ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE

Guidance on requirements for substances in articles

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Draft Version 4.0

LEGAL NOTE

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European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

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.[1] 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. When needed, 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.

The judgement of the European Court of Justice of 10 September 2015 in case C-106/14[2] clarified the scope of the notification and communication obligations under Articles 7(2) and 33 of REACH, which also apply to articles that are present in complex products (i.e. products composed of several articles) as long as these articles keep a special shape, surface or design and do not become waste. According to the Court's judgement:

1. Article 7(2) of the REACH Regulation must be interpreted as meaning that, for the purposes of application of that provision, it is for the producer to determine whether a Candidate List substance of very high concern, is present in a concentration above 0.1% weight by weight of any article it produces and, for the importer of a product made up of more than one article, to determine for each article whether such a substance is present in a concentration above 0.1% weight by weight of that article.

2. Article 33 of the REACH Regulation must be interpreted as meaning that, for the purposes of application of that provision, it is for the supplier of a product one or more constituent articles of which contain(s) a Candidate List substance of very high concern in a concentration above 0.1% weight by weight of that article, to inform the recipient and, on request, the consumer, of the presence of that substance by providing them, as a minimum, with the name of the substance in question.

Following the judgement, ECHA initiated a fast-track update procedure and published an updated Version 3.0 of this guidance document in December 2015, correcting the key parts of the guidance that were no longer consistent with the conclusions of the court's judgement, and in particular removing examples.

The present Version 4.0 is a more comprehensive update of the guidance, following a normal three-step guidance consultation process, including a consultation of the Partner Expert Group (PEG) selected from ECHA's accredited stakeholders. This version aims primarily at aligning further the text of the guidance and introducing new examples that are consistent with the conclusions of the Court judgement.

[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).
[2] The judgment of the Court of Justice in case C-106/14 is available at: http://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=C-106/14

Document History

Version	Changes	Date
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
Version 4.0	xxxxx	Xxxx

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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**[3]. The guidance particularly assists companies in deciding if they have to fulfil registration (Article 7(1)), communication (Article 33) and/or notification (Article 7(2)) 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. It is therefore aimed at:

- Persons responsible for REACH compliance within companies producing, importing and/or supplying articles in the European Economic Area (EEA, but henceforth referred to simply as "EU")[4], in particular purchasing, production and sales managers.
- Only Representatives[5] of non-EU companies producing and exporting articles to the EU.
- Experts from industry associations and other stakeholder organisations informing companies about the requirements for substances in articles under REACH.

A company is an **article producer**[6] if it produces articles within the EU, regardless of how the articles are produced and where they are placed on the market. An **article importer**[7] is any company located inside the EU that imports articles from countries that are located outside the EU. Article producers and importers (as well as other actors in the supply chain such as retailers) are also **article suppliers**[8], if they place articles on the market in the EU. 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 EU).

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 Appendix 1). Other REACH provisions may also apply to certain substances in certain articles, e.g. authorisation requirements, restrictions (see Appendices 1 and 2).

[3] 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)).
[4] The REACH Regulation applies to the European Economic Area (EEA), i.e. the 28 EU Member States and Iceland, Liechtenstein and Norway. Whenever the EU is referred to in the text of this guidance, Iceland, Liechtenstein and Norway are also covered.
[5] Non-EU producers of articles may appoint "Only Representatives" to fulfil all REACH obligations of the importers of their articles in the EU. The role and obligations of an Only Representative are explained in detail in chapter 2 of the Guidance on registration.
[6] producer of an article: means any natural or legal person who makes or assembles an article within the Community (Article 3(4)).
[7] 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)).
[8] 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)).

Table 1: Obligations described in the present guidance

Obligation:	Registration of substances in articles (chapter 4)	Notification of substances in articles (chapter 3)	Communication of information on substances in articles (chapter 3)
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 (Art. 7(6)) (subchapters 3.3.1 and 4.3.2)	yes	yes	no
based on "exclusion of exposure" (Art. 7(3)) (subchapter 3.3.2)	no	yes	no

1.2 Structure of the guidance

The present document is structured to facilitate work on how to identify and fulfil obligations under Articles 7 and 33 of the REACH Regulation for substances contained in 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.

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 an exemption from the notification obligation apply to my case? (see chapter 3)

4. Is there an intended release of substances from my article and what are the consequences of this? Can an exemption from the registration obligation apply to my case? (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 obligations for substances in articles and directs the reader of the guidance to the corresponding chapters.

Appendices 3 to 6 provide supplemental examples and information to the chapters mentioned above.

In order to accommodate the largest audience, all calculations are presented both in a narrative way and with mathematical equations. The latter can be identified in Boxes (main text) or with a grey background (in examples).

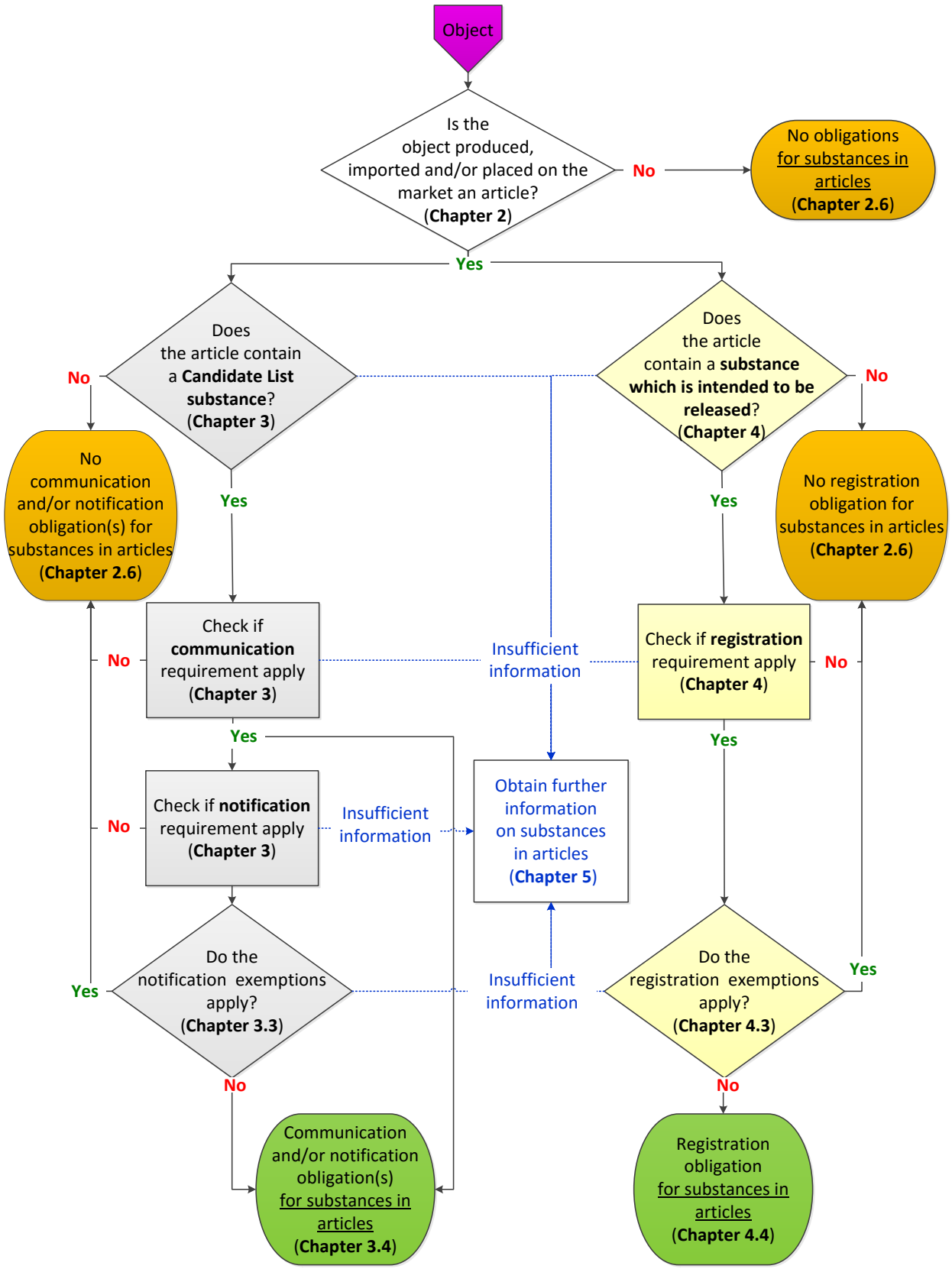

Figure 1: General processes for identifying obligations for substances in articles according to Articles 7 and 33

1.3 Examples in the guidance

The main text of the guidance and appendices 3 and 4 contain several examples to illustrate how to proceed when checking whether substance in articles legal requirements apply. These examples are not intended to be exhaustive.

Appendix 5 illustrates with examples the challenges of identifying Candidate List substances in articles incorporated in complex objects and how they can they be addressed in practice.

Appendix 6 contains examples aiming to cover several issues in a more overarching manner.

In most of the examples no specific substances are mentioned due to the dynamic nature of the "regulatory status" of a substance.

The table below summarises the purpose of each example included in the guidance.

Table 2: List of examples in the guidance and their purpose

Chapter/ Appendix	Example	Purpose
Deciding whether an object is an article		
Chapter 2.2	Example 1: Blasting grit Example 2: Postcard	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 shape, surface or design of the object.
Chapter 2.3	Example 3: 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 4: 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 5: 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.
How to decide on which articles in a complex object the notification requirement apply		
Chapter 3.2.2	Example 6: Painted foldback clip	To illustrate how to decide on which articles in a specific complex object the notification requirement apply.
Calculation of the concentration of a Candidate List substance in articles		

Chapter/ Appendix	Example	Purpose
Chapter 3.2.3.1	Example 7: Calculation of the concentration of a Candidate List substance in an article made from a mixture	To illustrate how the concentration of a Candidate List substance should be determined **in an article made from a substance or a mixture**.
Chapter 3.2.3.1	Example 8: Calculation of the concentration of a Candidate List substance in coated articles	To illustrate how the concentration of a Candidate List substance should be determined when **an article is coated** by incorporating a coating mixture containing that substance into an article.
Chapter 3.2.3.1	Example 9: Calculation of the concentration of a Candidate List substance in a complex object made up of two articles joined together using a mixture	To illustrate how the concentration of a Candidate List substance should be determined over the total weight of **a complex object** made by using a mixture containing that substance to join two (or more) articles.
Calculation of the total tonnage of a Candidate List substance in articles		
Chapter 3.2.3.2	Example 10: Calculation of the total amount of a Candidate List substance in different articles	To illustrate how the total tonnage of a Candidate List substance should be determined in **different articles**.
Chapter 3.2.3.2	Example 11: Calculation of the total amount of Candidate List substance(s) for a complex object	To illustrate how the total tonnage of Candidate List substance(s) should be determined for an **object made of two (or more) articles joined together by using a mixture**.
What information to communicate for complex objects		
Chapter 3.4.1	Example 12: What information to communicate when supplying a complex object	To show what **information to communicate** when supplying a complex object (e.g. made up of two articles joined together using a mixture).
Identification of an article with intended release substances		
Chapter 4.1	Example 13: Intended release of substances from articles	To illustrate an **article** fulfilling the conditions to be considered as **containing substances** which are **intended to be released**.
Registration tonnage threshold for a substance intended to be released		
Chapter 4.2	Example 14: Calculation of tonnage of a substance intended to be released	To illustrate how to calculate the **tonnage** of a substance intended to be released from an article.

Chapter/ Appendix	Example	Purpose
Chapter 4.2.1	Example 15: Critical concentration level for substance in a mixture intended to be released	To illustrate how to calculate the **critical concentration level** for a substance in a mixture intended to be released.
Borderline cases on deciding whether an object is an article		
Appendix 3	Several examples on borderline cases on deciding whether an object is an article (listed in Table 6 in Appendix 3).	To show borderline cases between articles and substances/mixtures in containers or on carriers.
Appendix 4	Examples 16 to 19 on deciding whether an object is an article in the processing sequence of natural or synthetic materials.	To show cases of setting the borderline between substances/mixtures and articles in the processing sequence of natural or synthetic materials.
Challenges of identifying Candidate List substances in complex objects		
Appendix 5	Example 20: Approach to identify which articles may contain certain Candidate List substances	To illustrate an approach to identify which articles may contain certain Candidate List substances.
Appendix 5	Example 21: Articles joined or assembled together in a very complex object	To illustrate on how to identify and differentiate all articles joined or assembled together in a very complex object.
Overarching examples		
Appendix 6	Example 22: Scented children's toys - toy with lemon scent (D-limonene)	Overarching example for checking if requirements under Article 7 apply for intended release of substance/mixture from articles, by using the overall approach shown in the flowchart in Figure 1.
Appendix 6	Example 23: Bicycle - handlebar grips, tyres' inner inflatable tubes, painted metal frame, tyres	Overarching example for checking if requirements under Articles 7 and 33 apply for Candidate List substances in articles, by using the overall approach shown in the flowchart in Figure 1.

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2 DECIDING WHAT IS AN ARTICLE UNDER REACH

When determining if and which REACH substance in articles requirements apply to a given object[9] which is produced, imported and/or placed on the EU market, the first step is to check whether or not the object is considered as an article under REACH. Objects may be simple, like a paper sheet, but can also be very complex, like a laptop computer, consisting of many articles.

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.*

An article is an object composed of one or more substances or mixtures which were given a specific shape, surface or design during the production process. It may be produced from natural materials, such as wood or wool, or from synthetic ones, such as polyethylene (PE). Most of the commonly used objects in private households and industries are themselves articles, or contain articles, e.g. furniture, clothes, vehicles, books, toys, kitchen equipment and electronic equipment.

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

Articles that are assembled or joined together remain articles, as long as they keep a special shape, surface or design, which is more decisive for their function than their chemical composition,[10] or as long as they do not become waste[11].

2.1 The function of an object

The term "function" in the article definition should be interpreted as meaning the intended purpose for which an object is to be used. 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 purpose of 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. An object may have multiple functions and they may have different levels of importance (e.g. "accessory function"), hence all these functions must be taken into account when deciding whether an object is an article or not.

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.

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.

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[9] The term "object" can in principle refer to any product in the supply chain.
[10] For further considerations, see the case of beads used in the production of bicycle tyres in example 23 (appendix 6).
[11] "Waste" as defined in the Waste Framework Directive (Directive 2008/98)

Example 1: Blasting grit

Grit for abrasive blasting primarily needs to be hard and have sharp edges to be applied as blasting medium (e.g. for glass engraving or stone etching). Its functions are e.g. to abrade, smooth, polish, scrub, or clean surfaces. Hardness and cleavage properties of the edges are in this case the main characteristics of a blasting grid.

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. The function(s) of the blasting grid is primarily dependent on those physical properties and not on the shape, surface or design of its particles. Therefore, blasting grid is to be regarded as a substance or mixture.

Example 2: Postcard

A postcard supports a picture or drawing and must primarily be suitable for writing or printing. The surface or paper fibers must support the graphite from a pencil, pen ink or printing ink. All these characteristics are more dependent on the shape and/or surface of the postcard than other physical characteristics that result from the chemistry of the materials used to make the postcard. Examples of such characteristics are e.g. tear resistance, lightness, softness and flexibility, which improve the quality of the postcard but do not determine its use. Therefore, the shape, surface or design of a postcard is more important for its function than its chemical composition. The postcard is to be regarded as an article.

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, to be an article, its **shape, surface or design must be deliberately determined and given during a production step.** Manufactured solid materials are by definition obtained in specific shapes and surfaces (e.g. granules, crystals, flakes, powders, etc.). These shapes and surfaces may be inherent to the physical properties of the manufactured materials. They may also be solely determined by the chemical starting materials used and the manufacturing process conditions applied. In both these cases, the manufactured materials are most likely to be substances, even though the shapes and surfaces may also be deliberately controlled for the main purpose of optimising the further processing and/or the handling of the solid materials.

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.

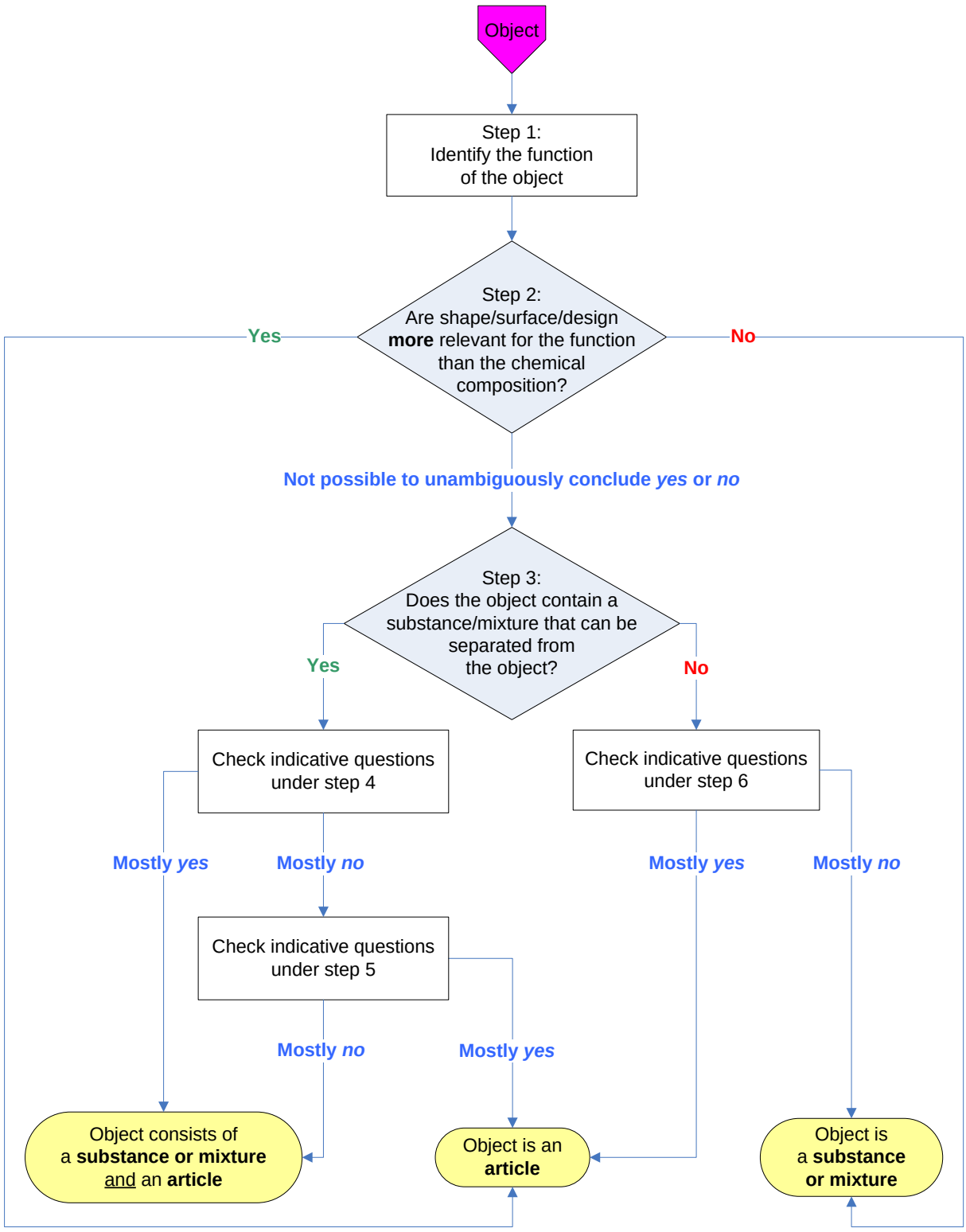


Figure 2: Decision-making on whether an object is an article or not

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

Step 2: Compare the importance of physical form and chemical characteristics for achieving the object's function. **If it can be unambiguously concluded 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 3: Wax crayon

A wax crayon consists of paraffin wax and pigments and is used for colouring and drawing on paper. The paraffin wax functions as a vehicle (carrier) for the pigments. 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 these questions can predominantly be answered with *yes* (i.e. 2 or 3 out 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) readers are advised to run the Navigator.

Example 4: 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*, the following questions should be used 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 these questions can be answered 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 subchapter 4.2.

Example 5: 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 3 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, the following indicative questions may be used 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 it 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 all 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 4 illustrates how to apply these indicative questions and gives examples from four different industry sectors.

Step 6 was developed to assess mostly objects which are further processed (e.g. semi-finished articles). The answer to indicative questions 6a and 6b may not be very helpful to reach a final conclusion for objects which are not intended to be further processed (and for which therefore questions 6c and 6d cannot be applied). For example, this is the case for objects containing a substance or mixture that cannot be physically separated from them and are not produced or manufactured to be further processed but rather to perform specific functions during their end-use (e.g. carbon electrodes for the manufacture of aluminium, grinding wheels made only of an abrasive material). In such cases, a deeper assessment may already need to be made to answer the question at step 2 more precisely. This is done by taking into account specific considerations applicable to the particular object under assessment.

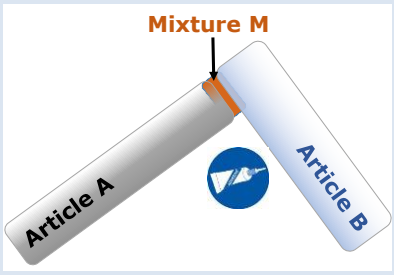
2.4 What is a complex object?

In this guidance, the term "complex object"[12,13] refers to any object made up of more than one article. In complex objects, several articles can be joined or assembled together in various manners. The more articles it is made of, the more complex an object becomes.

Examples of how articles can be incorporated into complex objects are given in Figure 3.

A) Articles mechanically assembled (i.e. articles assembled without the incorporation of substance(s)/mixture(s))

Example(s): pair of (metallic) scissors, foldback clips



B) Joining together two or more articles using substance(s)/mixture(s)

Example(s): block of sticky notes, glued chip in a bank card, unpainted bicycle frame

Figure 3: Types of complex objects

"Very complex objects", as generically illustrated in Figure 4 below, is a term used in this guidance to refer to further combinations of simpler complex objects such as those described in Figure 3 plus further articles. Examples of very complex objects are multi-socket power strips, sofas, bicycles, mobile phones, computers, video cameras, cars and aircraft.

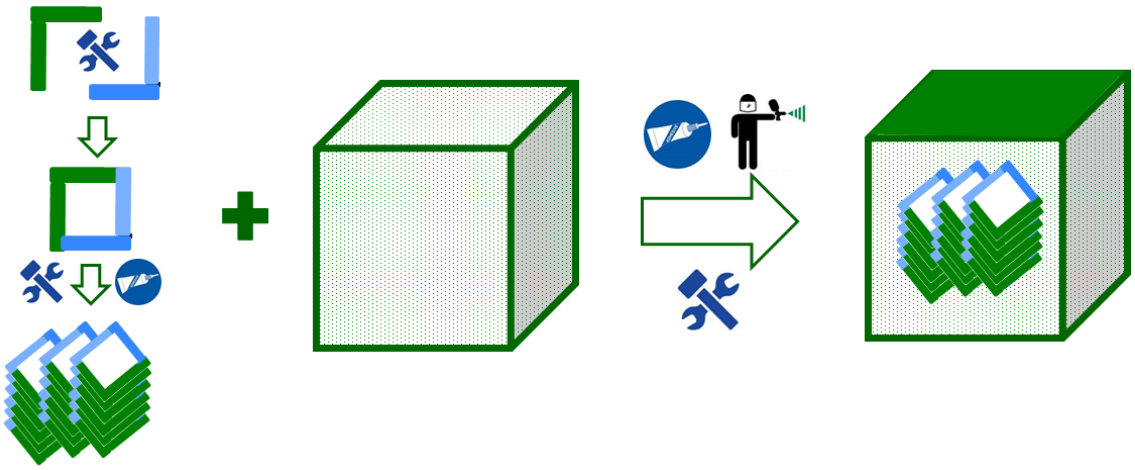


Figure 4: Illustration of a very complex object

[12] The terminology "complex object" in this document corresponds to the term "complex product" as used in the Court Judgement in the case C-106/14.

[13] The articles that are assembled or joined together in a complex object remain articles, as long as they keep a special shape, surface or design, which is more decisive for their function than their chemical composition, or as long as they do not become waste. The question whether a complex object itself may fulfil the definition of article turns solely on a determination according to the criteria laid down in Article 3(3) of REACH and explained in the previous subchapters.

2.5 Packaging

Substances, mixtures and articles can be contained inside packaging, such as a carton, a plastic wrapping or a tin can. In principle, the main functions of packaging may be containment and delivery of e.g. substances or mixtures, protection for the product packaged, and presentation or aesthetic purpose. In many cases, it also contributes to the safety of humans and the environment during handling or use of the content. Therefore, packaging is to be considered as an article because its shape, surface or design is more important than its chemical composition for the above mentioned functions. **The packaging is not a part of 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 as separate articles).

2.6 Documenting conclusions

Article producers who use a substance or mixture in the production of their article are to be seen as downstream users of the substance(s) under REACH. According to Article 36(1)[14] of the REACH Regulation, article producers using a substance or mixture in the production of their articles should keep available all the information they require to carry out their REACH obligations. Even if it has been concluded that no obligations under REACH apply, the company 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 objects are articles, substances or mixtures,
- the checking if specific requirements apply for these, based amongst others on the information received from the suppliers.

Documenting these elements 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.

[14] "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 […]"[15] 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

3 REQUIREMENTS FOR CANDIDATE LIST SUBSTANCES IN ARTICLES

Under REACH each producer, importer and supplier of articles bears responsibility for ensuring the safe use of the articles he places on the EU market. 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 (SVHC identification). 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 subchapters.

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 Registry of Intentions (RoI) on ECHA's website.

Before submitting an intention to prepare an Annex XV dossier on SVHC identification, Member State Competent Authorities (MSCAs) or ECHA often prepare a risk management option analysis (RMOA). The RMOA is a voluntary process, i.e. not defined in the legislation, which promotes early discussion on substances which may require further regulatory action.[15] 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 published RMOA concludes on whether regulatory risk management is required. 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 should be included in the RoI. The PACT and the RoI facilitate a timely preparation

[15] 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

for complying with possible obligations that could result when a substance is eventually put on the Candidate List. **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 the subsequent parts of this chapter only apply to the substances included in the Candidate List. Other sources of information such as those provided above are just meant to help companies in identifying substances that are under authorities' scrutiny and might be included in the Candidate List in the future.

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 EU producers and importers into the EU of articles that contain the substance, under certain conditions. It can also trigger communication obligations down the supply chain for 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 of the use of the article, the appropriate risk management measures to guarantee the safe use of articles containing Candidate List 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 an article containing a substance has to provide to the recipient of the article (Article 33(1)) or to a consumer (Article 33(2)) relevant safety information, available to him, when both the following conditions are met:

- The substance is included in the Candidate List for authorisation, and
- The substance is present in articles produced and/or imported above a concentration of 0.1% (w/w),

The information is to be provided **to the recipient of the article when the article is supplied** for the first time after the inclusion of the substance into the Candidate List and **to the consumer upon request by that consumer**, within 45 calendar days of that request and free of charge.

If no particular information is necessary to allow safe use of the article containing a Candidate List substance, e.g. when exposure can be excluded at all life cycle stages of the article including disposal,[16] **as a minimum the name of the substance in question has to be communicated** to the recipients of the article or to consumers. The information provided should make it clear that the substance is on the Candidate List and that this is the reason for giving the information.

The term "recipients" refers to industrial or professional users and distributors, but not to consumers.

[16] It is recommended to document the reasons that lead to the conclusion that no information other than the substance name only is necessary to be communicated to allow the safe use of the article (see subchapter 2.6).

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

- The Candidate List 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 (complex objects);
- There is no tonnage trigger for these obligations.
- A distributor supplying articles to consumers does not comply with his communication obligation toward a consumer upon request, just by referring the consumer to his own supplier, or the producer/importer of the articles

3.2.2 Notification of Candidate List substances in articles

The notification obligation of importers and producers of articles under Article 7(2) of REACH aims at providing ECHA and the Member State competent authorities with information on the presence of Candidate List substances in articles. This information may be used to identify a need for initiating regulatory risk management procedures under REACH (authorisation and restriction) or under other EU legislation. Non-confidential information contained in the notifications will also be made available to stakeholders and the general public on the ECHA website. This is part of ECHA's contribution to increase the information on the presence of Candidate List substances in articles available to the general public. In turn, it should encourage the actors in the supply chain to comply with their legal obligations to communicate the appropriate information for the safe use of articles.

Notification of a substance in articles is required from producers and importers of articles when all the following conditions of Article 7(2) are met:

- The substance is included in the Candidate List for authorisation, and
- The substance is present in articles produced and/or imported above a concentration of 0.1% (w/w), and
- 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, and
- Exemptions do not apply (see subchapter 3.3 for further details).

The substance concentration threshold of 0.1% (w/w) applies to each article as produced or imported. This threshold applies to each article of a complex object. An importer of a complex object is importer of the various articles the complex object is made from, and must therefore have the necessary information for each one of them, for the purpose of being able to comply with notification obligations.

The EU producer of a complex object containing an article with a relevant concentration of a Candidate List substance does not need to notify the Candidate List substance(s) present in that article, if it has been supplied to him by an EU supplier. In this case, the Candidate List substance must indeed have been notified upstream by the EU importer or producer of the article already.

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. On the contrary, if an EU actor produces or imports several articles containing the same Candidate List substance and triggering notification obligations, one notification for this substance is sufficient.

Example 6: Painted foldback clip

A painted foldback clip is made by assembling a painted bent strip of steel with loops at both edges and two handles of bent stiff metallic wire.

- A Candidate List substance concentration threshold of 0.1% w/w should be assessed in relation to the painted bent strip of steel and to each one of the handles.
- An importer of a painted foldback clip should get the necessary information from his non-EU supplier to assess the notification conditions for each one of these articles and, if met, to submit a notification to ECHA. For effects of notification, the handles could be grouped because they are articles of the same type.
- An EU producer of the painted bent strip of steel should have the necessary information provided to him by his supplier(s) of the paint to assess the notification conditions for his produced article and, if met, to submit a notification to ECHA.
- An EU actor, who merely assembles the handles and the painted bent strip of steel to become the painted foldback clip, does not have notification obligations. The notification obligations apply to actors up the supply chain (i.e. producers and importers of the wire, the steel foil or the painted bent strip of steel).

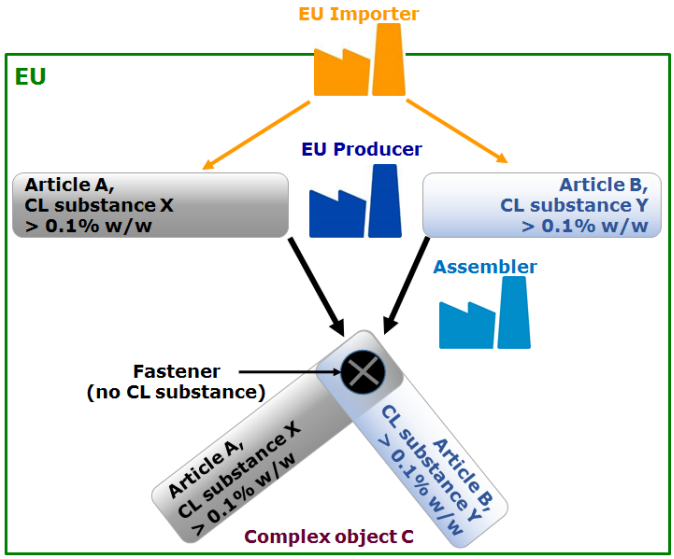
A notification is not required for a substance in articles which have been produced or imported before the substance has been included on the Candidate List for authorisation.

Tables 3 and 4 contain some typical scenarios illustrating who in the supply chain bears the notification obligation for articles incorporated in complex objects, coated articles and coated complex objects. Table 3 focusses on objects assembled, joined or coated in the EU, while Table 4 focusses on imported complex objects. It should be noted that the basic principles are illustrated for simple scenarios, however these principles are applicable to more complex cases and complex supply chains.

Table 3: Scenarios illustrating notification obligations in the supply chain for objects assembled, joined or coated in the EU

Objects assembled, joined or coated in the EU
<u>Scenario 1</u>: Articles which are mechanically assembled in the EU Description: an actor in the EU, called "assembler", assembles mechanically articles A and B using a fastener, i.e. without using a new substance or mixture. • Article A contains the Candidate List substance X > 0.1% w/w • Article B contains the Candidate List substance Y > 0.1% w/w • The fastner contains no Candidate List substance The assembler, during the assembling of complex object C, does not use any Candidate List substance as such or in a mixture.

Objects assembled, joined or coated in the EU



CL substance: Candidate List substance

Notification obligations:

EU importer or **producer** of articles A and B is required to submit a:

- notification for Candidate List substance X in article A;
- notification for Candidate List substance Y in article B.

Assembler of complex object C: no notification is required, because the notification obligation rests with the EU importer or producer of the articles A and B (further up in the supply chain).

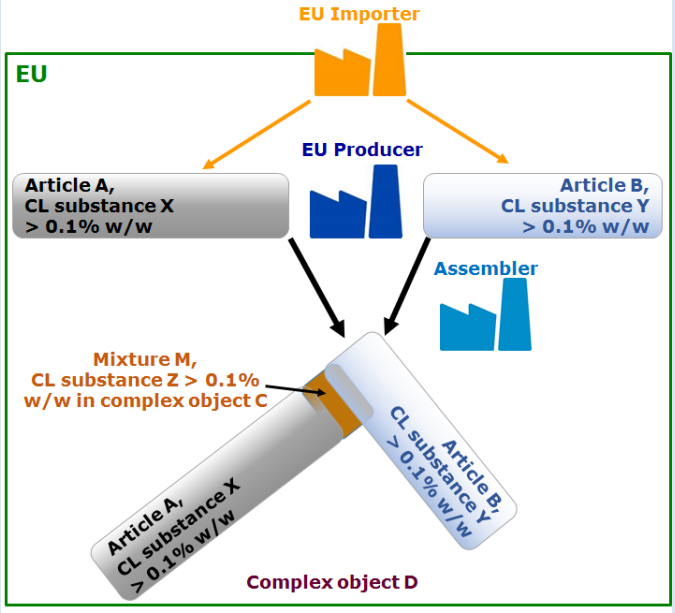
Scenario 2: An assembler joins articles in the EU with a substance or a mixture

Description: an actor in the EU, called "assembler", joins articles A and B with a mixture which contains a Candidate List substance when making complex object D.

- Article A contains the Candidate List substance X > 0.1% w/w
- Article B contains the Candidate List substance Y > 0.1% w/w
- The mixture M (e.g. adhesive, solder) used to join articles A and B contains the Candidate List substance Z; the concentration of that substance in the complex object D is > 0.1% w/w

The assembler, in this case, uses a mixture containing a Candidate List substance Z during the assembling process of complex object D.

Objects assembled, joined or coated in the EU



Notification obligations:

EU importer or **producer** of articles A and B is required to submit a:

- notification for Candidate List substance X in article A;
- notification for Candidate List substance Y in article B.

Assembler of complex object D is required to submit a:

- notification for Candidate List substance Z in complex object D.

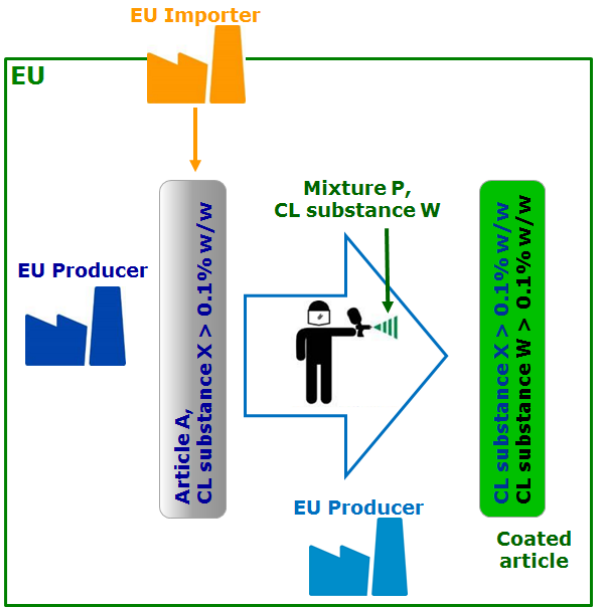
CL substance: Candidate List substance

Scenario 3: Produced or imported article which is coated in the EU with a substance or a mixture

Description: an EU producer coats an article by using a (coating) mixture containing a Candidate List substance.

- (Uncoated) article A contains the Candidate List substance X > 0.1% w/w
- The mixture P (e.g. paint) used to coat article A contains the Candidate List substance W; the concentration of that substance in the coated article is > 0.1% w/w

The EU actor that coats the article incorporates the Candidate List substance W onto the article during the coating operation.



Notification obligations:

EU importer or **producer** of (uncoated) article A is required to submit a:

- notification for Candidate List substance X in (uncoated) article A;

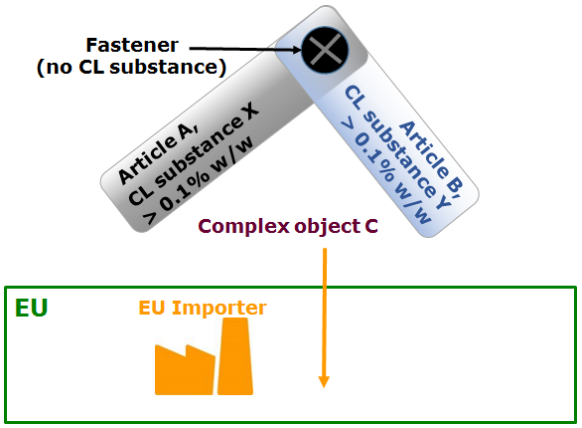
EU producer of coated article is required to submit a:

- notification for Candidate List substance W in the coated article.

Objects assembled, joined or coated in the EU
CL substance: Candidate List substance

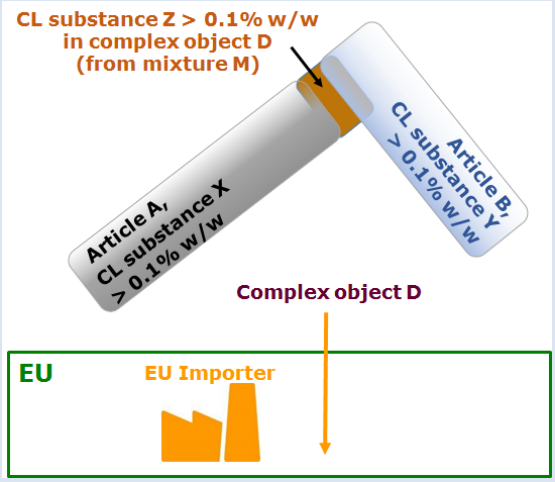
An EU actor who assembles, joins or coats an article that was supplied to him by a supplier in the EU should be able to rely on the fact that this article supplier has a legal obligation to provide him with information, according to Article 33(1) of the REACH Regulation. In case an EU actor wishes to voluntarily prepare and submit a notification to re-assure himself that the articles he places on the market are compliant with REACH[17], such a submission will be accepted by ECHA. Note that this is not a legal requirement.

Table 4: Scenarios illustrating notification obligations for EU importers of complex objects

Importing complex objects into the EU
Scenario 4: Importing a complex object resulting from assembling mechanically two or more articles Description: an EU importer imports a complex object C which is made of: • article A containing the Candidate List (CL) substance X > 0.1% w/w, • article B containing the Candidate List substance Y > 0.1% w/w, and • the fastener containing no Candidate List substances      **Notification obligations:** **EU importer** of complex object C is required to submit a: - notification for Candidate List substance X in article A; - notification for Candidate List substance Y in article B. CL substance: Candidate List substance
Scenario 5: Importing a complex object resulting from joining two or more articles with a substance or a mixture Description: an EU importer imports a complex object D which is made of: • article A containing the Candidate List (CL) substance X > 0.1% w/w, • article B containing the Candidate List substance Y > 0.1% w/w, and • the (dry) material resulting from the use of mixture M (e.g. adhesive, solder), which contains the Candidate List substance Z, to join articles A and B; the concentration of that substance in the complex object D is > 0.1% w/w

[17] (For example if that actor has been unable to obtain a confirmation from his EU supplier that a notification was previously submitted by the producer or importer of the articles used in his production process(es))

Importing complex objects into the EU



Notification obligations:

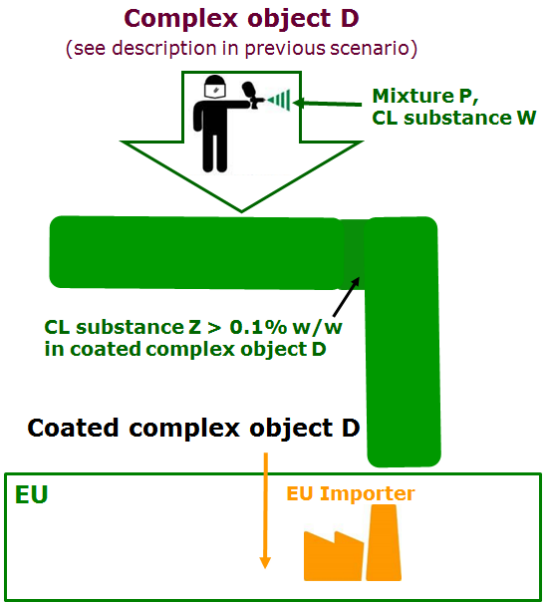
EU importer of complex object D is required to submit a:

- notification for Candidate List substance X in article A;
- notification for Candidate List substance Y in article B;
- notification for Candidate List substance Z in complex object D.

CL substance: Candidate List substance

Scenario 6: Importing a coated complex object

Description: an EU importer imports the complex object D described in the previous scenario which in addition has been coated with a mixture P (e.g. paint), which itself contains the Candidate List substance W ; this coating resulted in a dry coating layer and an overall concentration of Candidate List substance W > 0.1% w/w over the total weight of complex object D.



Notification obligations:

EU importer of the coated complex object D is required to submit the notifications mentioned in the previous scenario. Additionally, the importer is also required to submit a:

- notification for Candidate List substance W in the coated complex object D.

CL substance: Candidate List substance

3.2.3 How to determine the concentration and the tonnage of a Candidate List substance in articles (communication and notification obligations)

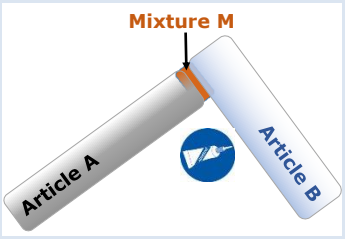
3.2.3.1 How to determine the concentration of a Candidate List substance in an article

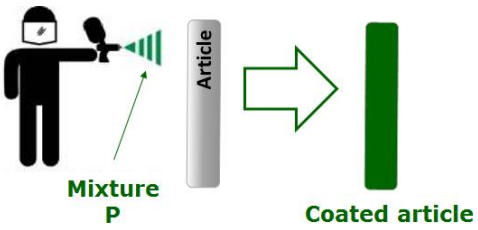
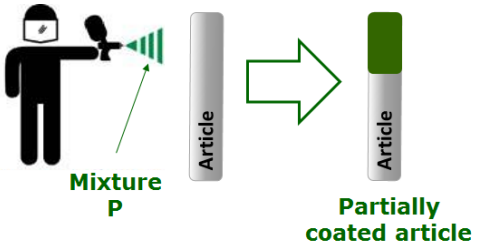
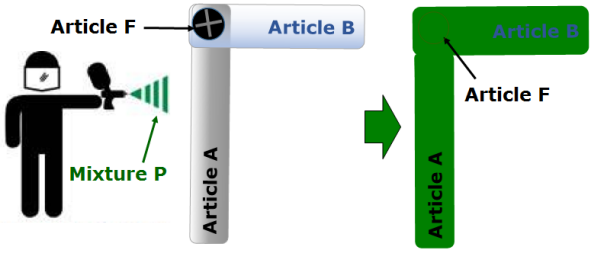
The determination of the concentration of a Candidate List substance is essential to check whether **communication** and **notification** obligations apply.

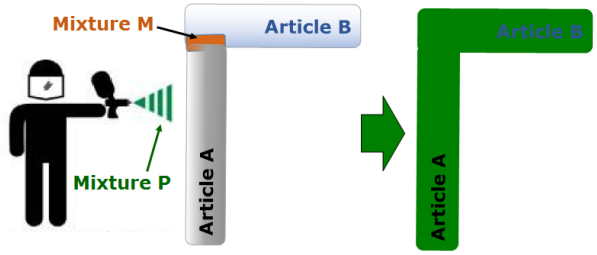
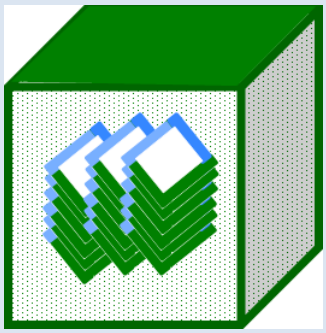
A Candidate List substance can be incorporated into an article during its production. It can also later on be incorporated into/onto an existing article (isolated or incorporated in a complex object) by using the Candidate List substance as such or contained in a mixture (e.g. coatings, primers, adhesives, sealants) and therefore becoming an integral part of the article (or of the complex object).

Table 5 illustrates several scenarios on how to determine the concentration of a Candidate List substance (weight by weight (w/w)) in an article. These scenarios represent the most common ways of incorporating a Candidate List substance into an article (isolated or incorporated in a complex object). For each of them, it is shown how to calculate the concentration of the Candidate List substance. The approaches for the scenarios of articles incorporated into complex objects and of partially coated articles are driven by practical considerations, in order to overcome the specific challenges of calculating the concentration in these particular cases, while ensuring that the main principles and objectives of the substance in articles provisions are fulfilled. It should be noted that the determination of the concentration of a Candidate List substance in an article must always be done on a case-by-case basis.

Table 5: Scenarios illustrating how to determine the concentration of a Candidate List substance (w/w) in articles

Scenario	Calculation of the concentration of a Candidate List substance (w/w)	Description/Example(s)
I. Article made from a Candidate List substance as such or in a mixture	The concentration of the Candidate List substance in the article is calculated over the total weight of the article, i.e. dividing the weight of the Candidate List substance in the article by the total weight of the article.	Example: injection moulded plastic article made from a mixture containing a Candidate List substance
II. Candidate List substance as such or in a mixture used for joining two or more articles (complex object)	The concentration of the Candidate List substance is calculated over the total weight of the complex object, i.e. by dividing the weight of the Candidate List substance in the complex object by the total weight of the complex object.	Complex object made by joining two articles A and B using a mixture M (e.g. adhesive, solder) which contains a Candidate List substance.  The total weight of the complex object is obtained by summing up the weight of article A, the weight of article B, and the weight of mixture M.
III. Candidate List substance		Examples of coating mixtures: paint, lacquer, varnish, functional coating

in coatings		
III. A) Fully coated article	The concentration of the Candidate List substance in the (fully/partially) coated article is calculated over the total weight of the coated article, i.e. dividing the weight of the Candidate List substance in the coated article by the total weight of the article	Article fully coated with mixture P which contains a Candidate List substance.  The total weight of the article is the sum of the weight of the (uncoated) article and the weight of the dry coating (layer).
III. B) Partially coated article		Article partially coated with mixture P which contains a Candidate List substance.  The total weight of the partially coated article is calculated as in scenario III. A) above.
III. C) Coated complex object	The concentration of the Candidate List substance is calculated over the total weight of the complex object, i.e. dividing the weight of the Candidate List substance in the coated complex object by the total weight of the coated complex object.	A complex object after being assembled is coated with mixture P which contains a Candidate List substance. i) The total weight of a coated complex object made by assembling mechanically articles A, B and F and then coated with a mixture P is calculated as follows: summing up the weight of article A, the weight of article B, the weight of article F, and the weight of the mixture P (dry coating).  Example: painted zipper sliders ii) The total weight of a coated complex object made by joining articles A and B with a mixture M and then coated with a mixture P is calculated as follows: summing up the weight of article A, the weight of article B, the weight of mixture M, and

		the weight of the mixture P (dry coating).  Example: painted bicycle frame
IV. Very complex objects	The calculation rules set out for scenarios I to III above apply for each article or simpler complex object.	Very complex objects are combinations of simpler complex objects plus further articles.  Examples: sofa, bicycle, mobile phone, car and aircraft.

Box 1 and Box 2 below illustrate how to calculate the concentration of a Candidate List substance (w/w) in articles or complex objects using mathematical equations. This complements the descriptions given in Table 5.

Box 1

If the information available to the producer or importer is the weight of the Candidate List (CL) substance in the produced or imported article, either isolated or incorporated into a complex object (see Table 5), then its concentration, as weight fraction (w/w), in the particular article (or complex object) can be determined using the following equation:

$$Conc_{CL\ subst.\ in\ article} = \frac{m_{CL\ subst.\ in\ article}\left[kg\right]}{m_{article}\left[kg/article\right]} \qquad (1)^{18}$$

Where,

$Conc_{CL\ subst.\ in\ article}$ is the concentration (w/w) of the Candidate List substance in the article or complex object;

$m_{CL\ subst.\ in\ article}$ is the weight (in kilogram) of the Candidate List substance in the article or

[18] Please note that the term $Conc_{CL\ subst.\ in\ article}$ in w/w in equation (1) should be understood as meaning the weight fraction: values between 0 and 1 (100% w/w = 1, 50% w/w = 0.5, 25% w/w = 0.25, 20% w/w = 0.2, etc.). The $Conc_{CL\ subst.\ in\ article}$ in % w/w is obtained by multiplying the weight fraction value by 100.

complex object;

$m_{article}$ is the weight (in kilogram) of the article or complex object.

Equation (1) above is applicable to all scenarios in Table 5: depending on the scenario, the concentration is calculated over the total weight either of an article (scenarios I, III. A) and III. B)) or of a complex object (scenarios II, III. C)).

Box 2

However, if the information available to the producer or importer is the concentration of the Candidate List (CL) substance in the mixture (w/w) incorporated into the article(s) and the concentration of that mixture (w/w) in the article or complex object, then the concentration of the Candidate List substance can be calculated using the following equation:

$$Conc_{CL\ subst.\ in\ article} = Conc_{CL\ subst.\ in\ mixture} \times Conc_{mixture\ in\ article} \quad (2)^{19}$$

where,

$Conc_{CL\ subst.\ in\ article}$ is the concentration (w/w) of the Candidate List substance in the article or complex object;

$Conc_{CL\ subst.\ in\ mixture}$ is the concentration (w/w) of the Candidate List substance in the mixture[20];

$Conc_{mixture\ in\ article}$ is the concentration (w/w) of the mixture in the article or complex object.

Equation (2) above is applicable to all scenarios in Table 5: depending on the scenario, the concentration is calculated over the total weight either of an article (scenarios I, III. A) and III. B)) or of a complex object (scenarios II, III. C)).

The examples below illustrate how to apply the calculation "rules" for scenarios I, II and III. A) set out in Table 5.

Example 7: Calculation of the concentration of a Candidate List substance in an article made from a mixture

An EU producer produces article G by injection moulding with a total weight of 3.0 kg (see scenario I in Table 5). It is made from a mixture of polyethylene which contains a Candidate List substance W at a concentration of 0.2% w/w – and hence the concentration in the article G is also 0.2% w/w.

Example 8: Calculation of the concentration of a Candidate List substance in

[19] Please note that the terms $Conc_{CL\ subst.\ in\ article}$, $Conc_{CL\ subst.\ in\ mixture}$ and $Conc_{mixture\ in\ article}$ in w/w in equation (2) should be understood as meaning the weight fractions: values between 0 and 1 (100% w/w = 1, 50% w/w = 0.5, 25% w/w = 0.25, 20% w/w = 0.2, etc.). The $Conc_{CL\ subst.\ in\ article}$, $Conc_{CL\ subst.\ in\ mixture}$ and $Conc_{mixture\ in\ article}$ in % w/w is obtained by multiplying the weight fraction value by 100.

[20] Please note that the term $Conc_{CL\ subst.\ in\ mixture}$ in equation (2) 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 (see example 8). The same term in equation (2) 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.

coated articles

An EU producer paints article H, using a paint (mixture P) containing a Candidate List substance W at a concentration of 5% w/w (see scenario III. A) in Table 5). The non-volatile content (solids) of that paint is 67% w/w. The total weight of the painted article H is 5.0 kg, including 0.10 kg of the dry paint.

The concentration of the Candidate List substance W should be determined in relation to the total weight of the painted article H according to Table 5 (scenario III. A)).

The mass of dry paint incorporated into the article is equal to the non-volatile content of the paint. If the solids content of the paint corresponds to 67% of the weight of the paint used, then the total weight of the paint used to paint article H is 0.15 kg [=(100/67)×0.1 kg]. The weight of the Candidate List substance W in the paint (mixture P) is obtained by multiplying its weight fraction (5/100=0.05) by the total weight of the paint (0.15 kg) which is equal to 0.0075 kg [=0.05×0.15 kg]. Therefore, the quantity of this substance incorporated in the painted article H is 0.0075 kg.

The weight by weight content of the Candidate List substance W in the painted article H is obtained by dividing the weight of the Candidate List substance W in the painted article H (0.0075 kg) by its total weight (5.0 kg) which gives 0.0015 (=0.0075 kg/5.0 kg), and corresponds to a concentration of 0.15% w/w.

The rationale described above is the same as using equation (1) in box 1 above, when knowing:
- the weight of the Candidate List substance W in the painted article H: $m_{CL\ subst.\ W\ in\ painted\ article\ H}$ = 0.0075 kg;
- the weight of the painted article H: $m_{painted\ article\ H}$= 5.0 kg.

Thus, the concentration (w/w) of the Candidate List substance W in the painted article H ($Conc_{CL\ subst.\ W\ in\ painted\ article\ H}$) can be calculated as follows:

$$Conc_{CL\ subst.\ W\ in\ painted\ article\ H} = \frac{m_{CL\ subst.\ W\ in\ painted\ article\ H}[kg]}{m_{painted\ article\ H}[kg/article]} = \frac{0.0075\ kg}{5.0\ kg} \approx 0.0015,$$

which corresponds to

$Conc_{CL\ subst.\ W\ in\ painted\ article\ H}$= 0.15% w/w.

The same result is reached by using equation (2) in Box 2.

The concentration (w/w) of the Candidate List substance W in the paint (mixture P), $Conc_{CL\ subst.\ W\ in\ paint\ (mixture\ P)}$, is 5% w/w. However, this value needs to be corrected by a factor for the dry paint incorporated into article H, to take into account the volatile content of the paint (mixture P): 5%×(100/67) = 7.5% w/w (or 0.075 weight fraction). This value is equal to the concentration of the Candidate List substance W in the dry paint ($Conc_{CL\ subst.\ W\ in\ dry\ paint}$).

The concentration (w/w) of the dry paint in the painted article H is $Conc_{dry\ paint\ in\ coated\ article\ H}$ = weight of the dry paint (kg)/weight of the painted article H (kg) = 0.10 kg/ 5.0 kg = 0.020 (or 2.0% w/w)

The weight by weight content of the Candidate List substance W in the painted article H ($Conc_{CL\ subst.\ W\ in\ painted\ article\ H}$) is calculated as follows:

$$Conc_{CL\ subst.\ W\ in\ painted\ article\ H} = Conc_{CL\ subst.\ W\ in\ dry\ paint} \times Conc_{dry\ paint\ in\ painted\ article\ H}$$

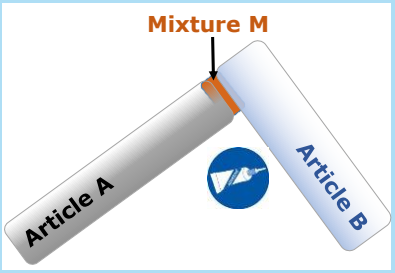
$$= 0.075 \times 0.020 = 0.0015$$

Thus,

$Conc_{CL\ subst.\ W\ in\ painted\ article\ H} = 0.15\%$ w/w

Example 9: Calculation of the concentration of a Candidate List substance in a complex object made up of two articles joined together using a mixture

An EU importer imports a complex object D which is the result of the combination of an article A (40 kg of weight), an article B (20.5 kg) and an adhesive resin (mixture M) which was used to join articles A and B (see scenario II in Table 5). After curing, the adhesive resin in the complex object D contains 8% w/w of the Candidate List substance Y and weighs 2.5 kg.



complex object D

The total weight of the Candidate List substance Y in complex object D is 0.2 kg, obtained by multiplying the weight fraction of the substance in the adhesive resin [=(8/100)] by the weight of the adhesive resin (2.5 kg).

The total weight of the complex object D is obtained by adding the weights of articles A and B and the weight of the adhesive resin: 40 kg + 20.5 kg + 2.5 kg = 63 kg.

Finally, the concentration of a Candidate List substance Y in the imported complex object D is calculated according to Table 5 (scenario II) over the total weight of the complex object. This is obtained by dividing the total weight of the Candidate List substance Y in complex object D (0.2 kg) by its total weight (63 kg) which gives 0.003 (=0.2 kg/63 kg), which corresponds to a concentration of 0.3% w/w.

The rationale described above is the same as using using equation (1) in box 1, when knowing:

- the weight of the Candidate List substance Y in the complex object D (CO D): $m_{CL\ subst.\ Y\ in\ CO\ D}$ = 0.2 kg;
- the weight of the complex object D: $m_{CO\ D}$ =63 kg.

Thus, the concentration (w/w) of the Candidate List substance in the complex object D ($Conc_{CL\ subst.\ Y\ in\ CO\ D}$) can be calculated as follows:

$$Conc_{CL\ subst.\ Y\ in\ CO\ D} = \frac{m_{CL\ subst.\ Y\ in\ CO\ D}[kg]}{m_{CO\ D}[kg/"complex\ object"]} = \frac{0.2\ kg}{63\ kg} \approx 0.003,$$

which corresponds to

$Conc_{CL\ subst.\ Y\ in\ CO\ D} = 0.3\%$ w/w.

The same result is reached by using equation (2) in box 2.

The concentration (w/w) of the Candidate List substance Y in the adhesive resin (mixture M) is $Conc_{CL\ subst.\ Y\ in\ mixture\ M}$ = 8% w/w (or 0.08 weight fraction).

The concentration (w/w) of the adhesive resin (mixture M) in the complex object D (CO D) is $Conc_{mixture\ M\ in\ CO\ D}$ = weight of the adhesive resin (kg)/weight of the complex object D (kg) = 2.5 kg/ 63 kg = 0.04 (or 4% w/w)

The weight by weight content of the Candidate List substance Y in the complex object D ($Conc_{CL\ subst.\ Y\ in\ CO\ D}$) is calculated as follows:

$$Conc_{CL\ subst.\ Y\ in\ CO\ D} = Conc_{CL\ subst.\ Y\ in\ mixture\ M} \times Conc_{mixture\ M\ in\ CO\ D}$$

$$= 0.08 \times 0.04 \approx 0.003$$

Thus,

$$Conc_{CL\ subst.\ W\ in\ coated\ article\ H} = 0.3\%\ \text{w/w}$$

3.2.3.2 How to determine the total amount of a Candidate List substance in different articles

One of the conditions of the **notification obligation** is the 1 tonne threshold per actor per year for the Candidate List substance present in all articles produced and/or imported, in a concentration above 0.1% w/w. This subchapter therefore illustrates how to calculate in practice the total tonnage of a Candidate List substance in different articles, in order to determine whether the tonnage threshold is exceeded or not.

The calculation of the total amount of a Candidate List substance present in all articles can be facilitated if certain articles can be grouped within the same "article type". The term "article type" is not defined under REACH; this term is introduced below, based in practical considerations, in order to give the possibility to article manufacturers/importers to group articles for notification purposes. However, this possibility to group articles for notification purposes should be used when appropriate only. Its purpose is to prevent the notifier from developing and submitting - and ECHA from receiving - multiple notifications containing exactly the same information, for the different articles falling under the same "article type". The term "article type" is used to refer to articles containing the same Candidate List substance which are similar enough to be grouped and described together as part of the same notification. Grouping articles under the same "article type" should not lead to the submission of a lower amount or lower quality of information. Examples of articles that may belong to the same article type are:

- wires made of the same alloy with different diameters,
- plastic tubes which differ only in size and thickeness, and
- handles of a foldback clip (see example 6).

Note that it is for the submitter of a substance in articles notification to decide on a case-by-case basis wether it is possible and practicable to group his articles by "article type". More detailed information on grouping under the same article type and more examples

are given in the *Manual - How to prepare a substance in articles notification*.[21]

The calculation of the total amount in tonnes of the same Candidate List substance in all articles produced or imported (either isolated or incorporated in complex objects), by the same actor, requires 3 steps:

1. Determination on whether the Candidate List substance in question is present at above the 0.1% w/w concentration threshold for each article produced or imported.

The calculation of the concentration of the Candidate List substances in articles or complex objects is done as described in subchapter 3.2.3.1.

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

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

If the weight by weight content of the Candidate List substance in the article is known or is calculated under step 1, then the amount in tonnes of the Candidate List substance is obtained by multiplying this value (concentration in weight fraction) by the total mass in tonnes of the produced or imported article (per year).

Only articles with the *same* concentration (see Table 5), can be grouped by "article type". When grouping articles, the total amount in tonnes of the Candidate List substance in each article type is obtained by multiplying the weight of substance per unit article (of that type) in tonnes by the total number of produced or imported articles per year.

Box 3

To calculate the total amount, in tonnes, of the Candidate List substance in each article or article type unit produced or imported per year ($m_{CL\ subst.\ in\ article\ type\ i}$) with a concentration of the Candidate List substance above 0.1% w/w, the producer or importer can use the following equation:

$$m_{CL\ subst.\ in\ article\ type\ i}\left[t/a\right] = \left(Conc_{CL\ subst.\ in\ article\ type\ i}\right) \times \left(\frac{m_{article\ type\ i}\left[kg/article\right]}{1000}\right) \times n_{articles\ type\ i}\left[articles/a\right] \quad (3)^{22,23}$$

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

$Conc_{CL\ subst.\ in\ article\ type\ i}$ is the concentration (w/w) of the Candidate List substance in the

[21] Available at https://echa.europa.eu/manuals

[22] 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.

[23] Please note that the term $Conc_{CL\ subst.\ in\ article\ type\ i}$ in w/w in equation (3) should be understood as meaning the weight fraction: values between 0 and 1 (100% w/w = 1, 50% w/w = 0.5, 25% w/w = 0.25, 20% w/w = 0.2, etc.). The $Conc_{CL\ subst.\ in\ article\ type\ i}$ in % w/w is obtained by multiplying the weight fraction value by 100.

article type i;

$m_{article\ type\ i}$ is the weight (in kilogram) per unit article of type i;

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

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

The total amount, in tonnes, of the Candidate List substance in all relevant articles produced or imported per year is calculated by summing up the amounts, in tonnes, calculated for each relevant article or article type under step 2.

Box 4

The total amount, in tonnes per year, of the Candidate List substance in all relevant article types (A, B, … n) produced or imported per year containing more than 0.1% w/w of the substance ($m_{CL\ subst.\ in\ all\ article\ types}$), can be obtained by summing up the amounts, in tonnes per year, calculated for each relevant article type ($m_{CL\ subst.\ in\ article\ type\ A}$, $m_{CL\ subst.\ in\ article\ type\ B}$, … , $m_{CL\ subst.\ in\ article\ type\ n}$) under step 2, using the following equation:

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

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, exceeds 1 tonne per actor per year, the producer/importer has the obligation of submitting a notification of substance in articles to ECHA for that Candidate List substance (see chapter 3.4.2). The notification should reflect all different articles and article types containing this Candidate List substance.

The examples 10 and 11 illustrate how to determine the total tonnage of a Candidate List substance in different articles and for articles in a complex object, respectively.

Example 10: Calculation of the total amount of a Candidate List substance in different articles

An EU producer produces 134 000 units of article G, per year, as described in example 7. Each article G has a total weight of 3.0 kg and contains the Candidate List substance W at a concentration of 0.2% w/w.

The same EU producer paints 360 000 units of article H, per year, as described in example 8. Each painted article H has a total weight of 5.0 kg and contains the Candidate List substance W at a concentration of 0.15% w/w.

The calculation of the total amount in tonnes of the Candidate List substance W in all articles produced per year is done by following the 3 steps explained in the text above.

Step 1. Determination of the concentration of the Candidate List substance W in each of the produced articles G and H.

The concentration of the Candidate List substance W in produced articles G and H was calculated in examples 7 and 8 in subchapter 3.2.1. As already mentioned above, the concentration of the substance is above the 0.1% w/w concentration threshold in both articles.

Step 2. Calculate the amount in tonnes of that Candidate List substance in each article

type produced per year where it is present above the 0.1% w/w concentration threshold.

Articles G:

The weight by weight content of the Candidate List substance W in an article G unit was calculated under step 1 and is 0.2% w/w, which corresponds to a weight fraction of 0.002. The total mass in tonnes of the produced 134 000 units of article G per year is calculated by multiplying that number by the weight of each unit in tons (3.0 kg/1000 = 0.0030 t): 134 000 (units/a) × 0.0030 (t/unit) = 402 t/a. The amount in tonnes per year of the Candidate List substance W in the produced articles G is obtained by multiplying concentration value in weight fraction (0.002) by the total mass in tonnes of the produced articles G per year (402 t/a): 0.002 × 402 t/a = 0.8 t/a.

The total amount of the Candidate List substance W in all produced articles G is 0.8 t/a.

The same result is reached by using equation (3) in box 3.
Thus, the total amount of the Candidate List substance W in all produced articles G ($m_{CL\ subst.\ W\ in\ articles\ G}$), in tonnes per year, can be calculated as follows:

$$m_{CL\ subst.\ W\ in\ articles\ G}[t/a] = \left(Conc_{CL\ subst.\ W\ in\ articles\ G}\right) \times \left(\frac{m_{articles\ G}[kg/article]}{1000}\right) \times n_{articles\ G}[articles/a]$$

$$= (0.002) \times \left(\frac{3.0}{1000}\right) \times 134000 = 0.8\ t/a$$

Articles H:

The weight by weight content of the Candidate List substance W in painted article H unit was calculated under step 1 and is 0.15% w/w, which corresponds to a weight fraction of 0.0015. The total mass in tonnes of the produced 360 000 units of article H per year is calculated by multiplying that number by the mass of each unit in tons (5.0 kg/1000 = 0.0050 t): 360 000 (units/a) × 0.0050 (t/unit) = 1800 t/a. The amount in tonnes per year of the Candidate List substance W in the produced articles H is obtained by multiplying concentration value in weight fraction (0.0015) by the total mass in tonnes of the produced articles H per year (1800 t/a): 0.0015 × 1800 t/a = 2.7 t/a.

The total amount of the Candidate List substance W in all painted articles H is 2.7 t/a.

[The same result is achieved by using equation (3) in box 3, as shown for article G above]

Step 3. Calculate the total amount in tonnes per year for all produced articles G and H. The total amount, in tonnes per, of the Candidate List substance W in all produced articles G and H by the producer, in tonnes per year, is obtained by summing up the amounts calculated for each article type G and H in the previous step: 0.8 + 2.7 = 3.5 t/a. This value is over the one tonne per year threshold.

The same result is achieved by using equation (4) in box 4.

Thus, the total amount, in tonnes per year, of the Candidate List substance W in all produced articles G and H ($m_{CL\ subst.\ in\ all\ articles\ G\ and\ H}$) can be obtained as follows:

$$m_{CL\ subst.\ in\ all\ articles\ G\ and\ H} = m_{CL\ subst.\ W\ in\ articles\ G} + m_{CL\ subst.\ W\ in\ painted\ articles\ H}$$

$$= 0.8 + 2.7 = 3.5\ t/a$$

Conclusion: The EU producer is required to submit an Article 7(2) notification for Candidate List substance W in the produced articles G and H.

Example 11: Calculation of the total amount of Candidate List substance(s) for a complex object

The EU importer mentioned in example 9 imports 1000 units per year of complex object D described in that example into the EU. This case is illustrated by scenario 2 in Table 5 (where the Candidate List substance Z in that scenario is the Candidate List substance Y in this example).

From the calculations in example 9, it is known that the complex object D contains the Candidate List substance Y in a concentration of 0.3% w/w, due to its presence in the cured adhesive resin used to join articles A and B. In addition to the information already provided in example 9, for the purposes of this example, the article A contains the Candidate List substance X at a concentration of 2.0% w/w and article B contains the Candidate List substance Y at a concentration of 6.0% w/w.

The calculation of the total amount in tonnes per year of the Candidate List substances X and Y in all imported complex objects D is done by following the 3 steps explained in the text above.

Step 1. Determination of the concentration of the Candidate List substances

The concentrations are known:

i) the concentration of Candidate List X in article A: 2.0% w/w,

ii) the concentration of Candidate List Y in article B: 6.0% w/w,

iii) the concentration of Candidate List Y in complex object D: 0.3% w/w,

Step 2. Calculate the amount in tonnes per year of Candidate List substances X and Y in articles and complex objects where they are present above the 0.1% w/w concentration threshold.

Articles A:

Following the same approach described in example 10, the amount in tonnes per year of the Candidate List substance X in articles A (incorporated in the imported complex objects D) is obtained by multiplying the concentration value in weight fraction (0.020) by the total mass in tonnes of the articles A [1000 (units/a) × 0.040 (t/unit) = 40 t/a]: 0.020 × 40 t/a = 0.80 t/a.

[The same result can be reached by using equation (3) in box 3]

Articles B:

The amount in tonnes per year of the Candidate List substance Y in articles B (incorporated in the imported complex objects D) is obtained by multiplying the concentration value in weight fraction (0.060) by the total mass in tonnes of the articles B [1000 (units/a) × 0.0205 (t/unit) = 20.5 t/a]: 0.060 × 20.5 t/a = 1.2 t/a.

[The same result can be reached by using equation (3) in box 3 above]

complex objects D:

From example 9, the total weight of the Candidate List substance Y in each complex object D is 0.20 kg. The amount in tonnes per year of the Candidate List substance Y in the imported complex objects D is obtained by multiplying that weight in tonnes by the number of imported complex objects D: 1000 (units/a) × 0.00020 (t/unit) = 0.20 t/a

Step 3. Calculate the total amount in tonnes per year of Candidate List substances X and Y in the imported complex objects D

The total amount, in tonnes per year, of the Candidate List substance X in articles A incorporated in the complex objects D is 0.80 t/a, since this substance is not present in articles B and in the adhesive resin (mixture M) used to make complex objects D. This value is below the one tonne per year threshold.

The total amount, in tonnes per year, of the Candidate List substance Y in articles B and in the complex objects D (as a result of using the adhesive resin (mixture M) to join the articles) is obtained by summing up the amounts calculated in the previous step: 1.2 t/a (articles B) + 0.20 t/a (complex objects D) = 1.4 t/a. This value is over the one tonne per year threshold.
[The same result is achieved by using equation (4) in box 4 above]

Conclusion: The EU importer
- is not required to submit an Article 7(2) notification for Candidate List substance X in article A;
- is required to submit an Article 7(2) notification for Candidate List substance Y in articles B and in complex objects D, as a result of using the adhesive resin (mixture M) to join the articles – see scenario II in Table 5.

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. Where there is uncertainty as to whether the 1 t/a tonnage threshold was reached, the producer and/or importer may choose to notify to ECHA even in cases where the tonnage is below that threshold. The production or the import of those articles may vary from one year to the other, depending on the market conditions. In this case, notifiers are encouraged to update their notification.

3.3 Exemptions from notification obligation

Two specific exemptions can apply to the notification of substance in articles:

(a) exemption based on exclusion of exposure and

(b) exemption for substances already registered for that use.

Note that it might require more resources and be more difficult to properly assess and document exclusion of exposure or to find out if the substance is already registered for the use, than to prepare and submit a substance in articles notification.

In the following subchapters some considerations on the applicability of the exemptions from substance in articles notification obligations are provided.

3.3.1 Exemption of substances already registered for that 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. This refers to any registration of that use of the substance in the same supply chain or any other supply chain, i.e. for this exemption from notification to apply, the registrant does not necessarily need to be in the same supply chain as the potential notifier.

In the particular cases where a producer or importer of articles has registration and notification obligations for the same substance in his articles, he is 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 is the same as the substance already registered;
- The use is the same as the use described in a registration of the substance, i.e. the registration refers to the use in the article.[24]

To ensure that the substance in question is the same as a substance that has already been registered, the names and numerical identifiers, such as EINECS number and CAS number, should be compared. In a number of cases, this is possibly not sufficient e.g. if the substance is a UVCB substance or if the entry in the candidate list does not contain these numerical identifiers. When deciding whether 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.

When deciding whether the substance can be regarded as already registered for that use, the potential notifier has to compare 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 the type of article.

Information on uses is based on the use descriptor system which includes elements specifying the sector of use (SUs), the type of products the substance can be found in (PCs), the type of releases to the environment (ERCs), the process types involved (PROCs) and the article category the substance ends up in (ACs). 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 notbe sufficient to conclude on the sameness of two uses for the purpose of establishing whether an exemption on the basis of Article 7(6) applies. **Therefore, the use in question has to be described more in detail than just by using elements of the use descriptor system.** For example, the Article Category 'Plastic articles' does not necessarily mean the registration is made to cover all plastic articles and all plastic materials. It could mean that use of the substance in some specific plastic articles is covered in the registration, while other plastic articles are not covered and assessed. The conclusion on whether the substance is considered as registered "for that use" and the considerations that led to it should be well documented in order to be able to demonstrate REACH compliance towards authorities, when required.

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

Article producers and importers seeking to apply the provisions of Article 7(6) have 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. Furthermore, it is recommended to document 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.

ECHA's dissemination portal for substance information, which can be accessed via the

[24] In this context, "use" includes the use of the substance in the production of an article and, after being incorporated into the article, the use of the substance in the article during its service life (period of time an article remains in service or in use). For an importer of an article, only the use of the substance in the article during its service life is relevant.

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. The description of the use available here for all life cycle steps consists mainly of elements of the use descriptor system, as well as use name and in some cases contributing activity names. The information will normally not be sufficient on its own to conclude on the sameness of two uses for the purpose of establishing whether an exemption on the basis of Article 7(6) applies.

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 the option 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 an 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(es) where the formulator of the mixture has incorporated the relevant information concerning the (safe) use into the main body of the SDS.[25]

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 level of detail provided by the descriptions of use 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 the substance can be identified (e.g. through the registration number in the SDS) and a manufacturer or importer of that substance asked for the uses he has registered this substance for, or whether he has registered it for the particular use.

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

The importers of articles that contain a Candidate List substance 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" .

[25] Further information on this issue may be found in chapter 7 of the "Guidance for downstream users".

They can obtain this information by:

- identifying manufacturers and importers of a substance who might have registered it for a particular use, for example through the available information on ECHA's dissemination portal or by searching on the internet, and then to contact directly the identified registrants;
- contacting trade associations, who might have information on the registration status of a particular substance and the uses the substance has been registered for.

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 use[26], including disposal[27].

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 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 stage[28] 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.
- Evidence or valid justification 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).
- Evidence or valid justification that the amounts of substance released from the article are contained by technical means or directly destroyed (e.g. during thermal

[26] The terms "normal conditions of use" and "reasonably foreseeable conditions of use" are explained in subchapter 4.1.
[27] 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".
[28] 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.

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 and its numerical identifiers (if available).
- 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 to demonstrate 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:
  - 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.
  - Whether or not articles are subject to abrasion (during normal wear and tear)
  - The disposal technology.

Some chemical substances are very firmly bound in the material, and the potential emission of these substances during use is therefore 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. Substances may also be released through normal wear and tear of articles (abrasion). In this case, the substances are released together with the article matrix, e.g. substances in car tyres.

3.4 What information to communicate and to notify

3.4.1 Communicating information according to Article 33

EU producers and importers of articles and all actors in the supply chain are required to communicate down the supply chain on the presence of the Candidate List substances (above 0.1% w/w). The information communicated should be sufficient to allow safe use of articles. While industrial/commercial actors in the supply chain should get this information as a matter of course, consumers have to request the information.

As the first actor in the article supply chain, an article producer or importer has to take into account all steps and activities involving his article down his supply chain, when identifying what information to compile and communicate. The actors further down the supply chain, who may have a more precise understanding of where and how the article is used by its next user(s), should each identify any additional information available to

them and relevant for the activities his customers carry out.

When identifying what information is necessary to compile and communicate to allow the safe use of the article, the supplier of an article has to consider all the life-cycle stages of the article. These can include e.g.:

- further industrial and professional processing or assembling of the articles;
- (re)packaging or storing the articles;
- industrial, professional and consumer end use of the articles, including installation and maintenance;
- recycling and disposal of the articles.

Furthermore, the supplier should consider foreseeable misuse of articles, in particular, by consumers.

For each life-cycle step, the information on safe use can include:

i. use conditions, e.g. temperature, outdoor/indoor, frequency, duration;
ii. risk management measures to reduce exposure and emissions, which are possible to apply in practice and effectively.

What information is relevant to be communicated should however be assessed and decided on a case-by-case basis, in order to ensure that it fits the purpose of ensuring the safe use of articles. Type and detail of information on any one article may differ depending on who the recipient is. For example, an industrial user would normally not need the advice that an article should be kept out of reach of children, whereas such information can be appropriate for consumers. Information on how to control exposure of workers to the substance when further processing an article would be relevant to an industrial and professional actor.

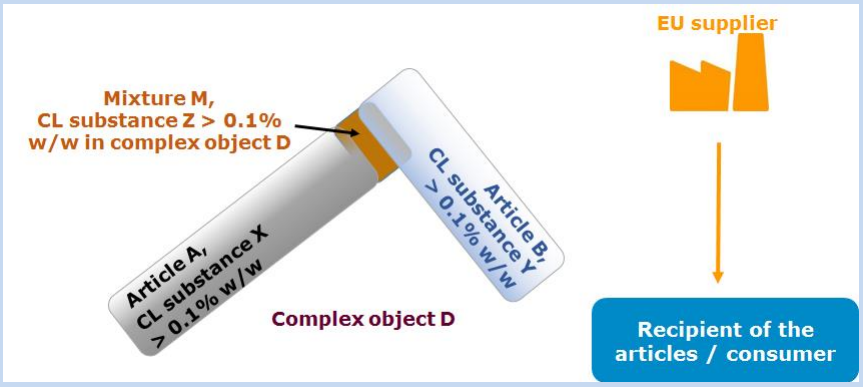
The identification of what safe use information is relevant for the recipient can also be guided by exposure/risk based considerations. If exposure of humans or environment is not possible or there is evidence that it is insignificant, the level of information needed is lower, i.e. the name of the substance may be sufficient. However, it should be kept in mind that, firstly, the communication obligations apply to substances of very high concern which are included in the Candidate List for authorisation, and secondly, exposure during all subsequent life-cycle stage including recycling and disposal should be considered.

All actors receiving information should follow the recommended use conditions and implement the recommended risk management measures. Moreover, they must pass on any relevant information to the next actor in the supply chain, or to consumers upon request, taking into account the expected uses and conditions of use of the article placed on the market.

In the case of complex objects, the communication requirements under Article 33 of REACH apply to each article, containing a Candidate List substance (>0.1% w/w), incorporated into a complex object. This is exemplified in example 12 for one case.

Example 12: What information to communicate when supplying a complex object

A company places on the EU market the complex object D (see scenario 2 in Table 3 and scenario 5 in Table 4 for further description of the case).



This supplier of articles is required to communicate information down the supply chain or to consumers upon request under Article 33 of REACH on the presence of
- the Candidate List substance X in article A,
- the Candidate List substance Y in article B,
- the Candidate List substance Z in complex object D

And any information needed, as a consequence of the presence of those substances, to ensure safe use.

The information should be compiled and structured in such a way that it can be communicated and used by its recipient in an efficient way. This is in particular important for very complex objects were much greater data-management and communications challenges arise.

The most appropriate **format for provision of information** may also vary, depending on the content and the addressee of the information (e.g. industrial or professional users, consumers).

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
- standard communication formats developed by industry sector associations
- IT systems or tools available to facilitate communication throughout the supply chain

The information to be communicated under Article 33 on Candidate List substances in articles can be combined/integrated with other legal communication requirements (e.g. under the General Product Safety Directive or sector specific legislation).

Regarding consumer requests according to Article 33(2), it is recommended to provide an answer to the request, even if there are no Candidate List substances present in the article, or if they are present at below 0.1% w/w.

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

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, although this is not a legal requirement. The notification should 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 REQUIREMENTS FOR 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 article[29]. **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.

[29] 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 13: Intended release of substances from articles

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

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

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

  Example: a size[30] 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 misuse of an article, i.e. against the producer instructions for use.

  Example: release from a tool, which a consumer uses (e.g. intensively during a long period of time) in disregard of the recommendations on operating time provided in the instructions for use.

- A release in an accident.

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

4.2 Registration 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

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

conditions of use[31] (this can be established by applying the criteria in section 3.1).

- The total amount of the substance present in all articles with intended release (i.e. including the amounts that are not intended to be released) produced or imported by one actor exceeds 1 tonne per year[32].

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 there is an applicable an exemption from registration; see subchapter 4.3) also their respective tonnage.

The tonnage of a *substance intended to be released* contained in articles, when knowing the (maximum) concentration of the *substance intended to be released* in the article as weight fraction, can be calculated by multiplying the total tonnage per year of *all articles* produced and/or imported by the (maximum) weight fraction of the *substance intended to be released* in the article. The total tonnage per year of *all articles* produced and/or imported can be obtained by multiplying the total number of articles by the weight of each article in tonnes per article.

Box 5

Following the explanation above, the tonnage of a *substance intended to be released* contained in articles can be thus calculated using the following equation:

$$m_{subs.}[t/a] = m_{articles}[t/a] \times Conc_{\max subs.\ in\ article} \qquad (5)$$

Where,

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

$m_{articles}$: 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.[33]

The total tonnage of articles produced and/or imported per year ($m_{articles}$) can be calculated using the following equation:

[31] Both of the conditions must be met, i.e. the intention to be released and the normal or reasonable foreseeable conditions of use.
[32] 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.
[33] Value between 0 and 1 (50% = 0.5, 25% = 0.25, 20% = 0.2, etc.)

$$m_{articles}\left[t/a\right] = m_{article\ unit}\left[t/article\right] \times n_{articles}\left[articles/a\right] \quad (6)$$

Where,

$m_{article\ unit}$: weight of one article [t/article].

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

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 in the article. Frequently, the concentration in terms of maximum weight fraction of the *mixture intended to be released* in the article is known, as well as, the concentration in terms of maximum weight fraction of the substance in the *mixture intended to be released* incorporated in the articles. When knowing these values, the multiplication of one by the other can be used to calculate the maximum concentration of the *substance intended to be released* in the article as weight fraction. Then, the tonnage of a *substance intended to be released* contained in articles can be calculated as already described above: multiplying the total tonnage per year of *all articles* produced and/or imported by the maximum weight fraction of the *substance intended to be released* in the article.

Box 6

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

$$m_{subs.}\left[t/a\right] = m_{articles}\left[t/a\right] \times Conc_{\max mixture\ in\ article} \times Conc_{\max subs.\ in\ mixture} \quad (7)^{34}$$

Where,

$m_{subs.}$ and $m_{articles}$ are defined in text box 6;

$Conc_{max\ mixture\ in\ article}$: maximum weight fraction of the *mixture intended to be released* in the article;[33]

$Conc_{max\ subs.\ in\ mixture}$: maximum weight fraction of the substance in the *mixture intended to be released*.[33]

Example 14: 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 by multiplying the total tonnage per year of the T-shirt produced (100 t/a) by the maximum weight fraction of the fragrance substance contained in the T-shirt (5/100=0.05): 100 × 0.05 = 5 t/a.

The same result can be reached by using equation (5) in box 5.

[34] Where $Conc_{\max mixture\ in\ article} \times Conc_{\max subs.\ in\ mixture} = Conc_{\max subs.\ in\ article}$

$$m_{subs.}[t/a] = m_{articles}[t/a] \times Conc_{\max subs.\ in\ article} = 100\ t/a \times 0.05 = 5\ t/a$$

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

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

- Not only the amounts intended to be released but the total amount in the articles needs to be considered. Thus, if the substance is also part of the article matrix, these amounts have to be considered as well.
- Only the amount of the substance that is actually in the final articles has to be considered,
  i.e. any amount that is incorporated in the articles and then lost during further production steps (e.g. through evaporation or wash out) does not have to be considered.
- If the same substance is intended to be released from different articles of one producer/importer, the substance volumes in all those articles have to be summed up[35].

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

4.2.1 Critical concentration level for substances in a *mixture 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. Since the tonnage threshold of the *substance intended to be released* in the articles is 1 t/a, the maximum weight fraction of the substance that can be in the *mixture intended to be released* without triggering registration obligations can be calculated by dividing this threshold value by the total weight of the mixture incorporated in articles. 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.

Box 7

[35] 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.

The maximum weight fraction of the substance that can be in the *mixture intended to be released* without triggering registration obligations ($Conc_{max\ subs.\ in\ mixture}$)[33] can be calculated using the following equation:

$$Conc_{\max subs.\ in\ mixture} = \frac{1\,t/a}{m_{articles}\,[t/a] \times Conc_{\max mixture\ in\ article}} \quad (8)$$

Where,

$m_{articles}$ and $Conc_{max\ mixture\ in\ article}$ are defined in text box 6.

Example 15: 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 dividing the 1 t/a threshold for substances contained in the fragrance mixture *intended to be released* in the toys by the total weight of the fragrance mixture incorporated in the toys [which can be calculated by multiplying the total weight of the toys imported every year 30 t/a) by the maximum weight fraction of the fragrance mixture in the toys (0.15 =15/100): 30 t/a × 0.15 = 4.5 t/a]: (1 t/a)/(4.5 t/a) = 0.22, which corresponds to 22% w/w.

The same result can be reached by using equation (8) in box 7.

$$Conc_{\max\ subs.\ in\ mixture\ of\ fragrances} = \frac{1\,t/a}{m_{toys(articles)} \times Conc_{\max\ mixture\ in\ toy(article)}} = \frac{1\,t/a}{30\,t/a \times 0.15}$$

$$= 0.22 = 22\%$$

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 requirements for substances intended to be released

The obligation to register substances intended to be released from articles identified as described in subchapters 4.2 does not apply in certain cases. This subchapter explains what has to be checked to establish if such an exemption applies.

4.3.1 General exemptions from registration requirements

A number of substances are exempted in general (i.e. whether on their own, in mixtures

or in articles) from registration[36] as sufficient information is known about these substances or registration are simply deemed inappropriate or unnecessary. Two of the most relevant exemptions[37] are for:

1. Annexes IV and V substances (exempted according to Article 2(7)(a) and (b)).
2. Recovered substances (Article 2(7)(d)).

The conditions set by REACH which have to be respected in order to benefit from these exemptions are described in the Guidance on registration.

4.3.2 Exemption of substances already registered for that use

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

For further information on this specific exemption applicable to the registration obligation for substances intended to be released in articles refer to subchapter 3.3.1.

4.4 Registration of substances in articles

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

[36] This exemption is also applicable to notification obligation for Candidate List substances.

[37] There are further general exemptions from registration that may apply to a substance, see the *Guidance on Registration* for more information also on these.

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 they are subject to substances in articles obligations. 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. Producers,importers and distributors of articles need to know if Candidate List substances are contained in their articles and at what concentrations.

This chapter provides general advice for suppliers of articles on how to obtain and then evaluate the information needed to comply with their substance in articles obligations. Appendix 5 provides complementary approaches for very complex objects, which nevertheless can also be useful for simpler complex objects or even for articles.

The main principles given in this guidance provide one approach to developing and implementing practical solutions which would ensure compliance with the requirements of the REACH regulation and achievement of its objectives. Other approaches may be acceptable, as long as they also ensure compliance with the Regulation and achievement of its objectives.

The level of effort for a company in obtaining the necessary information will largely depend on whether it has a quality management system and/or an alternative means of ensuring traceability of raw materials and articles compositions in place or not. Such 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. Certain tools, such as (IT) tools, can also be used to transfer information and manage communication in the supply chains, for risk assessment, and for product design and development.

Note that ECHA's dissemination portal also contains relevant information available on substances (e.g. identification, properties, uses) for suppliers of articles.

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 and efficient way of gathering the information needed in order to identify one's obligations under REACH. Chemical analysis, although a possible way to identify and quantify substances in articles, is time consuming, costly and difficult to organise.

5.1.1 Standardised REACH information from suppliers in the EU

Information needed to identify and comply with requirements for substances in articles under REACH can often be derived from standardised information that is required under other provisions of REACH from suppliers based in the EU. **Suppliers of substances or mixtures**, for instance, have to provide their customers with safety data sheets according to Article 31, or, where a safety data sheet is not required, with available and relevant safety information and details on regulatory requirements (e.g. 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.

An EU producer of articles receives an SDS for a Candidate List substance on its own or in a mixture used in the production of an article. Hence, information on a Candidate List substance incorporated in the produced article is available to the producer

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.

5.1.2 Voluntary information tools to exchange information on articles

Certain IT systems and tools facilitate the communication and transfer of standardised information in complex supply chains and streamline information flow. They may also help to identify and address the responsibilities of producers of articles, formulators and manufacturers of substances in specific supply chains.

Several sector-specific and more general information systems and tools have been 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.

5.1.3 Requesting information up the supply chain

Where the information received or available is not sufficient to check compliance and comply with REACH, producers, importers and other suppliers of articles may consider obtaining the necessary information by pro-active requests in the supply chain. Obtaining a comprehensive overview of the substances contained in articles and mixtures and their (exact) concentrations from supliers would be the best approach, in terms of efficiency, compliance, and anticipation of impacts of future regulatory actions. If this approach does not work or would be too costly to implement, then suppliers of articles should focus on critical information needed as an alternative. Hence, 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-EU 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.
- In many cases the exact composition of articles or mixtures, which can often be confidential information, is not needed to clarify whether requirements for substances in articles have to be fulfilled. For example, it may be possible to rule out notification or communication obligations for substances in articles 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. As a last resort, it is recommended that requests in the supply chain or criteria included in supply contracts are targeted 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.

- Information requests up the supply chain for substances in mixtures intended to be released from articles, should be focused on substances exceeding the concentration calculated to be critical as shown in subchapter 4.2.1. This is because the concentration 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**.

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 sector knowledge, publicly available information sources and conclusions from chemical analysis. A possible step-wise approach to identify and confirm which Candidate List substances may present in articles is provided in Appendix 3.

5.1.4 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 article suplier's compliance with REACH. In doing so the following aspects ought to be considered:

- What is being declared? Is this relevant to the article supplier, in particular producer or importer, to check compliance?
- 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, request access to any documentation supporting the declaration.

Likewise it is not advisable to accept without question test reports provided by suppliers. Such reports should be checked to make sure they demonstrate compliance. The following points should be taken into account when test reports are used to document checking for compliance.

- A test report should include the following elements:
  - Name and address of 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 check that that the test documented in the report was conducted with the product as currently 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 their production. Such analyses performed routinely for checking compliance with other legislation or for 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 Challenges of chemical analyses

Where chemical analysis of substances in articles is undertaken, the following issues have to be kept in mind.

- 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 it[38].
  - 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. Note that substances may consist of several constituents (for more information please consult the Guidance on substance identification).
  - Some analytical methods may show the presence of certain elements (e.g. halogens) rather than the presence of specific substances.
  - If the identity of the substances of potential concern is not known it may be difficult to assign suitable analytical methods. Furthermore, where a large number

[38] 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.

of different substances are contained, incorporated in an article several analyses may be needed to identify all the substances.

- Quantitative measurement of substance concentrations requires additional analysis.

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.

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 the presence ofgaseous substances can be excluded).
- 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. Topics covered by other guidance documents

Importers, producers and other suppliers of articles may also have other roles and thus have further obligations under REACH than those described in detail in the present guidance. For example: if an article producer purchases substances inside the EU for use in the production process of his articles, he also has to fulfil downstream user requirements.[39] if the substances are instead purchased outside of the EU, the article producer has the role of importer of substances along with the related obligations, such as registration.[40] 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. Appendix 2 lists relevant parts of the REACH Regulation for producers, importers or suppliers of articles.

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

Figure 5 below shows the main REACH processes or activities that may affect producers and importers of articles. It also identifies the main relevant lists of substances available on ECHA's website.

[39] Please refer to the *Guidance for Downstream users* at http://echa.europa.eu/guidance-documents/guidance-on-reach.
[40] Please refer to the *Guidance on registration* at http://echa.europa.eu/guidance-documents/guidance-on-reach.

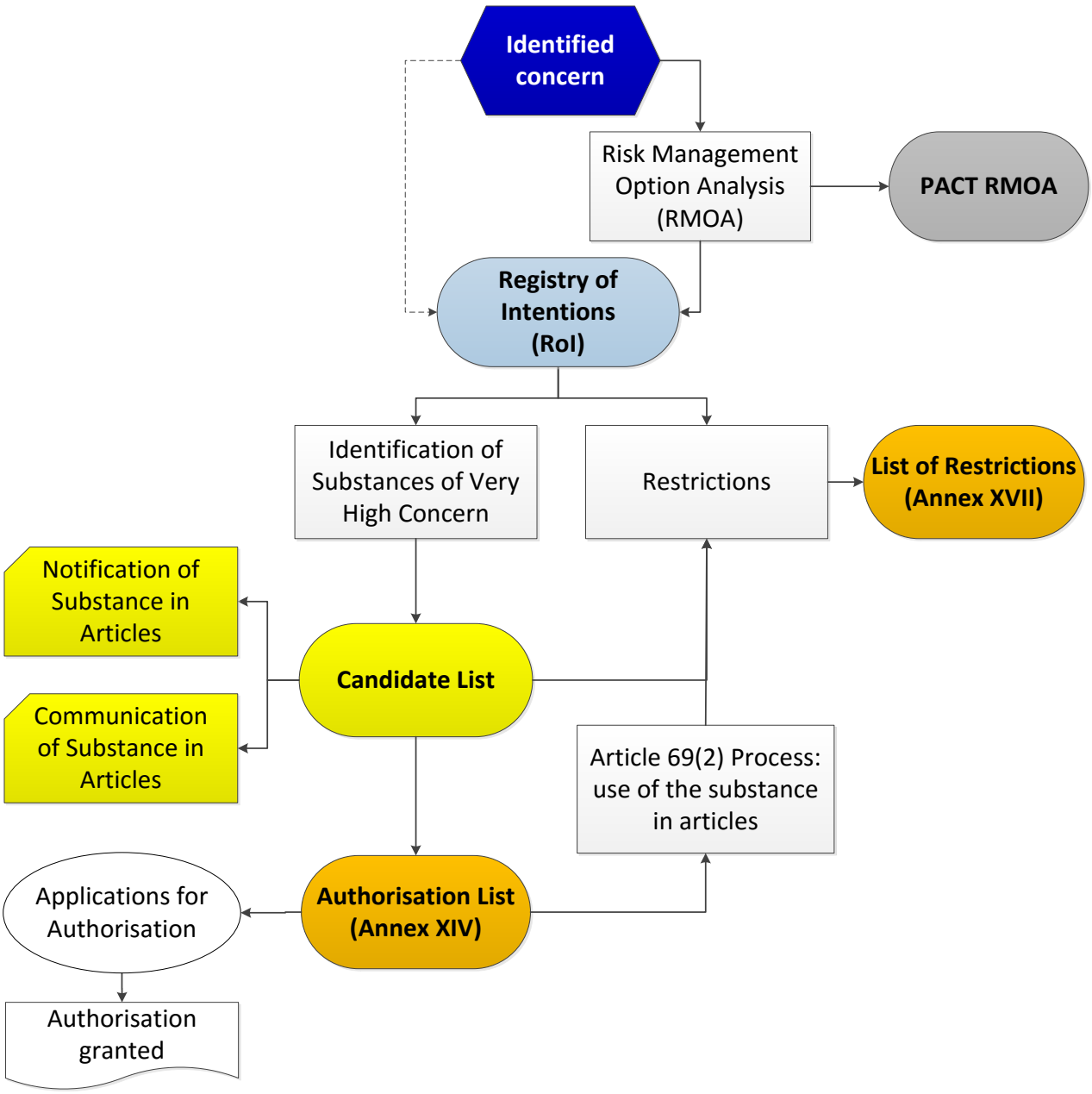


Figure 5: REACH processes or activities that may affect producers and importers of articles and the relevant lists of substances.
Note that the dashed line means that a substance may be included in RoI without having gone through an RMOA by an authority; ▭ represents a process or activity; ⬭ indicates a list of substances available on ECHA's website (in orange or yellow, the lists mentioned in the legal text, in grey the list that is not, and in light blue the list that has both characteristics [41]), ▭ indicate obligations of industry covered in this guidance.

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

[41] For example, the RoI dedicated to restriction's annex XV is mentioned in Article 69(5) of REACH.

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

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 EU 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 EU-supplier of an Authorisation List substance must communicate that fact in section 15.1 of the safety data sheet (SDS)[42] or when applicable 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.[43] 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 the preparation of an application for authorisation.[44]

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

The content of substances in articles can be restricted or banned under the **restrictions** procedure.[45] Article producers and importers have the obligation to comply with the restrictions and conditions set out in Annex XVII of the REACH Regulation[46]. The list of substances subject to restrictions in Annex XVII is available on the ECHA website.[47]

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 subsection 15.1 of the SDS or when applicable in other information supplied 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 (Article 31(9)(c) of REACH).

For an Authorisation List substance and after the sunset date, according to Article 69(2) of REACH, ECHA assesses whether the risks for the uses of that substance in articles are

[42] 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.
[43] For more information, please refer to the *Develop an application strategy* webpage at http://echa.europa.eu/applying-for-authorisation/develop-an-application-strategy.
[44] Please refer also to *How to apply for authorisation* webpage at http://echa.europa.eu/applying-for-authorisation.
[45] The general procedure is set out in Articles 69 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/.
[46] 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.
[47] Available at: https://echa.europa.eu/addressing-chemicals-of-concern/restrictions/substances-restricted-under-reach.

adequately controlled. If ECHA concludes that they are not, then ECHA prepares an Annex XV dossier proposing a restriction for those uses. Such a proposal may result in a restriction on the presence of that substance in articles, including imported articles.[48]

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, Directive 2000/53/EC on end-of life vehicles (ELVs) or Regulation 850/2004 on persistent organic pollutants (POPs).

[48] 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

Appendix 2. Parts of the REACH Regulation of particular relevance for suppliers of articles

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 (covered by this guidance).
- **Article 7** defines under which circumstances article producers and importers have to register or notify substances in articles (partially covered by this guidance).
- **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 (covered by this guidance).
- **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.

Appendix 3. Borderline cases between articles and substances/mixtures in containers or on carriers

Subchapter 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 6: Summary of borderline cases described in Appendix 3

Object	Conclusion	
	article with an integral substance/mixture	combination of an **article** (functioning as a container or a carrier material) and a **substance/mixture**
printer cartridge		**x**
spray can with paint		**x**
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 7: Borderline cases of substances/mixtures in containers
(continued in table 8)

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.
Conclusion	combination of an article and a substance /mixture	combination of an article and a substance /mixture	see table 9

Table 8: Borderline cases of substances/mixtures in containers (continuation of table 7)

Object	Battery	Desiccant bag	Detector tube[49]
Function	Provide electric current	Absorb air humidity	Measure concentration of substances in air
Question 4a: If the substance/mixture were to be removed or separated from the object and used independently from it, would the substance/mixture still be capable in principle (though perhaps without convenience or sophistication) of carrying out the function?	**NO**, the electrolyte and the electrode active materials as such cannot provide any electric current outside the battery. Housed in other containers without the specific design of a battery, they would also fail to provide energy. The "container part" of the battery, empty of the electrolyte, is also not able to fulfil its function. However, there are different types of electrolytes which could be used in one battery casing.	**YES**, the desiccant substance would still absorb humidity.	**NO**, the printed scale on the detector tube is necessary to read the measured concentration.
Question 4b: Does the object act mainly (i.e. according to the function) as a container or carrier for release or controlled delivery of the substance/mixture or its reaction products?	**NO**, the electrolyte and the electrode active materials are not released from the battery, thus the container does not have a function of "delivering" it and does not control its release.	**NO**, the desiccant is not released from the bag.	**NO**, it is not the intention to deliver a substance, because the intention of this object is that the chemical reaction takes place within the object.

[49] 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[49]
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 9	combination of an article and a substance/mixture	see table 9

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Table 9: Additional indicative questions for borderline cases of subs./mixtures in containers

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

Table 10: 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[50] and the wipe is disposed of separately.	**YES**, the mixture is burnt during the use phase of the candle.
Conclusion	combination of an article and a substance/mixture	combination of an article and a substance/mixture	combination of an article and a substance/mixture

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

Table 11: Applying indicative questions to pressure sensitive adhesive tapes[51]

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 article and a substance/mixture	see table 8

[51] 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 12: Applying additional indicative questions to pressure sensitive adhesive tapes

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

Appendix 4. Examples of setting the borderline between substances/mixtures and articles in the processing sequence of natural or synthetic materials

In subchapter 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, drawing conclusions on the status of the same type of raw material in different sectors should be avoided, as the material 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 subchapter 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, textiles (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.

Example 16: 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.

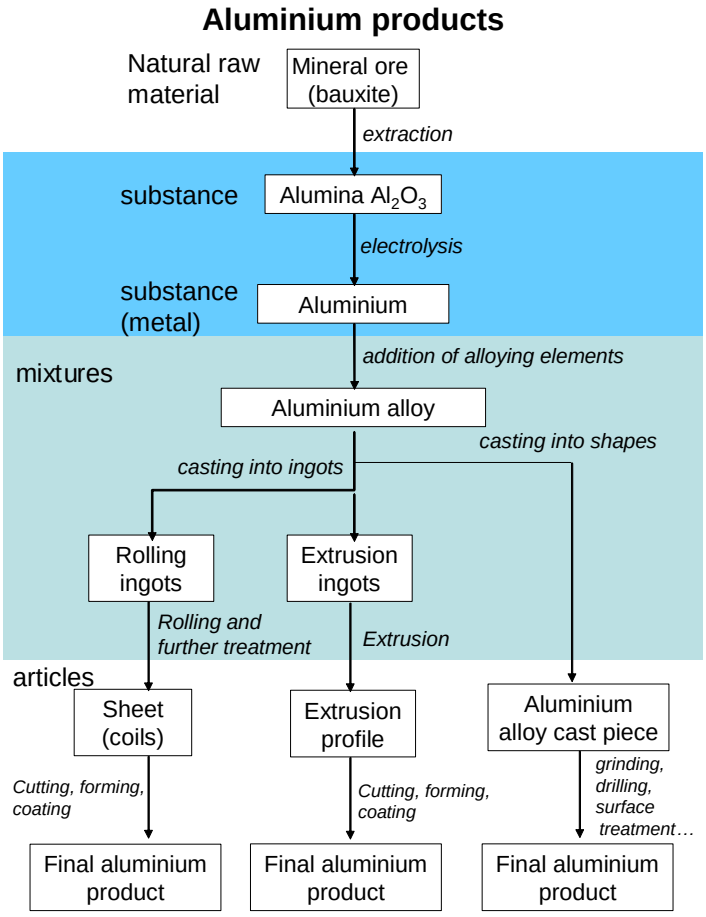

Figure 6: Transition from bauxite to final aluminium products

The transition point from mixture[52] 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.

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

Table 13: 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 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 6 above are discussed with regard to the borderline between mixture and article status.

Aluminium alloy – rolling ingots – coils

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

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

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

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

Aluminium alloy – extrusion ingots – extrusion profiles

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

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

The extrusion process significantly changes the form of the ingots in many ways, whereas the processing steps carried out with the extrusion profiles only result in modifications of that basic shape. This shows that the transition point of the material should be after the extrusion process. The basic chemical composition of the material (aluminium alloy) is not changed during the entire processing, although through coating or surface treatment (e.g. anodising) or lubrication (e.g. greasing, oiling, etc.) substances/mixtures may be added. Also in this case, the question is not helpful in determining the transition point.

Table 14: 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.

Example 17: 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.

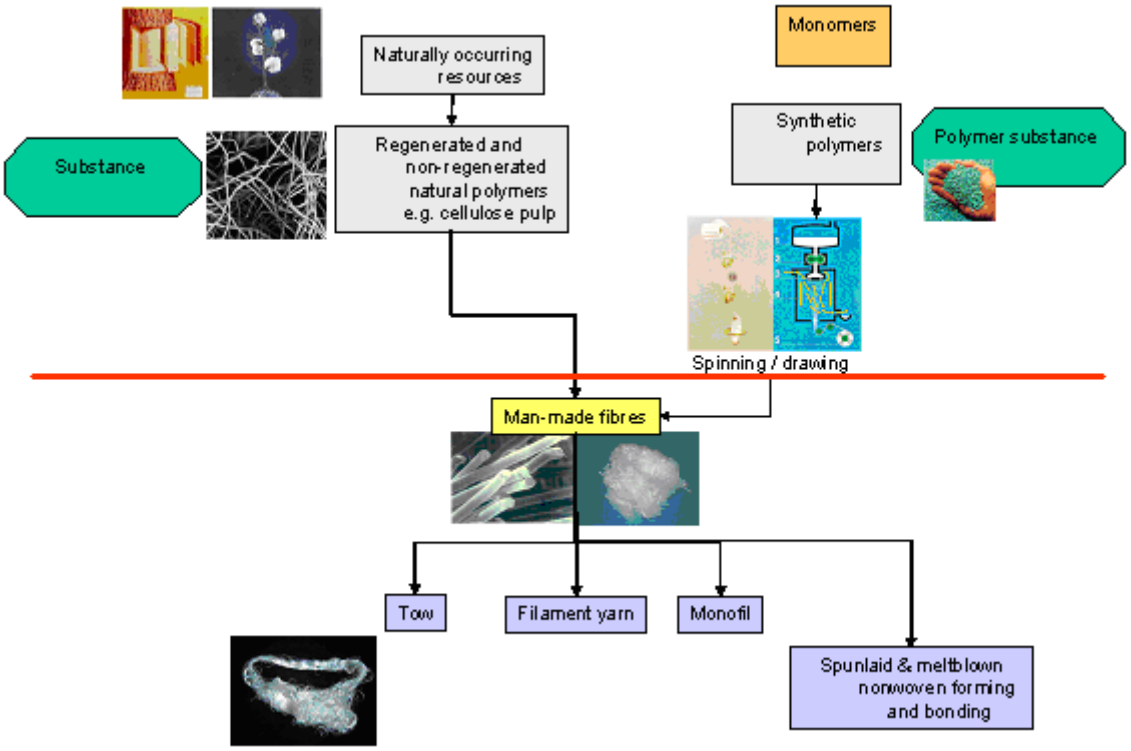

Figure 7: Transition from raw materials to final textile/non-woven products

Table 15: Applying indicative questions to different stages of textile/non-woven processing

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

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

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

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

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

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

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

Example 18: 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.

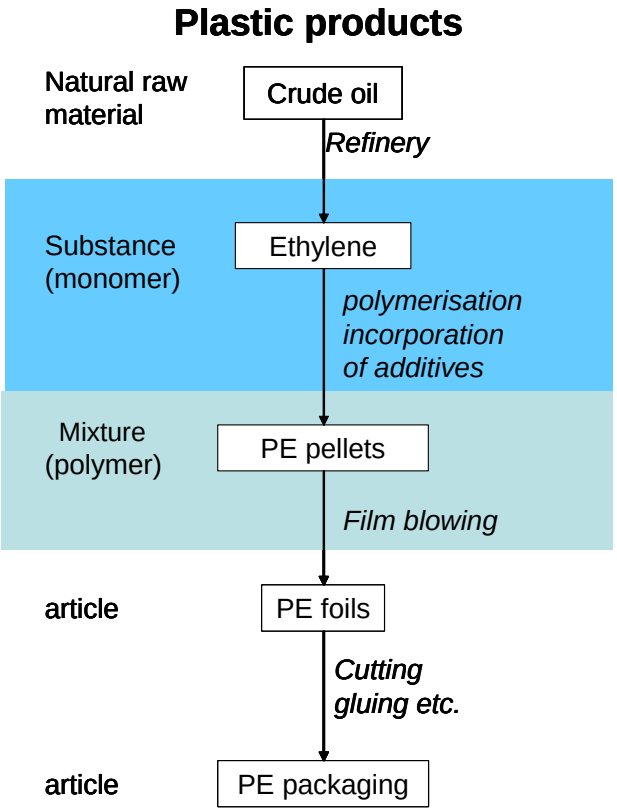

Figure 8: Transition from crude oil to plastic products

Table 16: 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.

Example 19: Paper processing

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

Figure 9: Illustrative example of the general transition point from wood to paper articles

Table 17: Applying indicative questions to different stages of paper processing

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

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

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

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

Appendix 5. Hints for facilitating the fulfilment of the requirements for Candidate List substances in articles

This appendix complements chapters 3 and 5 of the guidance. It proposes possible approaches and examples to overcome difficulties that may arise when trying to identify which Candidate List substances could be contained in articles incorporated in complex objects. .

Very complex objects are the main focus of these approaches and hints. However, they can also apply to simpler complex objects and even to (individual) articles.

The assessment of the Candidate List substances in articles requirements must always be done case-by-case for each article in a complex object, and depending in particular on the manner they werejoined or assembled together. The principles provided in chapter 3 for simple scenarios are applicable to the simplest as well as the most complex objects.

The determination of the presence and concentration of Candidate List substances in all articles joined or assembled together in a very complex object 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. Depending on the case and position in the supply chain, actors may need to use either a "bottom-up" approach (i.e. from the simplest components – articles or simplest complex objects - to the very complex object) or "top-down" approach (i.e. from the very complex object to the simplest components), or a combination of both, for all articles incorporated in such an object, in order to obtain the necessary information to fulfil their obligations.

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 where articles are joined or assembled together. It is recommended always to document the approches applied and basic considerations so that each duty holder is able to justify his conclusions towards customers and national enforcement 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. There are some public sources, including information on ECHA's dissemination portal or other hints given in ECHA's website, 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.

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

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

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. *Identify all articles (e.g. in a very complex object) and 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: polyethylene (PE), polypropylene (PP), polycarbonate (PC), Polyvinylchloride (PVC), polystyrene (PS), Acrylonitrile-butadiene-styrene (ABS), polyesters, polyurethanes, nylons, epoxy resins, 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;[53]
- 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);
- main uses of substances and materials in articles;[54]
- 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.

Step 4. *Confirm the presence of the identified Candidate List substances in the articles concerned.*

[53] For a definition and list of technical functions refer to chapter R.12 Use description of the Guidance on information requirements and chemical safety assessment.
[54] For example, by using use descriptors sector of use category (SU), chemical product categories (PC) and/or article category (AC), or more specific information available. For further information on use descriptors and how to describe uses refer to chapter R.12 Use description of the Guidance on information requirements and chemical safety assessment.

The confirmation of the presence of Candidate List substances in the articles could be done by requesting information up in the supply chain and evaluating the information provided by suppliers as explained in subchapter 5.1. Chemical analysis can also be used as a complementary intrument to information flow in the supply chain, as explained in subchapter 5.2.

Some difficulties can arise when applying this approach. For example, it may be difficult to identify Candidate List substances present as impurities either from the production or manufacturing processes or by contamination. Furthermore, importers may also encounter difficulties onthe use of certain Candidate List substances in imported articles not used anymore in the EU in the manufacture or production of materials or articles, i.e. if they are not aware of past uses of those substances.

Example 20: 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 articles incorporated in the jacket in order to identify communication obligations under Art. 33 of REACH and potential obligation to notify Candidate List substances under Article 7(2).

By following the steps above, the article importer can identify Candidate List substances that are more likely to be present in the different articles assembled or joined in an outdoor jacket to request further targeted information from his non-EU supplier. These steps on their own do not allow certainty on whether a particular Candidate List substance is present.

In step 3, the importer focuses his searches for 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 PC34);
- the manufacture or processing of the materials in the table above, in particular those with relevant technical functions likely to provide 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 wishes to know if there are Candidate List substances that less likely to be present in the identified materials. For that, the importer also searches for information on Candidate List substances that are less likely to be present in those 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 a position to request further target information from his non-EU supplier.

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 confidence on compliance and also reduce costs for potential chemical analyses, 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 a very complex object

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 21: Articles joined or assembled together in a very complex object - 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 may 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, capacitors, resistors, transistors, inductors, diodes, microprocessors, microchips, fans, screws, among other objects. These objects are often mounted together by using substances/mixtures (e.g. solders, adhesives). 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 separately. 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.

The most useful way to identify the articles incorporated into a printed circuit board is to trace back in the supply chain until the point at which one or more substances or mixtures were converted to an article and/or incorporated into an article or into a complex object (e.g. coating, adhesive).

If such an identification cannot be done based on the information available, an EU importer or EU producer may use other rules of thumb to try to identify each article in the printed circuit board.

For example, the concerned actor may consider all of the following:

(a) articles and complex objects which can be physically disassembled or separated; and then do the same for each complex object individually until all articles are identified;

(b) objects which were already articles (not substances or mixtures) before they were assembled or joined in the printed circuit board (including ones that can no longer be physically disassembled or separated);

(c) materials which were incorporated in articles or complex objects by using substances or mixtures (e.g. coatings, adhesives, solders).

This approach may trigger further communication with suppliers up in the supply chain. The relevant supply chain(s) must be followed as suggested above to get the necessary information for compliance.

The principles set out in chapter 3 are applicable in regard to the use of Candidate List substances or mixtures containing Candidate List substances that are incorporated in the printed circuit board or any other article or complex object in it.

In principle, EU actors that only assemble the printed circuit board should receive relevant information from suppliers resulting from their obligations under REACH (e.g. Article 31 or 32 for substances or mixtures, Article 33(1) for articles). Importers of printed circuit boards should ensure that they get enough information to comply with their communication and notification obligations (e.g. within the framework of contracts

with non-EU suppliers).

A printed circuit board comprises a large number of articles and complex objects. Hole-mounted capacitors are examples of such complex objects within a circuit board.

The hole-mounted capacitors are soldered or glued onto printed circuit boards by the producer of the printed circuit boards. A capacitor is made from e.g. conductors, the dielectric, connectors, wires and the casing.

The approach described above for the printed circuit board is applicable e.g. to the capacitor, in particular the identification of all articles incorporated in it. Applying that approach, the EU producer of a printed circuit board should obtain relevant information on the components of the capacitor from his supplier. An importer of a capacitor may obtain relevant information on the components of the capacitor (and potentially on how it was produced) from his non-EU supplier.

In order to comply with communication and notification obligations regarding the capacitor, the EU importer or the EU producer of the printed circuit board should get information on the presence of Candidate list substances above 0.1% w/w in the articles incorporated in the capacitor in accordance with the principles set out in chapter 3. In addition, and where possible in practice, the approaches set out in Chapter 5 may apply.

What was above described for the capacitor is applicable to any other complex object (e.g. transistor, microprocessor, fan) in the printed circuit board.

Appendix 6. Illustrative cases for checking if the requirements under Articles 7 and 33 apply

This appendix contain examples aiming at covering several issues in a more overarching manner. They illustrate how to apply the different steps in the flow chart shown in Figure 1 in subchapter 1.2. (and ultimately how to use the Guidance) to check the registration requirement under Article 7(1) of REACH (example 22) and the communication and notification requirements under Articles 7 and 33 (example 23). Note that the assessment of the substances in articles requirements should always be done case-by-case.

Example 22: Scented children's toys

The scented children's toys addressed in **this** example are articles (not complex objects) and contain fragrance substances - with an intended release. The case is chosen to illustrate how an importer of articles can assess if registration obligations apply and evaluate the information provided by the non-EU supplier on the substances contained in the imported article from his non-EU supplier.

Information provided by the non-EU supplier:

- Information on content of substances to be released: (a) the lemon scented toy contains D-limonene (fragrance); (b) there are no Candidate List substances on the frangrance mixture intended to be released.

The following is assumed:

- Import per year: 1 million scented toys
- Weight of toy (article) containing the fragrance mixture: 20 g
- No information on registration
- No information on the presence of Candidate List substances in the toy, besides that for the fragrance mixture.

Substance identification

In order to obtain information on the substances to be released from the lemon scented toys (articles), 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/MS[55].

A total of 11 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[56]. 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

[55] GC/MS - Gas chromatography/mass spectrometry
[56] Or in table of harmonised entries in Annex VI to CLP available at http://echa.europa.eu/information-on-chemicals/annex-vi-to-clp

obtained from ECHA's C&L Inventory.

Information on D-limonene in the toys

Substance identifiers	*Harmonised Classification*	*Concentration in the toy (mg/kg)* [57]
Name: D-limonene *EC no. 227-813-5* *CAS no. 5989-27-5* *Index no. 601-029-00-7*	*Flam. Liq. 3; H226* *Skin Irrit. 2; H315* *Skin Sens. 1; H317* *Aquatic Acute 1; H400* *Aquatic Chronic 1; H410*	*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.

The importer can also calculate how many toys can be imported before reaching the threshold of 1 t/a for D-limonene. That number can be calculated by dividing the tonnage threshold for the substance by the quantity of that substance in each article in tonnes per article. In this case, (1 t/a)/(16×10^{-9} t/toy) = 62.5×10^{6} toys/a, this is the importer can import 62.5 million toys per year before reaching the threshold of 1 t/a for D-limonene, which triggers registration obligations.

Box 8

The maximum number of articles that can be imported (or produced) before reaching the tonnage threshold of 1 t/a ($n_{max\ articles}$) for a substance intended to be released from the articles, which trigger registration obligation, can also be calculated using the equation below.

$$n_{\max articles} = \frac{1\,t/a}{Conc_{subst.\ in\ article} \times m_{article\ \ unit}\left[t/article\right]} \qquad (9)$$

Where,

$Conc_{subs.\ in\ article}$: weight fraction of the *substance intended to be released* in the article;
$m_{article\ unit}$: weight of one article [t/article].

In this example:

$$n_{\max toys} = \frac{1\,t/a}{Conc_{subst.\ in\ toy} \times m_{toy\ \ unit}\left[t/toy\right]} = \frac{1}{\left(800\times10^{-6}\right)\times\left(20\times10^{-6}\right)} = 62.5\times10^{6}\ \text{toys/a},$$

The result calculated using equation (9) is the same as that explained in the text.

[57] According to the Toys Safety Directive (Directive 2009/48/EC), when D-limonene is added to a toy or components thereof at concentrations exceeding 100 mg/kg, the name of this substance shall be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet.

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 toy (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 an SVHC included in the Candidate List?
(consult chapters 4 and 5)

As the importer has limited information provided by the non-EU supplier and the results from the chemical analysis that he decided to undertake, he could do the following to obtain more information on the presence of Candidate List substances in the toys:

1) Check the supply chain (non-EU supplier) 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 Candidate List substances are not present in the article.

2) 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 Candidate List substances (see appendix 3). Based on his findings, he may request further information from his non-EU supplier.

3) Plan and perform screening for substances on the Candidate List by analytical methods if no information is obtained from the non-supplier 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) Check if the concentrations of substances identified in the screening analysis are above the 0.1% w/w concentration threshold; If the concentration is above, calculate the amount those substances and assess whether the tonnage threshold for notification 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 articles.

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 and the weight of each toy 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 4.3.2 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 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.

Example 23: Bicycle

A bicycle is an example that illustrates a case where a complex object is produced by combining a number of articles (or simpler complex objects) 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 of the same type per year. The importer asked his non-EU supplier for a general description of the bicycles and articles contained in each of them, as well as for specifications for the bicycles and articles contained in each of them. In order to comply with his 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 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 his 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, wheel prism reflectors, rear reflector, lamp, lamp housing, bolts, nuts, o-rings etc.

The importer can already identify articles in some complex objects (e.g. painted frame,

saddle, seat post, rims, spokes, wheel 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, tyre inner tubes, brakes). For these, the importer needs to request further information from his non-EU supplier on the articles and materials 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 exemplifies materials that may be present in the composition of (individual) articles or objects in the bicycle. It is not intended 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, wheel prism reflectors, rear reflector, lamp housing
Rubber	Tyres, tyre inner tubes, rim brake pads (brakes), o-rings
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
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 complex 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;
- the materials the articles/objects are made of (when that information was not yet available);
- 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.

Following the 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;
- The painted metal frame;
- The inner inflatable tubes (inserted between the tyres and the wheel rims);
- The tyres.

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 produced by an injection moulding process.

The handlebar grips weigh 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 doughnut-shaped tube weighs 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 weighs 7.0 kg with a total tube length of 2.5 m and a diameter of 3.0 cm. The paint coating has a thickness of 0.2 mm and a density of 2.0 g/cm^3. The non-volatile substances content (solids) of the paint used is 45% w/w and it contains a Candidate List substance 3 at a concentration of 1.8% 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, combined and impregnated with a rubber mixture in a roller machine. Each 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 high temperature. The curing process stimulates vulcanization between the different rubber materials providing the final shape and design of the tyre.

The nylon fibres in the cloth and the steel wires in 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 Candidate List substance 4 at a concentration of 1% w/w. The weight of the rubber in the casing is 0.15 kg, in the tread 0.20 kg and in the beads 0.030 kg. The cured tyre, containing the nylon cloth, the bundled steel wires and the rubbers, weighs 0.50 kg. During vulcanization, the rubber materials of the beads, the casing and the treads are cured together resulting in the final rubber part of the tyre body. These rubbers with different compositions cannot be separated anymore after vulcanization. Vulcanisation seems to change the shape and surface of the covering rubber layer of the bundled steel wires in the beads, since after that process, it becomes integrated in the final rubber tyre body.

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

Example: Bicycle - handlebar grips, tyre 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, tyre 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 tyre inner inflatable tubes, the painted metal frame and tyres incorporated in the bicycle are themselves articles or complex objects containing 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	0.05	*Not applicable*
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.

<u>Painted metal frame</u>

Data on the painted metal frame:
- Weight of the painted metal frame: 7.0 kg
- Total tube length: 2.5 m
- Tube diameter : 3.0 cm = 0.030 m
- Paint coating thickness: 0.2 mm = 0.0002 m
- Density of dry paint: 2 g/cm^3
- The non-volatile substances content (solids) of the paint used: 45% w/w
- The concentration of the Candidate List substance 3 in the liquid paint: 1.8% w/w.

The weight by weight content of the Candidate List substance 3 in the painted metal frame ($Conc_{substance3.\ in\ frame}$) is obtained by dividing the weight of the Candidate List substance 3 in the painted metal frame ($m_{substance3.\ in\ frame}$) by its total weight ($m_{painted\ frame}$=7.0 kg).
[*This is the same as using equation (1) in Box 1*]
However, the weight of the Candidate List substance 3 in the painted frame is not known and needs to be calculated. Its value is equal to the quantity of that substance in the dry paint incorporated into the frame, which is calculated in three steps.
First, we calculate the weight of dry paint incorporated in the frame. This quantity is calculated by multiplying the volume of the paint incorporated in the frame, which is obtained by multiplying the painted surface area by the thickness of the paint layer, by the density of the dry paint:
Total surface painted (approx.): (total tube length) × (tube diameter × π) = 2.5 m × (0.030 m × π) ≈ 0.24 m^2
Volume of dry paint: total area painted × paint coating thickness = 0.24 m^2 × 0.0002 m = 4.7×10^{-5} m^3
Weight of dry paint: volume of dry paint × density of dry paint = (4.7×10^{-5} m^3)× (2×10^3 kg/m^3) = 0.094 kg
Second, we calculate the quantity of the (liquid paint) used for painting the frame. The mass of dry paint incorporated into the frame is equal to the non-volatile content of the paint. Therefore, the weight of paint used is calculated by multiplying the weight of dry paint (0.094 kg) by the factor 100/45, which gives: 0.094 kg × (100/45) = 0.21 kg.
Third, the weight of Candidate List substance 3 in the paint incorporated in the frame is obtaining by multiplying the weight fraction of the substance (1.8% w/w = 0.018) by the quantity of paint used for painting: 0.018 × 0.21 kg = 0.0038 kg.

Finally, as mentioned above, the weight by weight content of the Candidate List substance 3 in the painted metal frame is obtained by dividing $m_{substance3.\ in\ frame}$=0.004 kg by $m_{painted\ frame}$=7.0 kg: 0.0038 kg/7.0 kg ≈ 0.00054 = 0.05% w/w.

The Candidate List substance 3 concentration in the frame is 0.05% w/w, which is not above the 0.1% w/w concentration threshold.

The concentration (% w/w) of the Candidate List substance 3 in frame ($Conc_{substance3.\ in\ frame}$) can also be calculated using the equation (2) in Box 2.

The concentration of the Candidate List substance 3 in the dry paint ($Conc_{substance.3\ in\ paint}$) needs to be corrected by a factor of 100/45 due to the (semi-)volatile substances contained in the paint which evaporate during the incorporation of the paint in the metal frame. Thus, $Conc_{substance.3\ in\ paint}$ = (100/45)×1.8% = 4.0% w/w.

The concentration of the paint in painted metal frame is calculated as follows: $Conc_{paint\ in\ frame}$ = 0.094 kg/7 kg = 1.3% w/w.

Thus, the concentration (% w/w) of the Candidate List substance 3 in the frame is given by:

$$Conc_{substance.3\ in\ frame} = Conc_{substance.3\ in\ paint} \times Conc_{paint\ in\ frame} = (0.040)\times(0.013) \approx 0.05\%\ w/w$$

Tyre

Data on the tyre:

- Total weight of the cured tyre: 0.50 kg
- Weight of casing rubber in the tyre: 0.15 kg
- Candidate List substance 4 concentration in the rubber casing: 10% w/w

- Weight of tread rubber in the tyre: 0.20 kg
- Candidate List substance 4 concentration in the rubber tread: 4% w/w
- Weight of the rubber layer of the two beads: 0.030 kg
- Candidate List substance 4 concentration in the rubber beads: 0.030% w/w

During vulcanisation, all the rubber parts become integral parts of the rubber part of the tyre. Therefore, the total quantity of Candidate List substance 4 in the rubber of the tyre is calculated by adding the total quantity of this substances in each rubber part, as follows: weight of Candidate List substance 4 in the casing rubber [Candidate List substance 4 concentration × weight of casing rubber in the tyre = 0.10 × 0.15 kg] + weight of Candidate List substance 4 in the tread [Candidate List substance 4 concentration × weight of tread rubber in the tyre = 0.04 × 0.20 kg] + weight of Candidate List substance 4 in the rubber layer of beads [Candidate List substance 4 concentration × weight of rubber layer of the two beads = 0.01 × 0.030 kg]] = 0.015 kg + 0.008 kg + 0.0003 kg = 0.023 kg

Thus, the concentration of Candidate List substance 4 in the rubber of the tyre is calculated by dividing the total weight of Candidate List substance 4 in the rubber of the tyre by the total weight of the cured tyre = 0.023 kg/0.50 kg = 0.047 = 4.7% w/w. [*This is the same as using equation (1) in Box 1*]

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 subchapters 3.2.1 and 3.4.1 of the guidance, for the handlebar grips, flexible rubber doughnut-shaped tubes (in tyre 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 each Candidate List substance in all article types imported per year where it is present above the 0.1% w/w concentration threshold

The number of bicycles imported in the year is 10,000. Therefore, the number of handlebar grips, flexible rubber doughnut-shaped tubes and bicycle tyres in the imported bicycles is 20,000 of each of these items ($n_{handlebars}$; n_{tubes}; n_{tyres}).

- Calculation of the total amount of the Candidate List substance 1 in the imported handlebar grips:

Since, the weight of a handlebar grip ($m_{handlebars}$) is 0.050 kg, the total weight of imported handlebar grips is calculated by multiplying the number of imported units by the weight of each unit in tons (0.050 kg/1000 = 0.000050 t): 20 000 (units/a) × 0.000050 (t/unit) = 1.0 t/a. The amount in tonnes per year of the Candidate List substance 1 in the imported handlebar grips is obtained by multiplying their total weight (1.0 t/a) by the concentration value of that Candidate List substance in weight fraction (0.5% w/w = 0.005): 1.0 t/a × 0.005 = 0.005 t/a.
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 that substance, is 0.005 t/a, which does not exceeds the threshold limit of 1 t/a.

The same result is reached by using equation (3) in the text box 3.
The Candidate List substance 1 concentration in each handlebar grip (*Conc handlebars*) is listed in the table above.

$$m_{CL\ subst.1\ in\ \text{handlebars}}[t/a] = \left(Conc_{CL\ subst.1\ in\ \text{handlebars}}\right) \times \left(\frac{m_{\text{handlebar}}[kg/\text{handlebar}]}{1000}\right) \times \left(n_{\text{handlebars}}[\text{handlebars}/a]\right)$$

$$m_{CL\ subst.1\ in\ handlebars}[t/a] = (0.005) \times \left(\frac{0.05}{1000}\right) \times (20{,}000) = 0.005$$

- Calculation of the total amount of the Candidate List substance 2 in the imported flexible rubber doughnut-shaped tubes:

The calculation is done as described for the imported handlebar grips above. The total weight of imported flexible rubber doughnut-shaped tubes is 2.0 t/a [= 20 000 (units/a) × 0.00010 (t/unit)] and the amount in tonnes per year of the Candidate List substance 2 in the flexible rubber tubes is 0.4 t/a [= 2.0 t/a × 0.2].
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.

The same result is reached by using equation (3) in the text box 3.
The Candidate List substance 2 concentration in each flexible rubber tube (*Conc tubes*) is listed in the table above.

$$m_{CL\ subst.2\ in\ tubes}[t/a] = \left(Conc_{CL\ subst.2\ in\ tubes}\right) \times \left(\frac{m_{\text{tube}}[kg/\text{tube}]}{1000}\right) \times \left(n_{\text{tubes}}[\text{tubes}/a]\right)$$

$$m_{CL\ subst.2\ in\ tubes}[t/a] = (0.2) \times \left(\frac{0.1}{1000}\right) \times (20{,}000) = 0.4$$

- Calculation of the total amount of the Candidate List substance 4 in the imported bicycle tyres:

The calculation is done as described for the imported handlebar grips above. The total weight of imported tyres is 10 t/a [= 20 000 (units/a) × 0.00050 (t/unit)] and the amount in tonnes per year of the Candidate List substance 4 in the bicycle tyres is (approx.) 0.5 t/a [= 10 t/a × 0.047].
The total amount, in tonnes per year, of the Candidate List substance 4 in the bicycle tyres 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.

The same result is reached by using equation (3) in the text box 3.
The Candidate List substance 4 concentration in each bicycle tyre (*Conc tyres*) is listed in the table above.

$$m_{CL\ subst.4\ in\ \text{tyres}}[t/a] = \left(Conc_{CL\ subst.4\ in\ \text{tyres}}\right) \times \left(\frac{m_{\text{tyre}}[kg/\text{tyre}]}{1000}\right) \times \left(n_{\text{tyres}}[\text{tyres}/a]\right)$$

$$m_{CL\ subst.4\ in\ tyres}[t/a] = (0.047) \times \left(\frac{0.5}{1000}\right) \times (20{,}000) = 0.47 \approx 0.5$$

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 tyre 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.

European Chemicals Agency
P.O. Box 400, FI-00121 Helsinki
http:/echa.europa.eu