowing that a special kind of plasticiser is used in such plastics helps answering the question whether this plasticiser is probably present in the article.

This approach allows suppliers of articles (EU or non-EU), in particular EU article importers and producers:

- to reduce the number of Candidate List substances which could be included in materials which are used in their articles, as well as on the likelihood of their presence or absence;
- to obtain information on possible concentration ranges of Candidate List substances in such materials, which could enable estimating the potentially contained amounts;
- to focus or target supply chain communication and/or chemical analyses.

Difficulties when applying this approach are related with the identification of Candidate List substances present as impurities either from the production or manufacturing processes or by contamination or the use of substances in imported articles not used anymore in the EU in the manufacture or production of materials or articles.

Example 1: Approach to identify which articles may contain certain Candidate List substances - outdoor jacket

A company based in the European Union imports outdoor jackets, which are water and stain repellent, breathable and lightweight. The importer of the outdoor jackets has got a general description of the jackets including information on the articles and materials of a typical jacket from his non-EU supplier:

Article name	Material	Article weight /kg
Top layer	100% polyester	0.2

Inner layer	100% polyester	0.05
Insert	91% polyester, 9% elasthane	0.1
Membrane	Polytetraflouroethylene (PTFE)	0.025
3 Zippers (considering only the plastic articles, not the metal article)	Polyamide	0.015
4 Hook-and-loop fasteners	Polyamide	0.005
8 Buttons	Metallic	0.02
1 Cord	Polyester	0.005

The importer wants to know if Candidate List substances may be potentially contained in the jacket in order to identify communication obligations according to Art. 33 of REACH and potential obligation to notify Candidate List substances in the articles contained in the outdoor jacket according to Art. 7.

The article importer follows the steps described in the text above in order to identify only possible Candidate List substances in the different articles assembled or joined in an outdoor jacket to request further targeted information to his non-EU supplier.

In the step 3, the importer focuses his searches of information on Candidate List substances - typically contained in or used in the production of clothing/outdoor jackets, in particular uses relevant for outdoor jackets (e.g. AC5, SU5 and PC34⁴⁹) and

- typically contained in or used in the manufacture or processing of the different materials identified in the table above, in particular with relevant technical functions regarding the required materials properties (e.g. for polyester he looks at technical functions such as softener, stabiliser, finishing agent, antistatic agent, antistain agent, waterproofing agent, pigment/dye).

The importer also searches for information on Candidate List substances that are unlikely to be present in the identified materials.

By combining all the information gathered, the importer was able to generate lists with a reduced number of Candidate List substances potentially present in the different materials used in the articles contained in the outdoor jacket (e.g. approximately 20 Candidate List substances expected to be present in the articles made of polyester fibres).

The importer of the outdoor jackets is now in position to further request target information from his non-EU supplier.

⁴⁹ See the use descriptor system explained in [chapter R.12 of the Guidance on information requirements and chemical safety assessment](#).

When using this approach, the number of Candidate List substances potentially identified as being contained in concerned articles is significantly reduced. Thus, companies could as a consequence save time and resources in communication with suppliers and customers, increase their level of compliance and also reduce costs for complementary periodic chemical analyses to check the actual content of candidate List substances in their articles, as well as consulting costs.

However, this approach must be used with caution. The result of this approach only gives indications about the likelihood that a certain material and therefore an article contains certain Candidate List substances. The results must be combined with further information received from the suppliers or in the last resort confirmed by performing chemical analysis. The EU supplier of articles is still responsible for the articles he places on the market and its compliance with the requirements for substances in articles under the REACH Regulation.

Identification and differentiation of all articles joined or assembled together in another product

Identification and differentiation of all articles joined or assembled together in final products, such as an aircraft, a car or an electronic equipment may be a challenging task, in particular for importers. The example below shows how to perform this task for a printed circuit board.

Example 2: Articles joined or assembled together in another article - printed circuit board

Note: This example addresses only the main issues to be considered, it does not intend to be exhaustive.

Electronics, such as printed circuit boards, are usually made of a large number of articles joined or assembled together to which the Candidate List substances in articles requirements of REACH would apply. Some of the articles used as components are joined together (e.g. glued, soldered etc.) by using substances and/or mixtures.

A printed circuit board consists of a plain layered board with printed wires, electronic articles (e.g. capacitors, resistors, transistors, inductors, diodes, microprocessors, microchips), other articles (e.g. fans, screws), operational facilities which often are fastened with solders or glue. Both the printed circuit board and the added articles and substances/mixtures consist of a series of different materials. e.g. rigid and soft plastics, metals, ceramics, glass etc.



Identification and differentiation of articles incorporated in the printed circuit board

A printed circuit board is made by assembling or joining many articles. The applicability of the substances in articles requirements under REACH must be assessed for all of these articles. The large number of articles and the fact that many of them are soldered and/or glued to the printed circuit board, may, however, make it a challenge to determine which of them already existed as articles before production of the printed circuit board.

When identifying the articles incorporated into a printed circuit board, all objects that can be disassembled from it, without being "destroyed" or be identified as objects that could be physically separated, must be identified.

If such an identification cannot be done based on the information available, an EU producer or importer needs to trace back in the supply chain until the point at which one or more substances or mixtures were converted to an article.

Regarding the use of Candidate List substances or mixtures containing Candidate List substances that are incorporated in the printed circuit board or any other article integrated into it, the approaches described in the examples in Appendix 3 can be applied to determine the concentration of Candidate List substances present in the particular concerned article.

The approach to identify which articles in the printed circuit board may contain certain Candidate List substances could be used to facilitate the request of information from the suppliers of the printed circuit board or other articles incorporated into it. This can be particular useful for importers of articles.

Supply chain communication

Due to the large number of articles incorporated in a printed circuit board, in order to illustrate how the supply chain communication is best carried out, only one article incorporated in the printed circuit board is used: a hole mounted capacitor. What is described for the capacitors below is applicable to any article incorporated in the printed circuit board, since several of those articles may potentially contain Candidate List substances.

The hole mounted capacitors are soldered or glued onto printed circuit boards by the producer of the printed circuit boards.

The capacitor is constructed as follows: The conductors (articles), the dielectric (article) and the wires (articles) are assembled and covered by a plastic casing (article) made directly from a polymer mixture with additives containing a Candidate List substance using a mould. The concentration of the Candidate List substance must thus be determined in relation to the plastic casing only (e.g. see examples 2 and 5 in Appendix 3). The concentration of the Candidate List substance in the casing is above the 0.1% w/w concentration threshold.

Substance in articles notification

The **producer or the importer of the capacitors** is required to submit a substance in articles notification to ECHA for that Candidate List substance if this substance is contained in the casings for the capacitors produced or imported in a quantity higher than 1 t/a. This may not be necessary when exemptions apply as explained in subchapter 3.3. The **EU producer of the printed circuit board** does not have to submit a notification to ECHA for the Candidate List substance present in the case of the capacitors above the 0.1% w/w concentration threshold.

1 The **importer of the printed circuit board** containing the capacitors is required to submit
2 a substance in articles notification to ECHA for that Candidate List substance if this
3 substance is contained in the capacitor casings in a quantity higher than 1 t/a in the
4 imported printed circuit boards. This may not be necessary when exemptions apply as
5 explained in subchapter 3.3. If the same Candidate List substance is contained in
6 different articles incorporated into an **imported circuit board** in a total quantity higher
7 than 1 t/a, the importer has to submit a substance in articles notification to ECHA for that
8 Candidate List substance describing each of the different articles and their use.

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Appendix 6. Illustrative cases for checking if requirements under Article 7 and article 33 apply

1) Scented children's toys

Scented children's toys are articles contain fragrance substances - 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 containing the fragrance mixture: 20 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 lemon scented toys, the importer does the following analyses:

- 1 Analysis for fragrance substance.
- 2 The toy with lemon scent is examined in an emission test to analyse the release.
- 3 Screening for extractable organic compounds by GC/MS⁵⁰.

A total of 11 sensitising fragrance substances are found in the analysis on fragrances; substance names and EC 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 EC and CAS numbers are searched in the [dissemination portal](#) on ECHA's website and other public databases for toxicological data. Classification is searched for on ECHA's [C&L Inventory](#)⁵¹. The example is focused on the fragrance substance D-limonene.

Information on concentration of the substance (D-limonene)

The concentration of D-limonene was determined in the toys. The classification was obtained from ECHA's [C&L Inventory](#).

⁵⁰ GC/MS - Gas chromatography/mass spectrometry

⁵¹ Or in table of harmonised entries in Annex VI to CLP available at <http://echa.europa.eu/information-on-chemicals/annex-vi-to-clp>

Table 14: Information on D-limonene in the toys

Substance identifiers	Harmonised Classification	Concentration in the toy (mg/kg)
<i>Name: D-limonene</i> <i>EC no. 227-813-5</i> <i>CAS no. 5989-27-5</i> <i>Index no. 601-029-00-7</i>	<i>Flam. Liq. 3; H226</i> <i>Skin Irrit. 2; H315</i> <i>Skin Sens. 1; H317</i> <i>Aquatic Acute 1; H400</i> <i>Aquatic Chronic 1; H410</i>	800

Information on amount of D-limonene used

The quantity of D-limonene in the scented toys can be calculated as the amount in each toy (800 mg/kg × 0.02 kg/toy = 16 mg/toy) multiplied by the number of toys imported annually (1,000,000 toys/a). The annual amount of D-limonene in the toys imported is 16 kg/a, which is below 1 t/a.

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

$$Number_{\max \text{ articles}} = \frac{1 \text{ t/a}}{Conc_{\text{subs. (w/ article)}}} = \frac{1 \text{ t/a}}{16 \text{ mg/toy}} = \frac{1 \text{ t/a}}{16 \cdot 10^{-9} \text{ t/toy}} = 62.5 \cdot 10^6 \text{ toys/a}$$

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

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

The importer can import 62.5 million toys before reaching the threshold of 1 t/a for D-limonene and trigger registration obligations.

Illustration of the decision process

Example: Toy with lemon scent (D-limonene)

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

YES.

Is your object an article? (consult chapter 2)

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

Is there an intended release of substances from the article? (consult chapter 4)

Fragrance substances are released during the use of the article. The release is an additional quality of the toy, otherwise the toy would not smell. Therefore their release is intended (under normal or reasonably foreseeable conditions of use).

Does the article contain a SVHC included in the Candidate List?

(consult chapters 4 and 5)

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

do the following:

- 1) Collect information on sector knowledge and typical content of substances in this type of article, standards like the toys directive etc. He would compare that information with the Candidate List for authorisation and may have doubts whether he can exclude the presence of SVHC. He does not find information on the fragrance mixtures intended to be released.
- 2) Check the supply chain requesting if any of the substances on the Candidate List is included in the article or the substances/mixtures used to produce the article or receive confirmation that SVHC are not present in the article. Check the supply chain and ask if the supplier of the fragrance substances can be identified. If yes, the importer of toys may try to obtain a safety data sheet.
- 3) Plan and perform screening for substances on the Candidate List by analytical methods if no information is obtained from the suppliers and content of SVHC is likely (see results above).
- 4) Check if identified substances are listed on the Candidate List (or in the PACT or RoI lists).
- 5) Calculate the amount of substances identified in the screening analysis and assess whether the tonnage threshold for registration could be exceeded.

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

YES. The total amount of fragrance mixture (containing 11 fragrance substances) is approx. 2 t/a.

Identify each substance intended to be released from the article.

A total of 11 fragrance substances were identified to be contained in the toy. During the emission test various compounds were detected and identified and information on their classification was obtained.

The output from the analysis was the names of the substances only. The [dissemination portal](#) and the [C&L inventory](#) on ECHA's website are consulted in order to obtain a CAS number and classification.

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

Substances exempted from registration?

NO. D-limonene is not exempted from registration.

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

Based on the chemical analysis, the content of D-limonene intended to be released is determined to be 800 mg/kg in the toy. The content of D-limonene in the toy is 16 mg as the weight of the inner part is 20 g.

Total amount > 1 t/a?

It is assumed that this toy is the only article containing D-limonene and imported by the company. The annual amount of D-limonene is calculated to be 16 kg/a, which is below 1 t/a.

Check for existing registration for that use.

The substance D-limonene has been already registered. The importer can check whether

the substance has been registered for that use by following the explanations given in subchapters 4.3.3 and 3.3.1.

→ **Conclusion on registration:** Registration of D-limonene in the imported toys is not required.

Comments on the case

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

There are more substances present in the toy, besides the fragrance substances. Therefore an emission test was also done. In the emission test a range of volatile substances released into the air was identified. Here, only the release was analysed and not the content. The emission test did not include the fragrance substances (fragrance mixture).

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

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

2) Articles for clothing and jewellery

The example represents a case from a important market sectors in the EU.

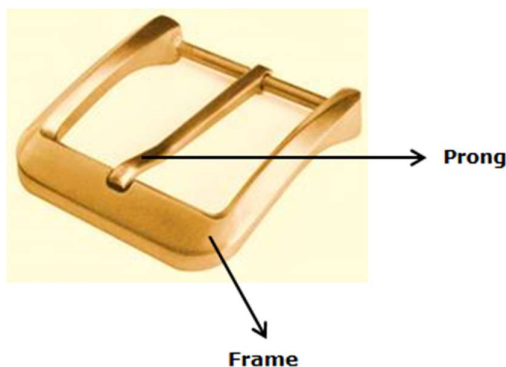
The reasons for selecting metallic articles in clothing and jewellery are based on the following criteria:

- Users and application: A large group of users and a wide application; the users include vulnerable groups such as children and pregnant women.
- Type of material: Metals represent a material used in many other articles than clothing and jewellery, which could make the case applicable for other producers/importers of articles.
- Exposure scenarios: An example of possible direct exposure to skin and migration of substances.
- Supply chain pattern: Represents a supply chain with high proportion of imported articles within the EEA. The supply chains may be global and complex.

This example also shows how importers of articles and other suppliers of articles may exclude or limit the presence of Candidate List substances in their articles. In this case, the importer sets upper limits for the content of those substances in the imported articles. Such an approach can be useful in cases where there are some uncertainties regarding the concentration of Candidate List substances and on the application of the REACH substances in articles requirements.

Produced/imported articles

- Jewellery rings made of metallic material moulded in single objects.
- Belt buckles made of a frame and a prong (see figure below). The frame and the prong are moulded separately in single metallic objects. The frame and the prong are assembled to produce the belt buckle.



Producer/Importer of articles

The company imports belt buckles and jewellery rings from a non-EEA country.

Substance identity

The company must consult the Candidate List for authorisation.

The metal frame and prong that are assembled in the belt buckle undergo a surface treatment during assembly where a Candidate List substance is incorporated in those parts by using a coloured and anticorrosion coating. The full composition of the metal alloy is not known to the importing company. The Candidate List substance provides the colouring and contributes to the anticorrosion properties of the outermost surface of the frame and the prong. It cannot also be excluded that the Candidate List substance is also present in the metal alloy matrix of these articles.

In order to check whether it has obligations according to the Articles 7(2) and 33, the importer can ask its non-EU suppliers directly about the content of the specific substances on the Candidate List.

It should be stressed that the placing on the market and/or use of certain substances are restricted under Annex XVII of REACH. This is the case for certain metals in certain types of articles. Therefore, article importers (and also producers) must comply with the conditions outlined in Annex XVII of the REACH Regulation which may establish limits on the presence of certain substances in articles as explained in subchapter 1.3 of the guidance. For instance, in the particular case of the jewellery rings, the conditions are set out in entries 23 on cadmium and its compounds, 27 on nickel and its compounds and 63 on lead and its compounds. The importing company has to ensure that the limits and conditions are complied with. This issue is not further covered in this example.

The importers and producers of articles may also establish voluntary limits and conditions to their suppliers regarding Candidate List substances. They may also pro-actively initiate contacts with their suppliers regarding the use of substances that may be included in the Candidate List in the future. For that, regular consultation of the PACT is recommended for advance notice of the substances that are on an authority's "radar" for exploring the potential need for regulatory risk management, as explained in section 3.1. of this guidance.

Information on concentration of the substance

The ways to obtain information suggested in chapter 5 of this guidance could be applied.

In this case, the company has an upper limit for the content of Candidate List substance in the frames and prongs of the belt buckles at 0.3% w/w and in jewellery rings at 0.01% w/w. The use of these maximum concentrations in the assessment will give a worst case scenario. Such limits can be established for example by procurement and contract specifications.

In a first phase, the composition of the metal alloy and coating used in the frames and prongs of the buckles was not made known in this case. However, it should be noted that the chemical compositions of certain coatings and metal alloys could be searched for in relevant publicly available sources (e.g. databases, reports, studies, etc.) . The importer may then ask its non-EU suppliers for specific information on the potential Candidate List substances present in these metal articles, as well as the production and coating process used to produce them.

If the information is not provided by the non-EU supplier, as a last resort the chemical composition of the coating (if it can be separated) and/or of the entire frame and prong that are assembled into the buckles may be obtained by routine chemical analysis (see subchapter 5.2).

Information on amount of substance used

The total yearly amount of the Candidate List substance in the articles of the company was estimated on the basis of the number of belt buckles imported the previous year, which will be equal to the number of frames and prongs imported. The calculations were based on the total number of belt buckles imported and the maximum concentration of Candidate List substances contained in each article incorporated in a buckle at 0.3% w/w.

Check for existing registration for a use

To be done according to subchapter 3.4.1 of this guidance to verify if possible exemptions may be applicable.

Illustration of the decision process using the flow chart in subchapter 1.2. of the guidance

Example: Metallic belt buckles and jewellery rings

1. Role in the supply chain.

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

YES.

2. Is your object an article under REACH?

Is your object an article? (consult chapter 2)

YES. The frames and prongs of belt buckles and jewellery rings are articles.

3. Registration obligation under Article 7(1) of REACH

Is there an intended release of substances from the article? (consult chapter 4)

NO.

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

4. Communication obligations under Article 33 of REACH

Does the article contain an SVHC included in the Candidate List?

(Consult chapters 3 and 5)

YES for the frames and prongs in the buckles. In this example it is assumed that after acting as recommended in the introduction to the case, the importer now knows that a specific Candidate List substance is contained in the frame and prong of the belt buckles.

NO for the jewellery rings (see below).

Determine the concentration of the Candidate List substance

The company limit for Candidate List substances in jewellery rings is 0.01% w/w, which is below the threshold limit at 0.1% w/w. From the routines implemented by the company as described in chapter 5, including aleatory chemical analysis, as well as based on their experience, the company ensures that these articles do not contain Candidate List substances above the upper limit set at 0.01% w/w.

For the metal frames and prongs of belt buckles, the company sets a limit of 0.3% w/w for the concentration of the Candidate List substance. Thus, the maximum concentration of the Candidate List substance in these articles exceeds the threshold limit of 0.1% w/w. It is not possible for the company to analyse large samples of frames and prongs assembled in the buckles and they assume that the concentration in all frames and prongs is 0.3% w/w. The company imports approx. 5,000,000 buckles per year (in total approx. 650 different orders/styles). In general, each type of article - frames and prongs of different shapes/styles - can be grouped as identical articles.

Based on experience from the implemented quality management system and aleatory tests, it is known that most of the articles assembled in the buckles contain much less than 0.1% w/w of the Candidate List substance, however, this fact is not documented by chemical analysis or certificates from the non-EU supplier. The company ensures that the concentration of the Candidate List substance in the frames and prongs is not higher than 0.3% w/w, but the company does not know exactly what is the concentration of the Candidate List substance in these articles. The importer needs to clearly communicate to their customers that the frames and prongs in the belt buckles contain a Candidate List substance above the 0.1% w/w concentration threshold.

Concentration above 0.1% (w/w)?

YES for the frames and prongs in the buckles. The concentration of the Candidate List substance in each article (frame and prong) exceeds the threshold concentration limit of 0.1% w/w.

NO for the jewellery rings.

→ **Conclusion on communication down the supply chain:** communicate information according to Article 33, as explained in subchapter 3.5.1 of the guidance, for the frames and prongs in the belt buckles. There is no communication obligations under Article 33 of REACH for the jewellery rings.

5. Notification of Candidate List substances in articles under Article 7(2) of

REACH

Calculate the total amount in tonnes of that Candidate List substance in all article types imported per year where it is present above the 0.1% w/w concentration threshold

The total amount of the Candidate List substance, in tonnes per year (t/a), in all frames and prongs of the belt buckles imported is calculated using equation (3) given in subchapter 3.3.2. of the guidance.

- The import of buckles in the previous year: 5,000,000 items (which is equal to the number of frames and prongs in the buckles - n_{frames} ; n_{prongs});
- The weight of one buckle is 0.1 kg divided as follows. The weight of the frame (m_{frames}): 0.085kg; the weight of the prong (m_{prongs}): 0.015 kg;
- The maximum Candidate List substance concentration in each article assembled in the buckle ($Conc_{frame}$; $Conc_{prong}$): 0.3% w/w.

Calculation of the total amount of the Candidate List substance in each article type assembled in the imported buckles per year where it is present above the 0.1% w/w concentration threshold:

- frames

$$m_{SVHC \text{ in frames}} [t/a] = (Conc_{SVHC \text{ in frames}} [\%]) \times \left(\frac{m_{frame} [kg/frame]}{1000} \right) \times (n_{frames} [frames/a])$$

$$m_{SVHC \text{ in frames}} [t/a] = (0.3\%) \times \left(\frac{0.085}{1000} \right) \times (5,000,000) = 1.3$$

- prongs

$$m_{SVHC \text{ in prongs}} [t/a] = (0.3\%) \times \left(\frac{0.015}{1000} \right) \times (5,000,000) = 0.23$$

The total amount, in tonnes per year, of the Candidate List substance in all frames and prongs in the imported buckles ($m_{SVHC \text{ in buckles}}$), containing more than 0.1% w/w of the substance, is obtained by summing up the amounts, in tonnes per year, calculated for each relevant article type ($m_{SVHC \text{ in frames}}$; $m_{SVHC \text{ in prongs}}$) using equation (4) given in subchapter 3.3.2. of the guidance.

$$m_{SVHC \text{ in buckles}} [t/a] = m_{SVHC \text{ in frames}} [t/a] + m_{SVHC \text{ in prongs}} [t/a] = 1.3 + 0.23 = 1.5$$

Is the total amount of the Candidate List substance > 1 t/a?

YES. The total amount of the Candidate List substance brought into the EU is 1.5 t/a. This amount exceeds the threshold limit of 1 t/a.

→ **Conclusion on substances in articles notification under Article 7(2) of REACH:**
notification of the Candidate List substance present in the frames and prongs of the

imported buckles is required, unless notification exemptions apply as explained in subchapter 3.4.

6. Check if exemptions to the notification of substances in articles apply
(consult subchapter 3.4)

Has the substance already been registered for that use?

NO. It is assumed that the Candidate List substance is not registered for that use.

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

The function of the substance in the articles:

A Candidate List substance provides colour and anticorrosion properties to the outmost layer of the metal material the frames and prongs are made of. It can also migrate to the outermost layer if present in the alloy matrix.

The use(s) of the article:

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

Reasonably foreseeable use(s): During the production of belts, the dermal exposure of workers is possible. In addition if welding or soldering is used when gases may be The end use of the belts is to be worn by consumers, with a possible direct dermal contact. Children may suck on the buckle in the end use situation.

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

The routes of exposure in the case of the Candidate List substance contained in the frames and prongs are dermal, inhalation and ingestion. Information on the assembly of belts may allow conclusion that inhalation is negligible in this case. However, dermal contact cannot be excluded during the production of belts and during the end use by consumers. Furthermore, there may be oral exposure of children.

Furthermore, it cannot be excluded that there will be a release of the Candidate List substance from the metal buckle after disposal, in particular because it is mostly located at the outermost layer.

Can exposure to humans or environment be excluded?

NO.

→ **Conclusion on exemptions from substance in articles notification:** the Candidate List substance present in the frames and prongs of the buckles cannot be exempted from the notification obligation. Notification is required as explained in subchapters 3.2.2 and 3.5.2 of the guidance.

7. Final conclusion

Conclusion: Communication of information down the supply chain and to consumers upon request according to Article 33 for the frames and prongs in the belt buckles is required. Additionally, notification of substance in articles is also required to be submitted to ECHA for this Candidate List substance present in the frames and prongs of the buckles.

Comments on the case

The case illustrates the possibility of using the maximum concentration or company upper limit of a specific Candidate List substance in articles as a worst case scenario for assessing whether an importer has an obligation under Articles 7(2) and 33. The use of the maximum concentration leads to the conclusion that both notification and communication of information is required for the frames and prongs in the belt buckles. A next step could include a more precise determination of the Candidate List substance concentration in the different articles assembled into the buckle by chemical analysis, but it is recommended only to do so as a last resort (subchapter 5.2). The information to be delivered within the supply chain, according to Article 33 is explained in subchapter 3.5.1. of the guidance.

It is recommended that you keep in your documentation records any certificates from suppliers of the buckles with the relevant information provided to you for each article constituting the buckle. Furthermore, you should also keep records of the data on yearly imported volumes that support your assessment. The documentation procedures to be applied during the assessment of the obligation under REACH could be implemented, for example, as a part of an existing quality management system.

3) Inflatable air chamber of a sleeping mattress

The case of an inflatable sleeping mattress made of an inflatable air chamber (article) and an air valve (article) presented below illustrates the different steps in the notification process and could be used as guidance to understand the different steps in the flow chart shown in subchapter 1.2.

The main reasons for selecting a PVC inflatable air chamber containing a Candidate List substance of sleeping mattresses as an example are the following:

- Users and application: A large group of users; the users may include vulnerable groups such as children and pregnant women. The air chamber is the most important article that allows a person to rest and sleep over it, when inflated.
- Type of material: Represent a plastic material (PVC) used in many other articles, which could make the case applicable for a range of different article producers/importers.
- Exposure scenarios: An example of possible direct exposure to skin and migration of substances. Exposure through inhalation may occur, in particular during sleep.

- Supply chain pattern: Represents a supply chain with a high proportion of imported articles.

Produced/imported articles

The article considered in this example is an inflatable air chamber made of polyvinyl chloride (PVC). This article is joined to an air valve made of acrylonitrile butadiene styrene (ABS) - which rotates and locks or opens for inflation or deflation - to make an inflatable sleeping mattress.

The PVC inflatable air chamber contains a Candidate List substance used as plasticiser.



Producer/Importer of articles

The inflatable sleeping mattresses, incorporating PVC air chambers, are imported from a non-EU country and then distributed to retailers within the EU.

Substance identity

The physical and chemical properties of the Candidate List substance make it suitable to be used as plasticiser in the production of the PVC inflatable air chambers. This plasticiser is not permanently bound to the PVC polymer, and may be therefore released from the PVC inflatable air chambers throughout their lifetimes. The reasons for inclusion of a substance of very high concern (SVHC) in the Candidate List can be found in the [Candidate List of substances of very high concern for Authorisation](#) on ECHA's website.⁵² The classification of a substance may be found in [C&L Inventory](#) on ECHA's website.⁵³

⁵² Available at <http://echa.europa.eu/candidate-list-table>.

⁵³ Available at <http://echa.europa.eu/information-on-chemicals/cl-inventory-database>.

Information on concentration of the substance

The importer has requested targeted information from its non-EU supplier about the composition of the mattresses, in particular if Candidate List substances are contained above the 0.1% w/w concentration threshold in any article joined or assembled into the mattress or in the mattress if substances and mixtures containing those substances are incorporated directly in the mattress during production.

Information on amount of substance used

The total yearly amount of the Candidate List substance in the PVC inflatable air chambers was estimated on the basis of the number of mattresses imported the previous year by the company. The calculations were based on the total number of inflatable air chambers, which is equal to the number of imported sleeping mattresses, and the concentration of the Candidate List substance in the PVC inflatable air chamber of the mattresses communicated by the non-EU supplier (see calculations below).

Check for existing registration for a use

To be done according to subchapter 3.4.1 of this guidance to verify if possible exemptions may be applicable.

Illustration of the decision process using the flow chart in subchapter 1.2. of the guidance

Example: PVC inflatable air chamber of a sleeping mattress

1. Role in the supply chain.

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

YES. The company is an importer of sleeping mattresses with PVC inflatable air chambers.

2. Is your object an article under REACH?

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

YES. The inflatable air chamber of a sleeping mattress is an article.

3. Registration obligation under Article 7(1) of REACH

Is there an intended release of substances from the article? (*consult chapter 4*)

NO.

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

4. Communication obligations under Article 33 of REACH

Does the article contain an SVHC included in the Candidate List?

(*Consult chapters 3 and 5*)

YES. According to the information provided by the non-EU supplier (in response to the request mentioned above) the PVC inflatable air chambers of the mattresses contain a Candidate List substance used as plasticiser.

Determine the concentration of the Candidate List substance.

In its response, the non-EU supplier also stated that the concentration of the Candidate List substance in the PVC inflatable air chambers of the mattresses was 30% w/w and no other articles assembled or joined together with this article contain Candidate List substances above the 0.1% w/w threshold. The importer did not find any reason to question the information given by the supplier and did not perform any chemical analysis of the different articles assembled or joined together into a mattress.

Concentration above 0.1% (w/w)?

YES. The concentration of Candidate List substance in the PVC inflatable air chamber of the sleeping mattresses exceeds the threshold limit of 0.1% w/w.

As the PVC inflatable air chamber of the sleeping mattress contains more than 0.1% w/w of a candidate List substance and the mattresses are distributed to retailers within the EU, the importing company has to give information on the presence of this Candidate List substance and on how to allow safe use of the article, including disposal, down its supply chain.

→ **Conclusion on communication down the supply chain:** communicate information according to Article 33, as explained in subchapter 3.5.1 of the guidance.

5. Notification of Candidate List substances in articles under Article 7(2) of REACH

Calculate the total amount in tonnes of that Candidate List substance in all articles types imported per year where it is present above the 0.1% w/w concentration threshold

The total amount of the Candidate List substance, in tonnes per year (t/a), in all imported mattresses incorporating the PVC inflatable air chambers is calculated using equation 3 given in subchapter 3.3.2. of the guidance.

- The import of mattresses the previous year: 150 000 items (which is equal to the number of the PVC inflatable air chambers - $n_{air\ chambers}$).
- The weight of the PVC inflatable air chamber of a mattress ($m_{air\ chambers}$): 0.9 kg
- The maximum candidate List substance concentration in the PVC inflatable air chamber of a mattress ($Conc_{SVHC\ in\ air\ chambers}$): 30% w/w.

The total amount of the Candidate List substance is:

$$m_{SVHC\ in\ air\ chambers} [t/a] = (Conc_{SVHC\ in\ air\ chambers} [\%]) \times \left(\frac{m_{air\ chambers} [kg / air\ chamber]}{1000} \right) \times (n_{air\ chambers} [air\ chambers / a])$$

$$m_{SVHC\ in\ air\ chambers} [t/a] = (30\%) \times \left(\frac{0.9}{1000} \right) \times (150000) = 40.5$$

Is the total amount of the Candidate List substance > 1 t/a?

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

→ **Conclusion on substance in article notification under Article 7(2) of REACH:** notification of the Candidate List substance present in the PVC inflatable air chamber is required, unless notification exemptions apply as explained in subchapter 3.4.

6. Check if exemptions to the notification of substances in articles apply

(consult subchapter 3.4)

Has the substance already been registered for that use?

NO. It is assumed that the Candidate List substance is not registered for that use.

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

The technical function of the substance in the articles:

The Candidate List substance used as plasticiser is not permanently bound to the PVC polymer and is therefore released from the PVC inflatable air chambers throughout their lifetimes.

The use(s) of the article:

Normal use(s): Inflatable sleeping mattresses incorporating the PVC inflatable air chambers for adults. However, it is reasonably foreseeable that these mattresses also will be used by children.

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

Exposure through inhalation may occur since the article is used indoors, as well as through skin contact. Exposure during the waste phase depends on the waste management method but cannot be excluded.

Can exposure to humans or the environment be excluded?

NO

→ **Conclusion on exemptions from substance in articles notification:** the Candidate List substance present in the PVC inflatable air chamber cannot be exempted from the notification obligation. Notification is required as explained in subchapters 3.2.2 and 3.5.2 of the guidance.

7. Final conclusion

Conclusion: Communication of information down the supply chain and to consumers upon request according to Article 33 for PVC inflatable air chamber in the sleeping mattress is required. Additionally, notification of substance in articles is also required to be submitted to ECHA for this Candidate List substance present in the PVC inflatable air chamber of the sleeping mattress.

Comments on the case

The case shows what and how information from the (non-EU) suppliers of the article should be used in the assessment. The case also illustrates the information to be communicated to recipients of the article and how a notification of substances in articles must be submitted to ECHA, as well as the information to be contained in it.

It is recommended that you document the results obtained by applying this guidance, as illustrated by this example as well as the notification made to ECHA and the information communicated down the supply chain. The results obtained by applying this guidance as illustrated with this example are recommended to be documented as well as the proof of notification submission to ECHA and records of the communication of information down the supply chain or to consumers if requested by them. It is also recommended that you keep in your documentation records any certificates from suppliers of the inflatable sleeping mattress containing the PVC inflatable air chambers with the relevant information provided to you and the data concerning the yearly imported volumes of inflatable sleeping mattress containing the PVC inflatable air chambers that support your assessment. The documentation procedures to be applied during the assessment of the obligation under REACH could be implemented, for example, as a part of an existing quality management system.

4) Bicycle

A bicycle is an example that illustrates a case where an article is produced from a combination of a number of articles mechanically assembled and/or joined together by using substance(s)/mixture(s).

The bicycle is made by assembling or joining together several articles that may contain Candidate List substances. Some of them are also frequently sold as spare parts and can be replaced in the bicycle.



A company has decided to import 10,000 bicycles per year of the same type. The importer asked its non-EU supplier for general description and specifications of the bicycles and articles contained on each one of them. In order to comply with its obligations regarding the REACH provisions on substances in articles, the importer

decided to use the approach and hints described in Appendix 5 to this guidance.

The importer followed the steps included in the approach to identify which articles may contain certain Candidate List substances provided in that Appendix. In the step 2, the importer decided to make a list of all articles joined or assembled in the bicycle.

Based on the description and specifications provided by its non-EU supplier, the importer identified all objects incorporated in the bicycle:

- Frame: e.g. top tube, down tube, seat tube, seat stay, chain stay, head tube; These metal articles are joined together by soldering them to make the frame; The whole frame is then painted.
- Saddle area: e.g. saddle, seat post, seat rails, seat clamp, seat post clamp, bolts, nuts, o-rings.
- Front set: e.g. handlebar grips, shock absorber, front brakes, front brake cables, forks, brake hoods, brake levers, gear levers.
- Wheels: e.g. spokes, hub, rims, tyres, inner tubes with valves and caps.
- Others: e.g. pedals, crank arms, front derailleur, rear derailleur, derailleur pulley, chain, front sprocket-wheels, (rear) cogset, gear cables, rear brakes, rear brake cables, wheels' prism reflectors, rear reflector, lamp, lamp housing, bolts, nuts, o-rings etc.

For some of these objects, the importer can already identify them as (individual) articles (e.g. painted frame, saddle, seat post, rims, spokes, wheels' prism reflectors). For others, based on the available information, the importer cannot identify all the (individual) articles joined or assembled together in the object (e.g. shock absorber, lamp, derailleurs, cogset, tyres, tyres' inner tubes, brakes). For these, the importer needs to request further information from his non-EU supplier on the articles used as components.

After identifying the different articles and/or objects assembled or joined together in the bicycle, the importer groups them according to the different materials they are made of, based on the information already available to him. In those cases where he could not identify all the materials in an object he decides to request further information from his supplier.

The list below only exemplifies the materials that are present in the composition of (individual) articles or objects or that the importer suspects may be present. It does not intend to be exhaustive or accurate.

Material	Article/object name (objects containing different materials are listed in more than one row)
Soft plastics	Saddle, handle bar grips, plastic tubes in sheathed cables, pedals, caps of inner tube of the tyre
Hard plastics	Brake hoods, brake levers, gear levers, wheels' prism reflectors, rear reflector, lamp housing

Rubber	Tyres, tyre's inner tubes, rim brake pads (brakes)
Metallic materials	Painted metal frame, cables, brakes, shock absorber, spokes, hub, rims, valve of inner tube of the tyre, crank arms, derailleurs, chain, front sprocket-wheels, (rear) cogset, bolts, nuts, o-rings
Coatings/paints	Painted metal frame, seat post, seat rails, seat clamp, seat post clamp, forks, bolts, nuts
Glass	Lamp
Not known	Tyres

Based on the information searches and information gathered, the importer was able to generate lists with a reduced number of Candidate List substances potentially present in the different materials listed in the table above used in the articles or objects contained in the bicycle.

Thus, the importer requests further information from his non-EU supplier:

- on (individual) articles in objects where the importer could not identify all of them and on their composition;
- on confirming the materials the articles/objects are made of (when that information was not yet available);
- on the potential presence and concentration of the Candidate List substances in the "shorter" lists generated above in the specific articles/objects.

In the request, the importer also explains the reason for his request.

The importer received detailed and reliable information from his non-EU supplier.

Due to the large number of articles included in the bicycle, from now on, in this example we focus only on the following articles/objects:

- The plastic handlebar grips (which one of them is an article);
- The painted metal frame is an article;
- The inner inflatable tubes (inserted between the tyre and the wheel's rim);
- The tyres.

Following his request, the importer received the following detailed information on objects listed above from his non-EU supplier:

Handlebar grips

The handlebar grips are plastic (PVC) articles and produced by the injection moulding process.

The handlebar grips weight 50g and contain 0.5% w/w of a Candidate List substance 1.

Inner inflatable tubes

An inner inflatable tube of a tyre consists of a flexible rubber doughnut-shaped tube with a metal valve for inflation and a cap. The inner tube should not leak air after being inflated. The doughnut-shaped tube weights 100 g and contains a Candidate List substance 2 at a concentration of 20% w/w.

Painted metal frame

The different steel tubes (as identified above) are joined together by soldering them using a metal alloy. The steel and the soldering metal alloy do not contain any Candidate List substance. The painted metal frame weights 5 kg with a total tube length of 2.5 m and a diameter of 10 cm. The paint coating has a thickness of 0.2 mm and a density of 2 g/cm³. The non-volatile substances content (solids) of the paint used is 40% w/w and contains a Candidate List substance 3 at a concentration of 2% w/w.

Bicycle tyres

The bicycle clincher tyre consists of a casing, a tread and two beads.

The casing consists of a body ply. The ply is made of cloth, where the threads consist of nylon fibres, which is combined and impregnated with rubber mixture in a roller machine. The bead contains a bundle of steel wires covered by a rubber layer. The tread is an extruded rubber profile that is brought over the tyre casing before the curing process in a mould under pressure and at elevated temperature. The curing process stimulates vulcanization between the different rubber materials providing the final shape and design to the tyre.

The nylon fibres and the cloth, as well the steel wires and the beads are incorporated in the tyre during production. The rubber used in making the casing contains a Candidate List substance 4 at a concentration of 10% w/w. The rubber mixture used to make the tread (rubber profile) contains the same Candidate List substance at a concentration of 4% w/w. The rubber layer in each bead contains also that Candidate List substance 4 at a concentration of 1% w/w. The weights of the rubber in the casing is 0.15 kg, in the tread is 0.20 kg and in the beads 0.030 kg. The cured tyre, containing the nylon cloth, the bundled steel wires and the rubbers, weights 0.50 kg. During vulcanization, the covering rubber layer of the bundled steel wires in the beads, in the casing and in the tread change their surface (between the contact surfaces of the different rubber parts) and shape being integrated in the final rubber tyre body. These rubbers cannot be separated anymore after vulcanization.

Illustration of the decision process using the flow chart in subchapter 1.2. of the guidance

Example: Bicycle - handlebar grips, tyres' inner inflatable tubes, painted metal frame, tyres

1. Role in the supply chain.

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

YES. The importer imports bicycles and therefore he must be considered importer of handlebar grips, tyres' inner inflatable tubes (including the flexible rubber doughnut-shaped tube), painted metal frame and tyres.

2. Is your object an article under REACH?

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

YES. The handlebar grips, the flexible rubber doughnut-shaped tube in the tyres' inner inflatable tubes, the painted metal frame and tyres incorporated in the bicycle are articles.

3. Registration obligation under Article 7(1) of REACH

Is there an intended release of substances from the article? (*consult chapter 4*)

NO.

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

4. Communication obligations under Article 33 of REACH

Does the article contain an SVHC included in the Candidate List?

(*Consult chapters 3 and 5*)

YES.

Article	Candidate List substance	Concentration / % w/w*	Total tonnage of Candidate List substance in articles/ t/a**
Handlebar grips	Candidate List substance 1	0.5	0.005
Flexible rubber doughnut-shaped tubes	Candidate List substance 2	20	0.4
Painted metal frames	Candidate List substance 3	0.03	<i>Not applicable</i>
Bicycle tyres	Candidate List substance 4	4.7	0.5

* See below under "Determine the concentration of the Candidate List substance"

** See below under "Calculate the total amount in tonnes of that Candidate List substance in all article types imported per year..."

Determine the concentration of the Candidate List substance

The concentrations of the Candidate List substance 1 in the handlebar grips and of the Candidate List substance 2 in the flexible rubber doughnut-shaped tube were communicated by the non-EU supplier and are listed in the previous table.

Painted metal frame

Weight of the painted metal frame: 5 kg

Total tube length: 2.5 m

Tube diameter: 1.0 cm = 0.010 m

Total surface painted (approx.): (total tube length) \times (tube diameter $\times \pi$) = 2.5 m \times (0.010 m $\times \pi$) \approx 0.08 m²

Paint coating thickness: 0.2 mm = 0.0002 m

Volume of dry paint: total area painted \times paint coating thickness = 0.08 m² \times 0.0002 m = 1.6 $\times 10^{-5}$ m³.

Density of dry paint: 2 g/cm³ = 2 $\times 10^3$ kg/m³

Weight of dry paint: volume of dry paint \times density of dry paint = (1.6 $\times 10^{-5}$ m³) \times (2 $\times 10^3$ kg/m³) = 0.032 kg

The non-volatile substances content (solids) of the paint used: 40% w/w.

The concentration of the Candidate List substance 3 in the liquid paint: 2% w/w.

The concentration of the Candidate List substance 3 in the dry paint ($Conc_{subst.3 \text{ in paint}}$) needs to be corrected by a factor of 100/40 due to the (semi-)volatile substances contained in the paint which evaporate during the incorporation of the paint in the metal frame. Thus, $Conc_{subst.3 \text{ in paint}} = (100/40) \times 2\% = 5\% \text{ w/w}$.

The concentration of the paint in painted metal frame is calculated as follows: $Conc_{paint \text{ in frame}} = 0.032 \text{ kg} / 5 \text{ kg} = 0.64\% \text{ w/w}$.

The concentration (% w/w) of the Candidate List substance 3 in frame ($Conc_{subst.3 \text{ in frame}}$) can be calculated using the equation (1) in the text in Appendix 3:

$$Conc_{subst.3 \text{ in frame}} = Conc_{subst.3 \text{ in paint}} \times Conc_{paint \text{ in frame}} = (5\%) \times (0.64\%) = 0.03\% \text{ w/w}$$

The Candidate List substance 3 concentration in the frame is 0.03% w/w, which is not above the 0.1% w/w concentration threshold.

Tyre

Quantity of Candidate List substance 4 in the casing rubber: Candidate List substance 4 concentration \times weight of casing rubber in the tyre = 10% \times 0.15kg = 0.015kg.

Quantity of Candidate List substance 4 in the tread: Candidate List substance 4 concentration \times weight of tread rubber in the tyre = 4% \times 0.20kg = 0.008kg.

Quantity of Candidate List substance 4 in the rubber layer of beads: Candidate List substance 4 concentration \times weight of rubber layer of the two beads = 1% \times 0.030kg = 0.0003kg.

Total quantity of Candidate List substance 4 in the rubber of the tyre: sum of the above calculated quantities = 0.015kg + 0.008kg + 0.0003kg = 0.023kg

Total weight of the cured tyre: 0.50 kg

Concentration of Candidate List substance 4 in the rubber of the tyre: (Total quantity of Candidate List substance 4 in the rubber of the tyre)/(Total weight of the cured tyre) = 4.7% w/w.

The concentration of the Candidate List substance 4 in the tyres is 4.7% w/w, which is higher than 0.1% w/w concentration threshold.

Concentration above 0.1% (w/w)?

YES for handlebar grips, flexible rubber doughnut-shaped tubes and bicycle tyres (see table above). The concentration of the Candidate List substance in each of these articles exceeds the threshold concentration limit of 0.1% w/w.

→ **Conclusion on communication down the supply chain:** communicate information according to Article 33, as explained in subchapter 3.4.1 of the guidance, for the handlebar grips, flexible rubber doughnut-shaped tubes (in tyres' inner inflatable tubes) and bicycle tyres included in the bicycles.

5. Notification of Candidate List substances in articles under Article 7(2) of REACH

Calculate the total amount in tonnes of that Candidate List substance in all article types imported per year where it is present above the 0.1% w/w concentration threshold

The total amount of the Candidate List substance, in tonnes per year (t/a), in all handlebar grips, flexible rubber doughnut-shaped tubes and bicycle tyres in the imported bicycles is calculated using equation (3) in Appendix 3 of the guidance.

- Number of bicycles imported in the year: 10,000 (therefore, the number of handlebar grips, flexible rubber doughnut-shaped tubes and bicycle tyres in the imported bicycles is 20,000 items - $n_{handlebars}$; n_{tubes} ; n_{tyres});
- The weight of a handlebar grip ($m_{handlebars}$) is 0.050kg; the weight of a flexible rubber doughnut-shaped tubes (m_{tube}) is 0.100kg; the weight of a bicycle tyre (m_{tyre}) is: 0.5kg;
- The Candidate List substance concentrations in each of these articles ($Conc_{handlebars}$; $Conc_{tubes}$, $Conc_{tyres}$) are listed in the table above.

Calculation of the total amount of the Candidate List substance 1 in the handlebar grips incorporated in the imported bicycles per year where it is present above the 0.1% w/w concentration threshold:

$$m_{SVHC \text{ in handlebars}} [t/a] = (Conc_{SVHC \text{ in handlebars}} [\%]) \times \left(\frac{m_{handlebars} [kg/handlebar]}{1000} \right) \times (n_{handlebars} [handlebars/a])$$

$$m_{SVHC \text{ in frames}} [t/a] = (0.5\%) \times \left(\frac{0.05}{1000} \right) \times (20,000) = 0.005$$

The total amount, in tonnes per year, of the Candidate List substance 1 in all handlebar grips, containing more than 0.1% w/w of the substance, is 0.005 t/a, which does not exceeds the threshold limit of 1 t/a.

Calculation of the total amount of the Candidate List substance 2 in the flexible rubber doughnut-shaped tubes (in tyres' inner inflatable tubes) incorporated in the imported bicycles per year where it is present above the 0.1% w/w concentration threshold:

$$m_{SVHC \text{ in tubes}} [t/a] = (Conc_{SVHC \text{ in tubes}} [\%]) \times \left(\frac{m_{tube} [kg/tube]}{1000} \right) \times (n_{tubes} [tubes/a])$$

$$m_{SVHC \text{ in tubes}} [t/a] = (20\%) \times \left(\frac{0.1}{1000} \right) \times (20,000) = 0.4$$

The total amount, in tonnes per year, of the Candidate List substance 2 in all flexible rubber doughnut-shaped tubes, containing more than 0.1% w/w of the substance, is 0.4 t/a, which does not exceeds the threshold limit of 1 t/a.

Calculation of the total amount of the Candidate List substance 4 in the tyres incorporated in the imported bicycles per year where it is present above the 0.1% w/w concentration threshold:

$$m_{SVHC \text{ in tyres}} [t/a] = (Conc_{SVHC \text{ in tyres}} [\%]) \times \left(\frac{m_{\text{tyre}} [kg/tyre]}{1000} \right) \times (n_{\text{tyres}} [\text{tyres}/a])$$

$$m_{SVHC \text{ in tubes}} [t/a] = (4.7\%) \times \left(\frac{0.5}{1000} \right) \times (20,000) = 0.47$$

The total amount, in tonnes per year, of the Candidate List substance 2 in all flexible rubber doughnut-shaped tubes, containing more than 0.1% w/w of the substance, is approx. 0.5 t/a, which does not exceeds the threshold limit of 1 t/a.

Is the total amount of the Candidate List substance > 1 t/a?

No. The total quantities of the Candidate List substances 1, 2 and 4 in all handlebar grips, flexible rubber doughnut-shaped tubes and bicycle tyres, respectively, in the imported bicycles (see table above) do not exceed the threshold limit of 1 t/a.

→ **Conclusion on substances in articles notification under Article 7(2) of REACH:** notifications for the Candidate List substances present in the handlebar grips, flexible rubber doughnut-shaped tubes and tyres in the imported bicycles are not required for the importer, because the total quantities are below the 1t/a trigger limit.

6. Final conclusion

Conclusion: Communication of information down the supply chain and to consumers upon request according to Article 33 for the Candidate List substances present in the handlebar grips, flexible rubber doughnut-shaped tubes (in tyres' inner inflatable tubes) and bicycle tyres included in the imported bicycles is required. The importer does not have notification obligation for those Candidate List substances.

Appendix 7. Information sources on substances in articles

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

Name	Source	Content
Information sources on substances in miscellaneous articles		
Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII to the REACH Regulation (EC) No 1907/2006 REACH Regulation, as amended)	http://echa.europa.eu/legislation/reach_legislation_en.asp	Restrictions on use and marketing of substances in various mixtures and articles, e.g. textiles and treated wood.
ECHA's public database with information on registered substances	http://apps.echa.europa.eu/registered/registered-sub.aspx	The information in this database was provided by companies in their registration dossiers, such as e.g. information on the identified uses of substances, which include uses of substances in articles (please note that the database allows only searches for substances, not for articles).
Substance-specific documents relating to Annex XIV Recommendations on ECHA's website	http://echa.europa.eu/chem_data/authorisation_process/annex_xiv_rec/subst_spec_docs_en.asp	For each of the prioritised substances, documents providing further background information also on the uses of substances are accessible.
News & Press Archive of ECHA	http://echa.europa.eu/news/archive_en.asp	Press releases of ECHA on the addition of substances to the Candidate List for authorisation also contain information on potential uses of these substances that was submitted to ECHA in Annex XV dossiers by EU Member States.
Monographs Database of the International Agency for Research on Cancer (IARC)	http://monographs.iarc.fr	IARC Monographs on the Evaluation of Carcinogenic Risks to Humans also contain information on production and use of substances.

Name	Source	Content
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.irc.ec.europa.eu/document/s/Biocides/EMISSION_SCENARIO_DOCUMENTS	Documents used to estimate the initial release of substances from biocidal products (or treated materials) to the environment.
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/projekte-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		

Name	Source	Content
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.

Appendix 8. Methods for the sampling and analysis of substances in articles

The non-exhaustive list below contains examples of sampling methods and analytical methods for substances in articles, and in particular methods for the determination of substances released from articles. Please note that the division of the list into different parts based on different types of article is not strict. The "Compendium of analytical methods Recommended by the Forum to check compliance with Reach annex xvii restrictions"⁵⁴ provides a ready reference of some available analytical methods that authorities or industry may use in order to assess the compliance with the restrictions set forth in Annex XVII to REACH. Some of those analytical methods can also be useful to determine the presence and concentration of Candidate List substances in some articles. More methods for different sectors and products can be obtained on the websites of [CEN](#) and its [national members](#).

Name	Source	Content
Methods for the sampling and analysis of substances in miscellaneous articles		
Standard ISO 14025 "Environmental labels and declarations - Type III environmental declarations - Principles and procedures"	http://www.iso.org	Standardised test Methods for chemical analysis of potential emission from articles.
ChemTest module of the EU Exposure Assessment Toolbox.	http://web.jrc.ec.europa.eu/eis-chemrisks/toolbox.cfm	Exposure testing methods, e.g. to quantify emissions of volatile chemicals from consumer products.
Collection of methods of the German Federal Office of Consumer Protection and Food Safety (BVL)	http://www.methodensammlung-bvl.de	Methods for sampling and analysis of different articles of daily use.
Methods for the sampling and analysis of substances in electrotechnical products		
Standard IEC/PAS 62596 "Electrotechnical products - Determination of restricted substances - Sampling procedure - Guidelines"	http://www.iec.ch	Strategies to obtain samples from electrotechnical products, electronic assemblies, electronic components that can be used for analytical testing to determine the levels of restricted substances.

⁵⁴ Available at <http://echa.europa.eu/about-us/who-we-are/enforcement-forum/enforceability-of-restrictions>

Name	Source	Content
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.
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		

Name	Source	Content
Standard EN 1122 "Plastics - Determination of cadmium - Wet decomposition method"	http://www.din.de	Method for quantification of cadmium in plastic articles. Other analysis methods include: - NAA (neutron activation analysis) - AAS (atomic absorption spectroscopy) - XRF (x-ray fluorescence spectroscopy)
Methods for the 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.

Name	Source	Content
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.

Appendix 9. Other legislation restricting the use of substances in articles

Instrument	Coverage	Conditions	Notes
Regulation (EU) 528/2012	Biocidal products	<ul style="list-style-type: none"> Active substances require approval Biocidal products require authorisation 	<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 	
Regulation (EC) No 1223/2009	Cosmetic products	<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 ⁵⁵) Directive 2002/95/EC	Electrical and electronic equipment falling under categories set in Annex IA to (WEEE ⁵⁶) 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 	

⁵⁵ Restriction of Hazardous Substances

⁵⁶ Waste Electrical and Electronic Equipment

Instrument	Coverage	Conditions	Notes
<p>Directive 89/106/EEC Directive 89/686/EEC</p> <p>Directive 93/42/EEC Directive 98/79/EC</p> <p>Directive 90/385/EEC</p>	<p>Construction products Personal protective equipment Medical devices In vitro diagnostic medical devices Active implantable medical devices</p>	<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 ⁵⁷) 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 ⁵⁸) 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 2009/48/EC	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) 	

⁵⁷ End-of-Life Vehicles

⁵⁸ General Product Safety

Instrument	Coverage	Conditions	Notes
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
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 	

Appendix 10. Parts of the REACH Regulation of particular relevance

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

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

The REACH Regulation as well as the Regulations amending it can be accessed through the website of [ECHA](http://echa.europa.eu).

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4 **European Chemicals Agency**

5 P.O. Box 400, FI-00121 Helsinki

6 <http://echa.europa.eu>