

# Articles

Requirements for Producers,  
Importers and Distributors

REACH: Info

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# Preface

Dear readers,

In the case of articles, questions arise under the REACH Regulation about how to differentiate between the term "article" and the terms "substance" and "mixture". Furthermore, companies that produce or supply articles have obligations to inform their recipients, who may be processors, distributors or users of articles, or consumers. In certain cases, they also have obligations towards the European Chemicals Agency (ECHA).

This brochure provides information on the various obligations of producers, importers and suppliers of articles under the REACH Regulation and provides a number of answers to the question of when an object is a substance or a mixture and when it is an article.

This is the English translation of the fourth, revised edition. The brochure has been fundamentally updated to include information on calculating the SVHC content in articles.

A 3D ball-and-stick model of a molecular structure is shown in the background. It features several purple spheres (likely oxygen atoms) and dark blue/black spheres (likely carbon atoms) connected by grey rods (bonds). The structure is partially obscured by a white rectangular box containing text.

# 1 General obligations under REACH

Under the REACH Regulation (EC) No. 1907/2006, manufacturers and importers of substances as such or in mixtures must register these substances at the European Chemicals Agency (ECHA) if the quantity of substance produced or imported is at least 1 tonne per year (t/a). In addition, substances must also be registered if they are contained in articles in the amount of at least 1 tonne per year and per manufacturer or importer, and are intended to be released.

No substance subject to registration may be manufactured or placed on the market without being registered.

According to Article 5 of the REACH Regulation, if there is an obligation to register a substance, it may not be manufactured or placed on the market in quantities exceeding one tonne per year without being registered. A technical dossier must be generated for registration. A production quantity of 10 tonnes per year or more requires manufacturers and importers to also prepare a chemical safety report that provides information on the impacts on human health and the environment. The dossiers are submitted for registration to the European Chemicals Agency in Helsinki. Some of the registered substances, especially those for which the risks cannot be concluded, are selected for a substance evaluation. This is in the responsibility of the member states' competent authorities.

Substances of very high concern for humans or the environment (SVHC, see chapter 6) may be subject to an authorisation process. To use these substances further or place them on the market, authorisation must be applied for. Restrictions can be defined for substances that represent an unacceptable risk.



## 2 Definition of an article

Article 3 (3) of the REACH Regulation defines an article as an object whose outer shape determines its function to a greater degree than its chemical composition. The chemical composition only plays a secondary role. This is also the criterion that differentiates it from a substance and a mixture. This does not mean that the chemical composition is not a characteristic of an article, it is just not the characteristic that defines it.


### Definition

#### Article 3 (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.

### Example

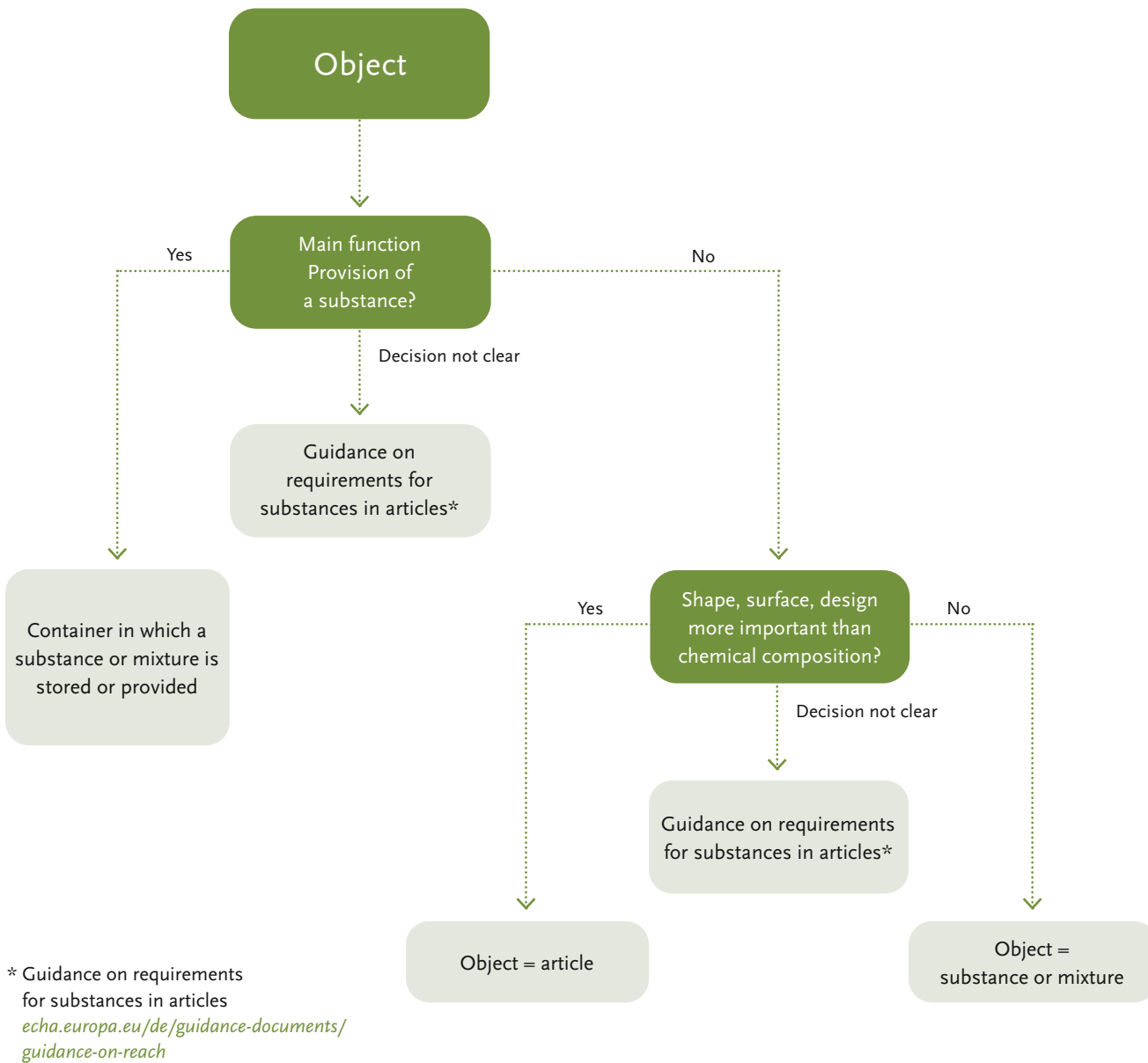
A table is an object made up of the articles tabletop and legs etc., regardless of whether made of wood, metal or plastic. Its shape is the decisive factor. A table may also be chosen because of its material on an individual basis, but its function as a table is not affected by this.



### 3 Differentiating between articles and substances/ mixtures

The question as to whether a material is considered an article or a substance/mixture cannot always be answered easily in individual cases and thus requires a detailed assessment. A number of criteria play a role in this process.

The diagram on the following page shows the basic principle for differentiating articles from substances even though it is a very simplified overview. When the questions about differentiation are more complex, we hope that this informational brochure can help you. This issue is also addressed in detail in the "Guidance on requirements for substances in articles" of the ECHA.



**Fig. 1** Diagram of the systematic differentiation of articles with respect to substances or mixtures under REACH



The table below provides several examples that were defined in one of the two categories at EU level. However, it only provides an overview of the basic differentiation between a substance and an article. The examples that follow explain the individual criteria that help differentiate between substances/mixtures and articles.

**Table 1** Decisions on borderline cases for the classification of substances or mixtures and articles

Material	Classification
Metal pipe	Article
Blasting abrasive	Substance or mixture
Aluminium foil	Article
Wire	Article
Welded wire	Substance or mixture *
Metal balls (ball bearings)	Article
CD cases (plastic)	Article
Paper	Article
Textiles	Article
Polyester fibres	Article
Packaging	Article
Pen	Mixture (in a container)
Printer/toner cartridge	Mixture (in a container)
Candles	Substance or mixture *
Battery	Article
Adhesive Tape	Article
Wet cleaning wipe	Mixture (on a carrier)
Metal bars	Substance or mixture
Machine (oiled)	Article or complex object made up of articles
Car tyres	Article
Glow stick	Mixture (in a container)

\* This is the view of the REACH-CLP-Biozid Helpdesk, as no final decisions have been made within the EU.

## Example

Filled toner cartridges for a laser printer are one example of how complex the differentiation can be. If only the empty cartridge is considered, it is an article. Classification is more difficult when the cartridge is filled.

This kind of cartridge, from a specific manufacturer, only fits into the intended copy machine or printer of this company. In this respect, the shape of the cartridge is not insignificant in the smooth functioning of the device. This is why the full cartridge tends to be classified as an article.

A more in-depth analysis, however, produces a different result. To arrive at this result, the REACH Regulation's definition of article must be set as a basis and the explanations in the "Guidance on requirements for substances in articles" must be observed.

The question of whether the toner can be removed from the cartridge and transferred to a similar container or can be transferred to paper in a different manner, even if may be more difficult or complicated to do so, becomes an important criterion in the decision. If this is possible, and this must also be assumed to be the case with toner, which can also fulfil its function independently of the cartridge, then this is a clear indication that it is not an article.

This system is more of a container that holds the substance or mixture and also controls its release. The main function of the toner cartridge is therefore to hold the pigments and release them appropriately with electronic control so that they are applied and set on paper in the form of letters, symbols, images etc. In addition, the substance or the mixture in this container is consumed during application.

### These three criteria

1. function of the toner independent of the cartridge,
2. cartridge = container,
3. consumption of the substance or mixture during use, lead to the conclusion that toner cartridges are containers with a substance or mixture.

The system as a whole is thus not an article.

■ A toner cassette is to be understood to be a mixture in a container (an article).





### Example

Another borderline case is the **spray can**, which may have a complex nozzle in order to apply paint evenly. Much like the case of the toner cartridge, this is ultimately also a container whose main function is to hold the paint to be applied to an object by way of a nozzle. The paint is consumed during application.

In this case, it can also be concluded that the empty spray can is an article based on the criteria applied to the interpretation of the toner cartridge. A full spray can is a container for a mixture, in this case, paint.

### Info

#### Conclusions for the two examples

1. Registration of the substance(s) in the toner or paint in accordance with Article 6 under the conditions specified there.
2. Possible information obligations in accordance with Article 7 (2) and Article 33 if SVHCs are contained in the material of the toner cartridge/spray can.
3. Classification and labelling of the mixture in accordance with CLP Regulation, if applicable.

The following pages explain the process for deciding whether an object is a substance/mixture or article, using other examples in the form of questions and answers.

### **Are candles mixtures or articles with intentional release of substances?**

The question has not been answered uniformly throughout the EU. According to the interpretation of the REACH-CLP-Biozid Helpdesk, which is also supported by the European Commission and the ECHA, candles are substances or mixtures and not articles because the shape of a candle is not the determining factor in its function. This means that the substances contained in the candle must be registered in accordance with Article 6 of the REACH Regulation.

■ Candles are substances/mixtures and not articles.

Regardless of whether a candle is a substance or a mixture, if the definition of article were applied, it would not be an article with intentional release of substances as per Article 7 (1), because the combustion products are not released intentionally, but cannot be prevented during use. The function of the wick during use is to feed liquid paraffin or wax to the flame. This means that the external shape of the candle first has to be dissolved by liquefying the paraffin/wax in order to sustain the combustion process. This is another criterion that supports the interpretation "candle = substance or mixture".

### **An engine block whose moving parts are oiled is imported: Does the lubricant used have to be registered when the engine block is imported?**

In the simplest case, the engine block is an article, but in the more complex case it is an object composed of individual articles within the meaning of the REACH Regulation. Oil that was used to lubricate parts of the engine block is part of the article if the parts were already treated upon import. Since it can be assumed that the intention is not to release this oil (see chapter 5 for more), it is not necessary to register the oil.

**What needs to be taken into consideration when importing nickel-plated pins or nickel-plated jewellery or wire products such as zinc-plated barbed wire?**

Nickel-plated pins and zinc-plated barbed wire are both articles as defined in the REACH Regulation. The shape determines the function in this case. The articles are made either of substances or of alloys (mixtures) that can be coated, e.g. with zinc or nickel, for finishing or to protect against corrosion. As mentioned above, the chemical composition also plays a role, e.g. when selecting the metal that is used for coating or finishing. Regardless of the metal coating, these objects are still articles whose function is clearly determined by the shape or design.

In the case of articles that contain nickel, possible restrictions found in Annex XVII of the REACH Regulation must be complied with, i.e. in the case of jewellery articles that come into contact with skin such as earrings, necklaces, bracelets etc.

**How are metal products generally classified under REACH?**

For metal products, the use plays an important role in differentiating between "article" or "substance/mixture". The "Guidance on requirements for substances in articles" shows an example using aluminium to differentiate between article/substance. According to it, an aluminium bar is considered a substance, while rolled or pressed products such as foils, sheets or profiles are considered to be articles. Therefore, the components of a bar must be registered if their quantity is at least 1 tonne per year and per producer/importer (Article 6 of the REACH Regulation).

The question about differentiating between a substance and an article is explained below using the example of sheets and wires in metal processing. A sheet is a metal plate that is defined by its thickness, i.e. for sheets, generally one of the three dimensions is a determining characteristic in the use of the term article.

The other two dimensions, length and width, are variable and depend on the final use of the sheet. This also applies for wire which is defined in two dimensions by its thickness with the length of the wire being variable. During subsequent processing of the sheets or wires, these characteristic dimensions are no longer changed.

In the guidance mentioned above, this approach is shown using the example of rolling (sheets) and pressing (press profiles) of aluminium, i.e. at the point where the input material takes on its characteristic dimension. This also applies for pulling wires.

One dimension is defined by rolling, two dimensions by pulling. These dimensions are also used to specify the final use of the materials. It is the determining factor here in the use of the term article regardless of what happens later with the sheet or wire, i.e. cutting, shortening, moulding, punching etc. are all further processing steps for certain subsequent uses of the sheet.

These differentiation criteria taken from the article guidance for aluminium can be applied to other metals, e.g. steel slabs. The shape of the slab is only characterised by the technological process used to produce it, and must also be available in specific sizes for further processing. But these are not the determining parameters for later use.

Slabs are pre-forms of the final sheets that do not yet have their final shape, i.e. they are not yet rolled for the dimension characteristic for use – the thickness of the resulting sheet. It is only referred to as an article from this point on.

In the case of importing wire (with the exception of welding wire), forged round steel or comparable products (zinc or nickel-plated), there is no obligation to register. Only substances in the articles that are to be intentionally released in accordance with Article 7 (1) need to be registered; however, this is generally not the case for metals.



**Are blasting abrasives substances/mixtures or articles as defined by REACH?**

Blasting abrasives can be metals or mineral materials, for example. Depending on where they are used, these materials have a preferred grain size, shape, angularity etc. They must, however, also have certain material properties, i.e. a certain composition, to fulfil their function.

If blasting abrasives were to be classified as an article, the shape of the particles (round, angular, raw etc.) would be more important than their chemical composition.

**The REACH-CLP-Biozid Helpdesk used the following questions to make its decisions.**

1. Are the shape, design, and/or surface important for the effectiveness of the blasting abrasive?
2. Are the shape, design, and/or surface decisive for the effectiveness of the blasting abrasive?
3. Can the blasting abrasive be replaced by another material?
4. Is the blasting abrasive universally useable?

With respect to 1:

The outer shape is important in many cases, depending on how it is used. A round shape is less abrasive, i.e. does not scrape as much, as an angular material, i.e. a coarse material would tend to be used to remove surfaces on a large scale.

With respect to 2:

Shape, design and/or surface are important but in most cases not more important than the chemical composition that is responsible for hardness, resilience or the melting point of a material. In most cases, the external shape, e.g. the formation of crystals, is determined solely by the chemistry of the material, i.e. for silicon carbide crystals that have particularly sharp edges.

With respect to 3:

Even though the material used can be replaced by other materials, it is generally not by any material but, depending on how it is used, only by those with similar properties, i.e. those with a similar hardness or melting point or also the requirement to be inert with respect to the surface to be treated.

With respect to 4:

Generally materials cannot be used universally but are also dependent on the targeted effect on the surface to be treated (shape, design), the material properties (chemistry), possible interactions with the surface to be treated (chemistry) etc.

The REACH-CLP-Biozid Helpdesk therefore assumes, given the answers to the second and third questions, that blasting abrasives are substances or mixtures as defined in the REACH Regulation mainly because the prerequisite for articles that the material properties be less important than the external form is not fulfilled.

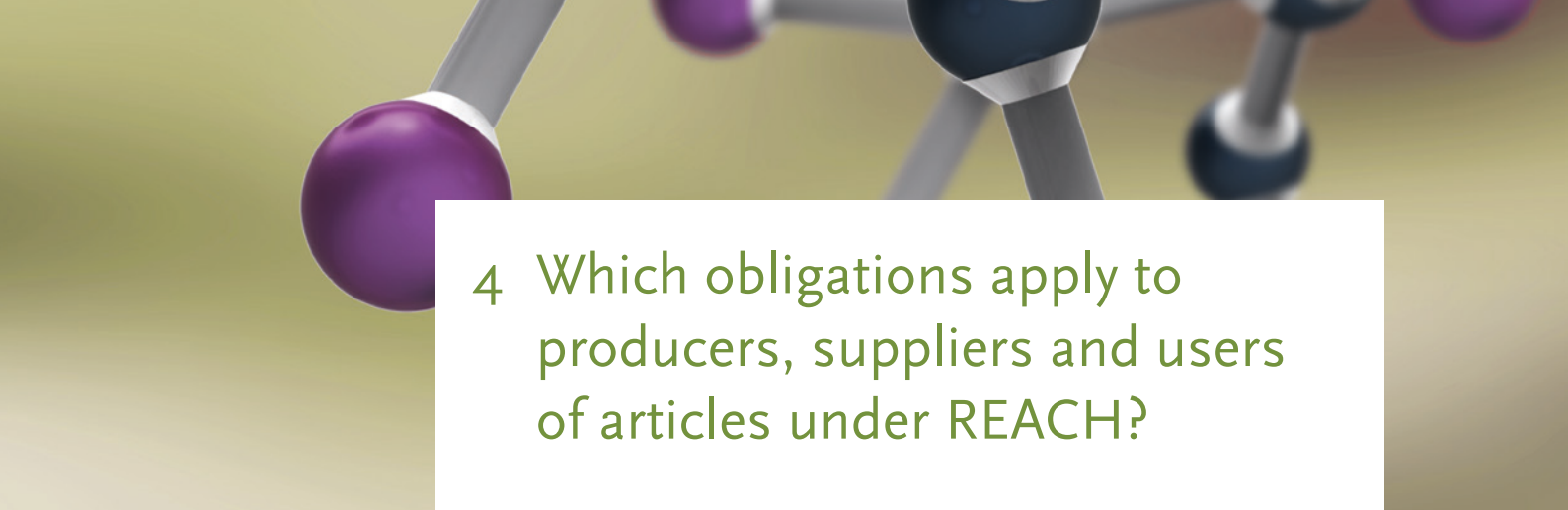
**Are desiccants, such as those that are enclosed in a small pouch with a camera or a hand bag, considered part of the article or are they substances/mixtures that need to be registered?**

The desiccants are not part of the article, in this case, the camera or hand bag – instead, they are substances or mixtures.

Silicon dioxide, which is generally used as a desiccant, must be registered in accordance with Article 6 if it is not a natural substance as defined in Article 3 (39) and the quantity reaches the threshold of 1 tonne per year. This also applies given the prerequisite that the substance is not deliberately imported, but only as an "extra" for the article.

The answer to this question was agreed upon with the European Chemicals Agency (ECHA).

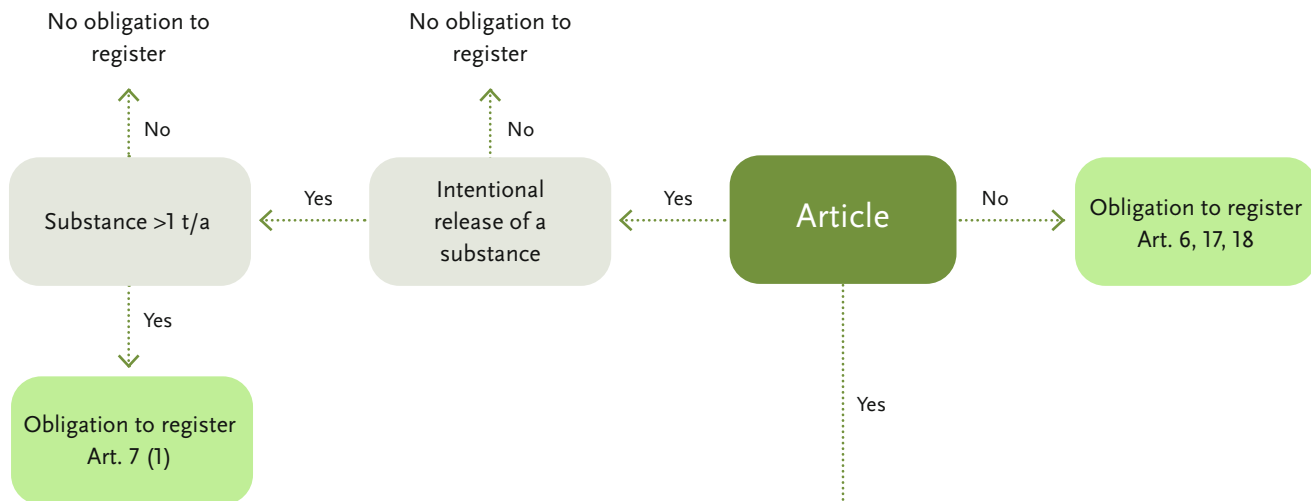




## 4 Which obligations apply to producers, suppliers and users of articles under REACH?

The producers, suppliers and users of articles can have both information and notification obligations as well as the obligation to register substances under the REACH Regulation in certain circumstances. The following decision-making tree shows an overview of these obligations and conditions. The REACH obligations are explained in detail for those affected in the following chapters.

## Registration obligations



## Information/notification obligations

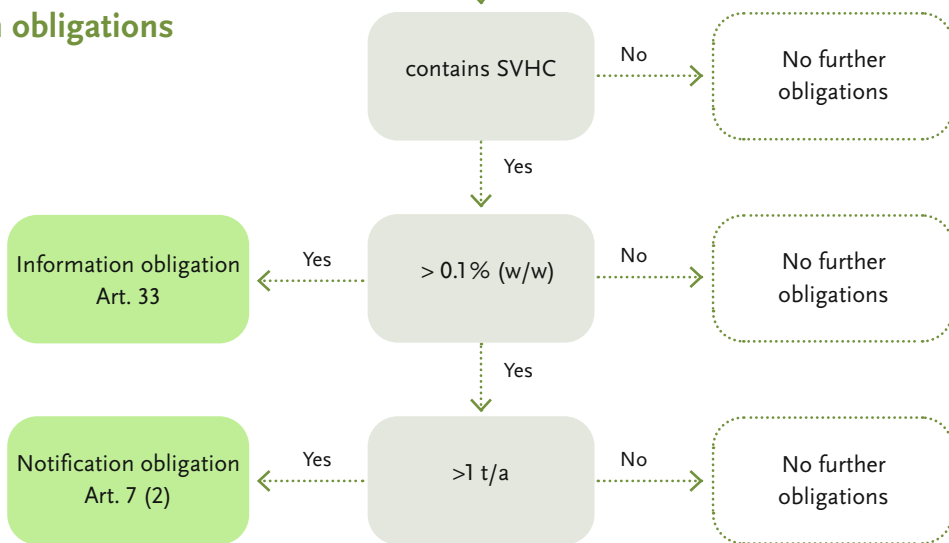


Fig. 2 Summary of the obligations of producers, suppliers and users of articles



## 5 Registration of substances in articles under REACH

The obligations to register under the REACH Regulation only apply to substances, and specifically to the substances on their own or to substances in mixtures. The prerequisite is that substances are produced or imported in quantities of at least 1 tonne per year. The conditions are described in Article 6.

Articles have a special status under REACH. Articles themselves do not have to be registered. Under certain circumstances, there are, however, obligations to register substances in articles if they are to be released or notification obligations if substances of very high concern are contained. The conditions are described in Article 7.

According to Article 7 (1), there is an obligation to register if a substance is intended to be released and the quantity of this substance in the articles exceeds 1 tonne per year. This quantity comprises the total quantity of the substance in all articles of the importer or producer.

The total quantity is made up both of the released quantity as well as the quantity (still) remaining in the article.

This means that a substance that is intended to be released from articles must be registered before the article is placed on the market.

**Exemption**

An exemption from registration of substances in articles is found in paragraph 6 of the same article. According to it, the substances in question do not have to be registered if they were already registered for the use in question. This means that upon registration of the substance by a manufacturer or importer of the substance, the use must have been included as an identified use in the registration. Registration does not have to take place in the supply chain.

**Info****Article 7**

- (1) Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both of the following conditions are met:
- a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
  - b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.
- (6) Paragraphs 1 to 5 do not apply to substances that have already been registered for that use.

## 5.1 What does "release under normal or reasonably foreseeable conditions of use" mean?

This article limits the release of a substance from an article to the following conditions.

The "normal" conditions describe the conditions under which an article is intended to be used and under which the release of the substance occurs.

In addition, other uses may arise that were not intended initially with regard to the use of the article declared by its producers or importers. Such uses involving the release of the substance should be "reasonably foreseeable" in order to establish the obligation to register.

Intentional release under normal or foreseeable conditions does not, however, include:

- uses that are explicitly excluded by the article producer or importer,
- uses that are to be avoided, e.g. warned against,
- accidents.

Upon closer inspection, there are few articles with intentional release of substances; one example is perfumed toilet paper. The actual function in this case is determined by the paper. Paper is an article. Treating the paper with a perfume that is intended to be released is a "secondary function" that does not, however, affect the actual "main function" of the paper. As a result, the paper cannot be regarded as a carrier whose main function is to release the perfume.

The following examples will illustrate this issue further:

**Is the abrasion of car tyres considered intentional release of substances as defined in Article 7 (1)?**

When car tyres are subjected to abrasion, this is not regarded as substances that are intentionally released under normal or reasonably foreseeable conditions of use. The abrasion is rather an unpreventable side effect of using the tyres, it is even undesirable. The substances therefore do not have to be registered.

**Textile fibres and yarns are coated with finish to make them easier to process or to improve the quality of the yarn. These substances/mixtures can be washed off again after being processed. Is this considered an intentional release of substances? Do the substances need to be registered when importing fibres treated this way in accordance with Article 7 (1)?**

The fibres/yarns are considered articles. The fibres are coated with finish to achieve a certain property in the fibres, e.g. to make them easier to process. This intended property only exists as long as the finish stays on the fibres. It is thus part of the fibres. Once the finish has fulfilled its function, e.g. once the fibres have been spun to yarn, it is removed again if necessary.

This release is not associated with the actual function of the substance (fibre finishing, improved processing properties of the fibres). It is rather the status of the substance changes under REACH when it is released. The "finish" substance becomes waste. Waste is exempted from registration obligations in accordance with Article 2 (2) of the REACH Regulation.

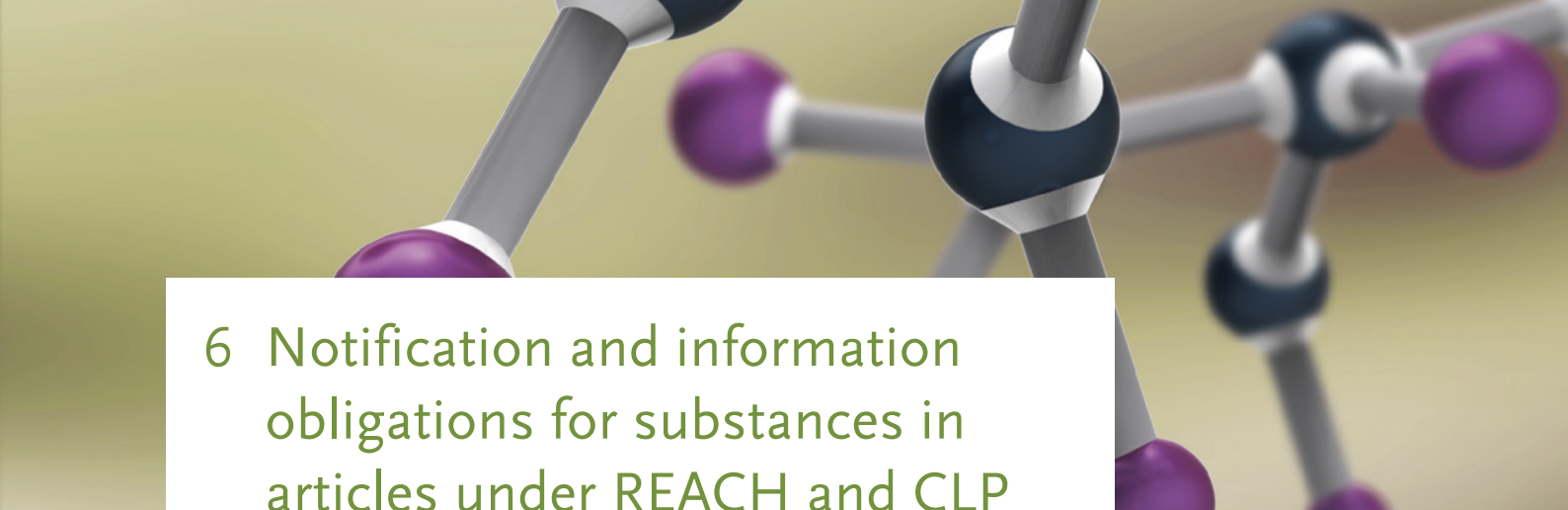


**Are wet cleaning wipes articles with intentional release of substances?**

Wet cleaning wipes are a carrier material because they contain a substance/mixture, e.g. a cleaning agent. The actual function of the object is to wipe the cleaning agent onto the surface to be cleaned and simultaneously remove the dirt in a single step. The agent contained in the wipe functioning as the carrier is essential to the cleaning process.

The cleaning agent could also be applied completely independently of the wipe, e.g. it could be sprayed on by a spray can and used by a cloth, sponge or other suitable material in a second step. The important factor is therefore the function of the cleaning fluid which is also consumed in the process. The function of the wipe as a wipe is only secondary compared to the chemistry of the cleaning agent.

Therefore, Article 7 (1) does not apply to wet cleaning wipes. Instead, the substances in the cleaning agent have to be registered in accordance with Article 6 under the conditions specified there.



## 6 Notification and information obligations for substances in articles under REACH and CLP

### 6.1 Notification and information obligations in accordance with Articles 7 and 33 of the REACH Regulation

Notification obligations to ECHA arise for producers and importers of articles in accordance with Article 7 (2). In addition, suppliers of articles are also obligated to pass on information to recipients and, upon request, to consumers, in accordance with Article 33.

These obligations come to bear when substances that have been identified as of very high concern are contained in a concentration of more than 0.1% weight by weight. This context gives rise to the following questions, which are answered in the section below:

- When do notification and information obligations arise for substances in articles?
- How are substances of very high concern identified?
- What is the basis for the 0.1% threshold?



### 6.1.1 When do notification and information obligations arise for substances in articles?

These information obligations do not affect all producers, processors and importers of articles. Only those actors who use substances of very high concern (SVHC) in articles or who supply these kinds of articles to a recipient or consumer are subject to these information obligations.

#### Info

##### Article 7

2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria under Article 57 and is identified in accordance with Article 59 (1), if both of the following conditions are met:
  - a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
  - b) the substance is present in those articles above a concentration of 0.1% weight by weight (w/w).

#### Info

##### Article 33

- (1) Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0.1% weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.
2. On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0.1% weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance. The relevant information shall be provided, free of charge, within 45 days of receipt of the request.

The notification obligation to the ECHA arises when an SVHC is contained in a concentration of more than 0.1% weight by weight and the total quantity of 1 tonne per year is exceeded for this substance. In relation to the total quantity, it must be kept in mind that the substance quantities of different affected articles may have to be added together. The producer or importer of the article is responsible for notification.

According to Article 7 (4), the following information must be reported to the ECHA in this case:

- Identity of the producer or importer of the article
- Registration number of the SVHC if available
- Identity of the SVHC
- Classification of the SVHC
- Use of the SVHC in the article
- Quantity range of the SVHC

The obligation to inform the recipients of an article in accordance with Article 33 also arises if an SVHC is contained in a concentration of more than 0.1% weight by weight. The total quantity of the substance, however, does not play a role here. In this case, the supplier of the article shall provide the recipient with the information available to him that is sufficient to use the article safely. This includes at least the name of the substance in question. The supplier provides the same information to the consumer, but only upon request.

■ The information obligation under Article 33 does not depend on the total quantity of SVHC, i.e. it already exists for an individual article with an SVHC content of over 0.1%.

### 6.1.2 How are substances of very high concern identified?

The criteria that characterize substances as being of very high concern are defined in Article 57 of the REACH Regulation (SVHC: Substances of Very High Concern). According to this, these are substances are classified as carcinogenic, germ cell mutagenic or toxic for reproduction 1A or 1B. The definition also includes substances that are persistent, bioaccumulative and toxic (PBT) as well as very persistent and very bioaccumulative (vPvB) substances (relevant criteria in Annex XIII of the REACH Regulation).

Substances with endocrine properties, i.e. properties that affect the hormone balance and substances with properties similar to those of PBT or vPvB can also be substances of very high concern. The latter are substances that are expected to cause serious impacts on humans and the environment even though they do not fall into the categories specified in accordance with the criteria.

The procedure under Article 59 must be completed successfully for a substance to be considered an SVHC.

The substances are identified in a process described in Article 59 and included in what is known as the Candidate List. Once they are included in the list, the notification and information obligations described above will apply (see Section 6.1.4).

## Info

### Criteria as per Article 57

- a) substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008;
- b) substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of Annex I to Regulation (EC) No 1272/2008;
- c) substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008;
- d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;
- e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;
- f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — 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 to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

To include a substance in the Candidate List, a dossier that fulfils the requirements set in Annex XV of the REACH Regulation must be created. This dossier can either be developed by a Member State or by the ECHA (at the request of the Commission). This dossier is published by the ECHA to give interested groups the opportunity to comment. The substance is then included in the Candidate List either directly or upon discussion in the Member State Committee (MSC).

If an agreement cannot be reached in the MSC, inclusion is decided in the comitology procedure. The ECHA publishes the list of candidate substances and updates it regularly once a decision has been reached on the inclusion of new substances. Figure 3 presents a short, schematic summary of the procedure.

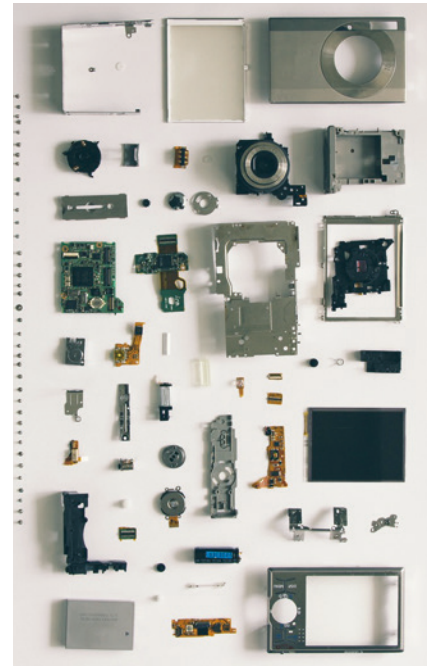
### 6.1.3 What is the basis for the 0.1% threshold?

With regard to the interpretation of the reference value for 0.1 percent by weight, an inconsistent approach has been taken primarily within the EU. However, the judgement of the Court of Justice of the European Union (CJEU) in Case C-106/14 established legal certainty.

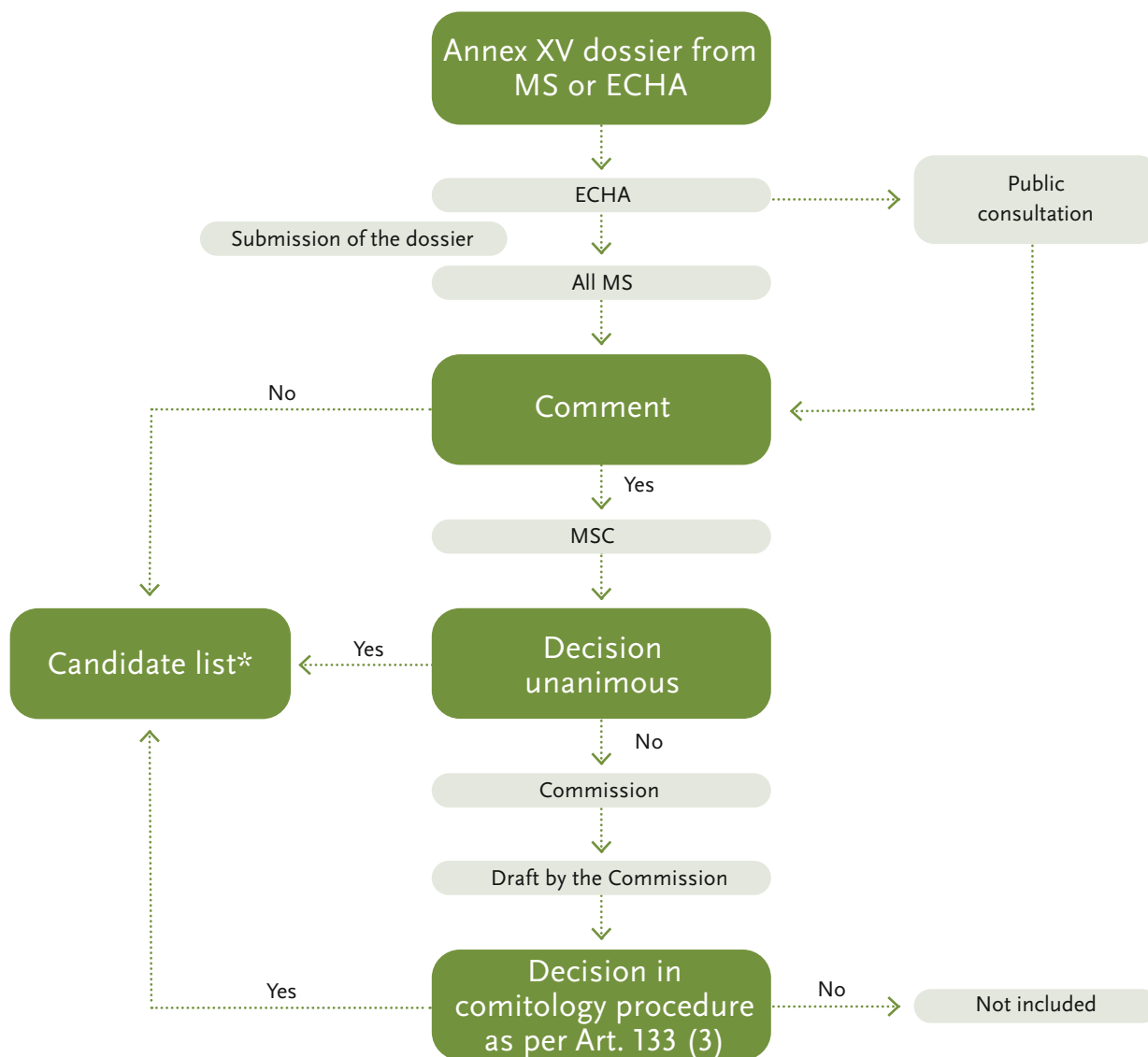
In its judgement, the CJEU reached the conclusion that an article that is incorporated into a complex product does not, as a general rule, cease to be an article as a result of being incorporated ("once an article, always an article").

Thus the percentage of the candidate substances is related to every individual (incorporated) article.

You can find a detailed analysis of this interpretation and its consequences in chapter 7.



The obligation to provide information pursuant to Article 33 does not relate to the complex product (here: a digital camera), but to the individual articles of the product.



\* <http://echa.europa.eu/web/guest/candidate-list-table>

MS: Member States  
MSC: Member State Committee

**Fig. 3** Summary of the procedure to identify substances for the candidate list

#### 6.1.4 When does the information stipulated in Article 7 (2) need to be submitted to the ECHA?

If an article contains a substance that fulfils the criteria above and is included in the candidate list as an SVHC, the producer or importer of this article shall inform the ECHA no later than 6 months after the substance is included in the Candidate List when both of the following conditions are met:

The substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year **and simultaneously** exceeds the concentration of the substance in these articles 0.1% weight by weight.

The following must be kept in mind here:

- The percentage-based concentration of the SVHC is calculated based on its presence in the respective article.
- Its total quantity in all articles is used as a basis for the tonnage of the candidate substance.
- Only those articles in which the concentration is above 0.1% weight by weight are considered to calculate the quantity threshold of the candidate substance of 1 tonne per year.
- If an article contains multiple candidate substances, the calculation is performed separately for each substance and not as the total of all candidate substances.

#### 6.1.5 Are there exemptions to the notification obligation for substances in articles?

The notification obligation set forth in Article 7 (2) can be omitted if the possibility of exposure of humans and the environment can be ruled out. The meaning of "normal or reasonably foreseeable conditions" has been explained in Chapter 5.

- There are exemptions to the notification obligation pursuant to Article 7 (2).

A further-reaching exemption to the obligation to notify the ECHA is contained in Article 7 (6). According to it, the notification obligation can be omitted for substances of very high concern if the substances have been registered for that use in accordance with Article 6. Registration does **not have to take place in the supply chain**.

## Info

### Article 7

- (3) Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.
- (6) Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use.

### 6.1.6 What information obligations are there for suppliers of an article as per Article 33?

According to the REACH Regulation, the name of the substance must be communicated to the recipient as a minimum. Furthermore, the supplier shall provide all information it has that is sufficient to allow safe use of the article.

The type of information that is passed on may also be determined by the recipient. A higher level of **expertise** can be expected from a professional user than from a consumer.

In addition, the professional user has other technical possibilities for minimising the risks stemming from substances. This is shown in the following example.

## Example

Dust may be generated when processing an article. In the case of commercial use, exposure of the recipient can be prevented by appropriate technical devices, such as an extraction system. For private users, it may be necessary to indicate the need for respiratory protection to prevent dust from being inhaled; for professional users, this recommendation can be replaced or supplemented by information about dust extraction.

On the premises of a professional user, children will also not have access so that it is not necessary to provide a corresponding instruction here. On the other hand, it may be absolutely necessary to provide this instruction for the same article when delivered to consumers.

### **In which form does this information have to be provided to the recipient of an article?**

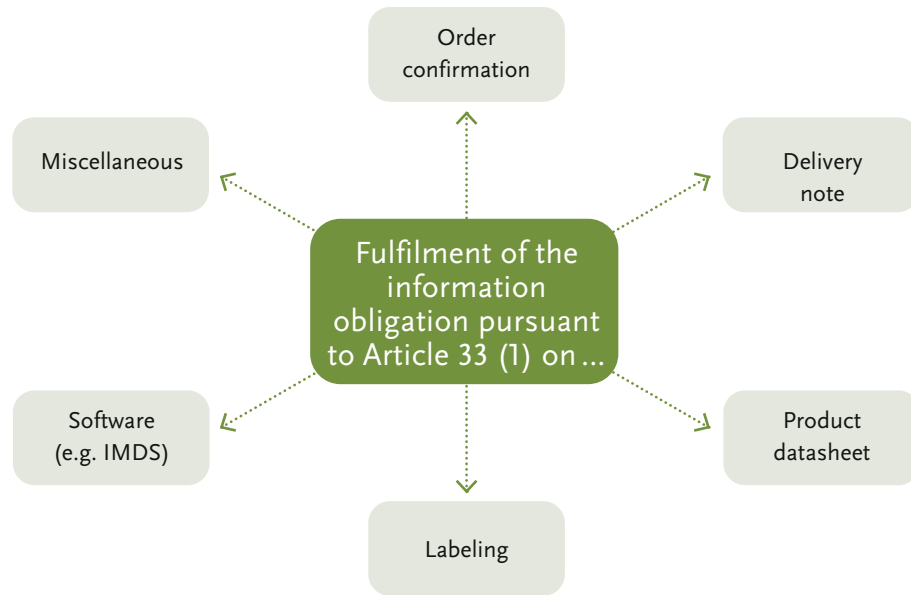
If the supplier of an article has an information obligation as per Article 33, it must provide the information to the recipient in a suitable form. However, the format and the channel are not defined. This means that it is generally possible to provide the information in hard copy or electronic form (see Fig. 4 on the following page). It is not sufficient to publish the information on the company's website because the provision of the information is considered an active process in the sense of "shall provide the recipient of the article".

■ The REACH Regulation does not define how the information as per Article 33 has to be passed on.

### **What language must be used to provide the information under Article 33?**

The REACH Regulation itself does not indicate which language the information has to be provided in. It is important, however, for the recipient to be able to understand the information provided. Therefore, the supplier of the article must use a language which the recipient can be assumed to understand. This is usually the official language of the country in question. If, however, the supplier and recipient regularly communicate in a different language, the information may also be provided in that language. On the other hand, the respective official language must be used for consumers in accordance with Article 33 (2).





**Fig. 4** Incomplete listing of options to fulfil the information obligation under Article 33 (1).

**Starting at what quantity does the information under Article 33 have to be passed on to recipients?**

The obligation to pass on information is only dependent on the concentration of the SVHC in the article. This means that, **regardless of the annual tonnage**, the information obligation always applies starting from a concentration of more than 0.1% weight by weight.

**Do the information obligations set forth in Article 33 also apply to "old articles", i.e. to articles that were produced long before REACH entered into force, that were temporarily stored and are now supplied to recipients in the form of spare parts?**

There is no exemption from these information obligations, including when an article that contains an SVHC was produced before REACH entered into force. If this article is supplied to a recipient and contains more than 0.1% weight by weight of an SVHC, the supplier must pass on the information required in Article 33 to the recipient.

**Who in the article supply chain is responsible if the information obligation is not met?**

According to Article 33 (1) of the Regulation, information on the presence of SVHCs must be passed along within the supply chain.

If an article contains more than 0.1% SVHCs, information about these substances must be passed on from actor to actor within the supply chain without a request from the recipient – in contrast to the information obligation towards the consumer in accordance with Article 33 (2).

The responsibility for researching whether an article contains SVHCs is in particular the responsibility of the actor (importer or producer) at the beginning of the supply chain for the relevant article. **This obligation, however, also directly affects every downstream supplier in the supply chain and is not limited to passing on information that has been provided to it.**

### **6.1.7 How can the consumer obtain information on SVHCs in an article?**

According to paragraph 2 of Article 33, a consumer also has the right to request information about the SVHCs from the supplier of an article. In this case, the article supplier has **45 days** to supply the information requested.

If a consumer suspects that an article contains an SVHC, it is initially advisable to contact the supplier of the article referring to the candidate list. It is in the supplier's own interest to have a satisfactory answer to this question. This means that it also has to obtain the relevant information.

If a consumer asks the supplier or producer of the article a question about the presence of SVHCs, it must supply the consumer with at least the name of the relevant substance within 45 days.

The consumer can submit the question to the supplier of the article, e.g. a department store or directly to the producer if known.

## 6.2 Notification obligation as per Article 40 of the CLP Regulation

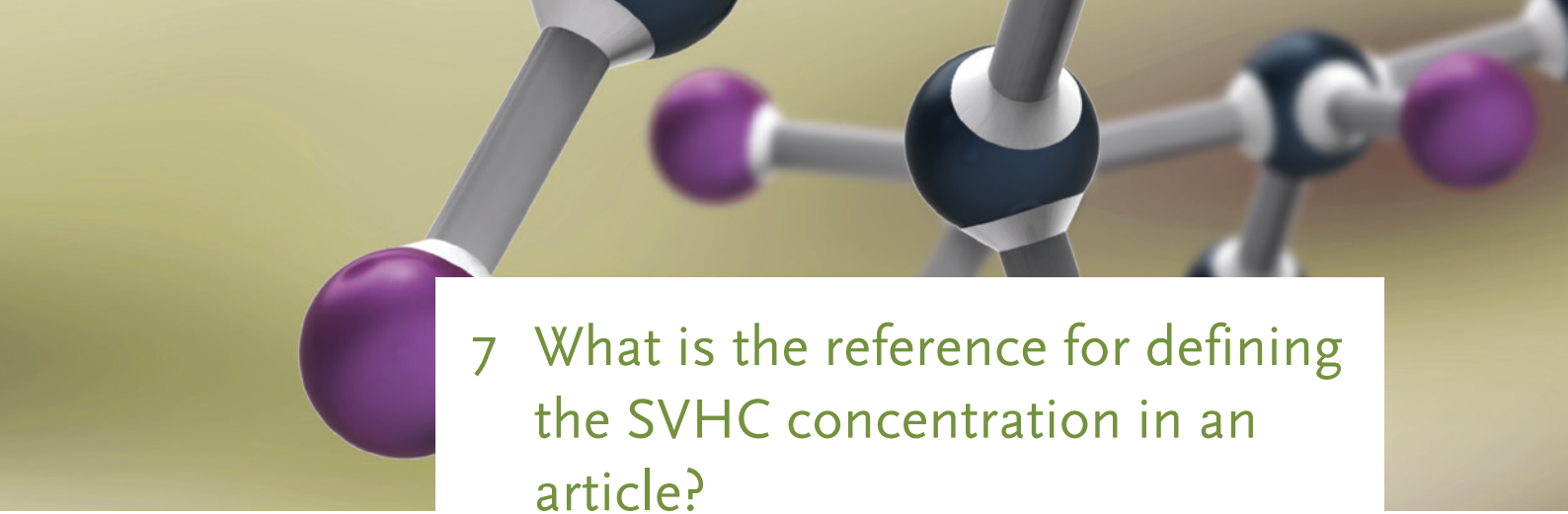
The importer or producer of an article also has an obligation to notify the ECHA if its article contains a substance that is required to be registered. This affects the substances that are contained in an article in a quantity of more than 1 tonne per year in accordance with Article 7 (1) of the REACH Regulation and are released under normal or reasonably foreseeable conditions (see chapter 5).

In accordance with Article 40 of the CLP Regulation, the relevant producer or importer of the article who places on the market a substance regulated under Article 39 of the CLP Regulation, provides the ECHA the following information, if it was not already part of registration:

- Identity of the producer/importer of the article
- Identity of the substance
- Classification and labelling of the substance
- Specific concentration limits, if applicable

## Info

1. Any producer or importer, or group of producers or importers (hereinafter referred to as 'the notifier(s)'), who places on the market a substance referred to in Article 39, shall notify to the Agency the following information in order for it to be included in the inventory referred to in Article 42:
  - a) the identity of the notifier(s) responsible for placing the substance or substances on the market as specified in section 1 of Annex VI to Regulation (EC) No 1907/2006;
  - b) the identity of the substance or substances as specified in section 2.1 to 2.3.4 to Annex VI to Regulation (EC) No 1907/2006;
  - c) the classification of the substance or substances in accordance with Article 13;
  - d) where a substance has been classified in some but not all hazard classes or differentiations, an indication of whether this is due to lack of data, inconclusive data, or data which are conclusive although insufficient for classification;
  - e) specific concentration limits or M-factors, where applicable, in accordance with Article 10 of this Regulation together with a justification using the relevant Parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006;
  - f) the label elements specified in points (d), (e) and (f) of Article 17(1) for the substance or substances together with any supplemental hazard statements for the substance, determined in accordance with Article 25(1).



## 7 What is the reference for defining the SVHC concentration in an article?

### 7.1 Once an article – always an article

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 does its chemical composition". More detailed definitions are not available. There have been varying interpretations within the EU with regard to the reference for an article in cases where an article is incorporated into complex product. The six member states Germany, Austria, Denmark, Belgium, Sweden and France as well as Norway hold contrasting views to the ECHA and the other member states, that in cases where an article is incorporated into a complex product, the individual article remains as such and thereby also continues to serve as the reference for calculating the SVHC concentration.

This interpretation was confirmed by the judgement of the Council of Justice of the European Union (CJEU) in Case C-106/14 in September 2015. According to this, an article that has been produced once does not, in principle, lose its article character if it is combined with one or more other articles to create a complex product. In brief, this is referred to as the principle:

*"Once an article – always an article"*

Some examples of individual articles are listed below that must also be considered for the calculation of the SVHC concentration if the respective articles are incorporated into a complex product.

This also means that information must be passed on, specifying the individual article that contains a candidate substance greater than 0.1 percent by weight.

■ The reference value for the information obligation is the individual article and not the product composed of several articles.

The following are examples of individual articles:

- Belt buckle
- Bicycle handlebar
- Shoe sole
- Computer housing

The "once an article – always an article" principle offers a number of significant advantages with regard to the transfer of articles:

- It achieves basic objectives such as the protection of human beings and the environment as well as transparency in the supply chain.
- The producer of a complex product may directly pass on the information obtained on individual articles (without additional calculations).
- Consumers who claim their right to information in accordance with Article 33 (2) of the REACH Regulation receive detailed information about which individual article contains a candidate substance. It is therefore much easier for them to assess the risks on their own when deciding whether to buy an article or not.
- If the information is not available for the individual articles of an imported complex product, thus necessitating a chemical analysis, it may be easier to analyse the individual articles than the complex product.
- EU-based producers and importers of articles are subject to the same obligations. The importer does not benefit from the "dilution effect" with regard to the concentration of a candidate substance in a complex product.

- It is known in the supply chain that an article contains a candidate substance. Thereby, the various actors involved along the supply chain are also informed that the continued availability of the article is subject to a degree of uncertainty as it may be the case that after the candidate substance is potentially included in Annex XIV, no approval is granted for the respective use. In this case, the article would not simply "disappear" from the market without warning.

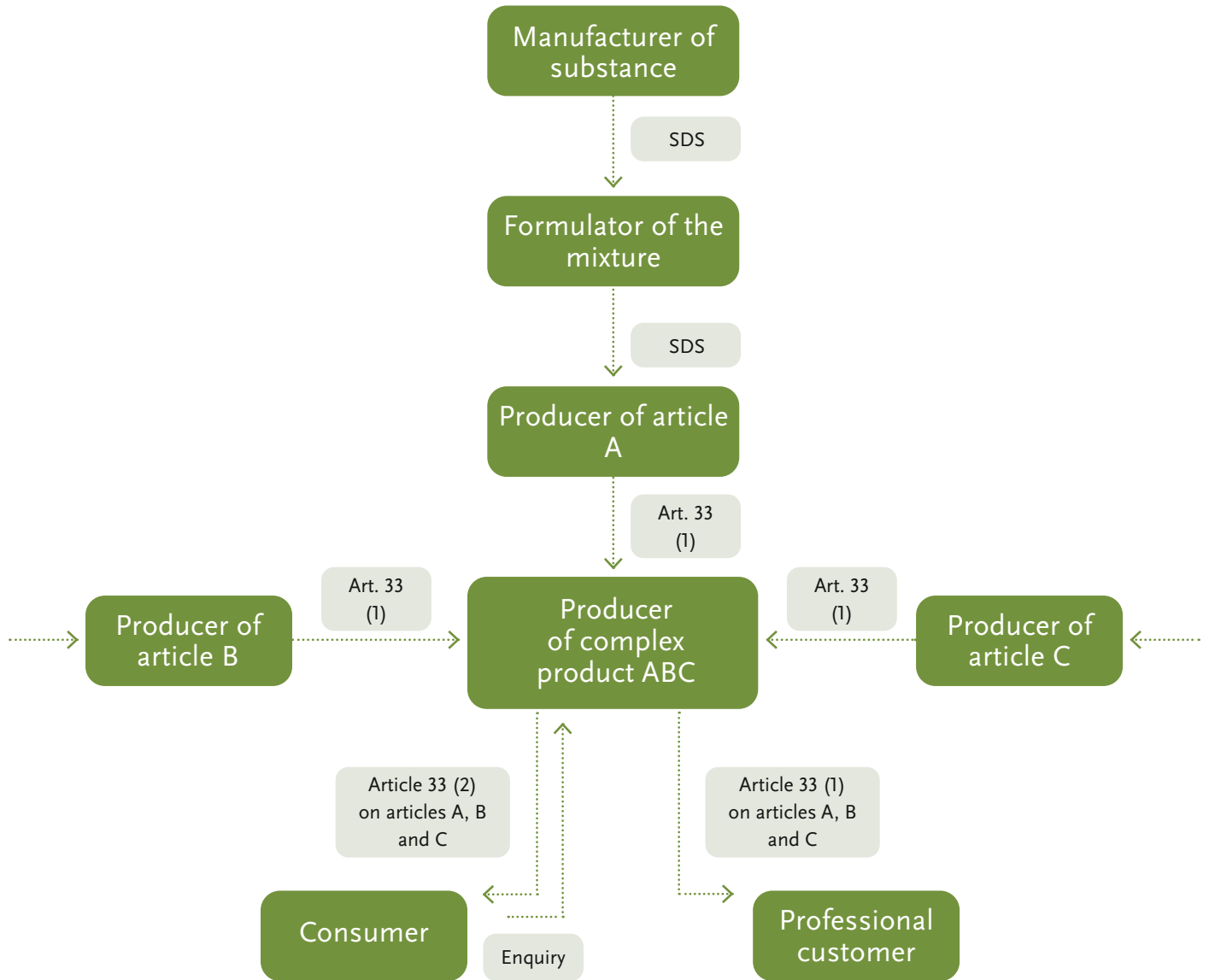
## 7.2 Fulfilment of the notification and information obligations for articles

The basic idea of the REACH Regulation is that the information on candidate substances is passed on within the supply chain (in the EU) from the manufacturer of the substance to the user of an article that contains this kind of substance. The substance manufacturer must provide a safety data sheet (SDS) and the formulator who uses this substance must also include relevant information in his SDS. The producer of an article is thus provided with the information on the candidate substance in the SDS and can pass this on to his customers (see Fig. 5).

Under certain conditions, however, producers or importers of complex products may experience difficulties in passing on information and hence also in fulfilling the legal obligations:

- Information obligations pursuant to Article 33 are not known in the supply chain.
- When importing an article, a supplier from outside of the EU is not willing or able to provide the information required.

The following describes a possible procedure for an article producer or importer to fulfil the notification or information obligations with respect to articles from the point of view of the German REACH-CLP-Biozid Helpdesk.



**Fig. 5** Flow of information for candidate substances in a supply chain within the EU. Substance manufacturers and formulators indicate these, if present, in the safety data sheet (SDS).



### 7.3 Some considerations regarding candidate substances

In order to even be in the position to comply with the information obligations pursuant to Article 7 (2) and Article 33 of the REACH Regulation with respect to individual articles, it is essential to have a good level of knowledge regarding the articles used in the production of a complex product or the assembly of the imported complex product. It is only with this knowledge that an assessment can be made regarding how unlikely or likely the presence of a candidate substance in the individual articles is (probabilistic approach) and how plausible information is on SVHC in the supply chain.

It is useful to obtain an overview of the possible uses of the substances in the current candidate list. This is because certain uses of the candidate substances render their presence in different materials more or less probable.

For instance, a plasticiser is possibly present in the bicycle grip made of soft PVC, but not in the metal frame of the bicycle. In particular, individual experience, research, justified suspicions or indications of the presence of candidate substances will also play a role here.

The REACH-CLP-Biozid Helpdesk has created a list of candidate substances identified to date (in German). This can be found using the link<sup>1</sup> below. Typical uses for each candidate substance are listed under the section "Verwendungsbereiche". In the event of doubt, for example, a specified use for a certain substance may justify further research or even the performance of an analysis. However, the list is not final. If a use is not listed, this does not thereby imply that the candidate substance concerned is not contained in the article.

.....  
<sup>1</sup> [www.reach-clp-biozid-helpdesk.de/SiteGlobals/Forms/Suche/DE/Kandidatenlistesuche\\_Formular.html](http://www.reach-clp-biozid-helpdesk.de/SiteGlobals/Forms/Suche/DE/Kandidatenlistesuche_Formular.html)

## 7.4 Production of articles

The question of the concentration of candidate substances in articles is varyingly difficult to answer in different situations – production within the EU or import of the article into the EU.

A producer of a complex product in the EU that obtains the individual articles from the EU receives information from each of the respective EU suppliers on whether a candidate substance is contained in an individual article. If this is the case, the producer passes this information, e.g. "candidate substance A >0.1% in the bicycle handlebar", to the recipient of the bicycle.

Despite the information obligation in force within the EU, the producer of complex products should nevertheless always check the plausibility of the information provided by the respective suppliers regarding these articles. In particular, the producer should consider whether it is plausible that the individual articles do not contain any candidate substances if no information is provided by the supplier on candidate substances.

## 7.5 Import of articles

An importer of a complex product or an EU producer of a complex product that imports individual installed articles from outside of the EU can, in contrast, be confronted with greater challenges.

When importing from outside of the EU, the importer may not initially receive any information on any candidate substances contained in the respective article as this information does not have to be passed on outside of the EU.

In view of the judgement made by the CJEU and particularly with due regard to the proportionality principle, the REACH-CLP-Biozid helpdesk suggests the strategy described below:

### 1. Communication with suppliers

The first step to complying with information obligations with regard to each individual article is making a contractual agreement with non-EU-based suppliers to pass on



information about SVHCs. This is especially important in order to be able to prove in case of doubt that an effort was made to comply with the obligation to exercise diligence.

If information was passed on, this information should be checked for plausibility on the basis of the considerations described in chapter 7.3; further discussions with the supplier may then ensue. There are a range of situations that can occur in the course of this:

- a.) Information on the concentration of candidate substances >0.1% is available. The information is **trustworthy** and plausible. In these circumstances, there is probably no need for further action on the part of the importer; the information can be passed onto the recipient of the article.
- b.) Information on the concentration of candidate substances > 0.1% is available. The information is **not trustworthy** or plausible. Further action is required, e.g. ranging from checking with the supplier right up to finally conducting an independent analysis.
- c.) Information on the concentration of candidate substances > 0.1% is not available. If no information is available, the importer must decide whether this is plausible. It may mean that the article does not in fact contain any candidate substances over 0.1% or that the concentration was inaccurately calculated with reference to the complex product. But no information may also mean that the supplier does not have any such information itself or is not observing the contractual agreements. In this case, the importer should take action.

## **2. Step-by-step analysis of candidate substances in articles**

An analysis is necessary if the supplier of the article does not provide any satisfactory information on the possible presence of candidate substances or despite the absence of information, there is a suspicion that a candidate substance is present.

Particularly in the case of complex products, which may also consist of a large number of very fragmented articles, it can be very difficult or time-consuming in individual cases to specify the concentration of candidate substances for each of these articles.

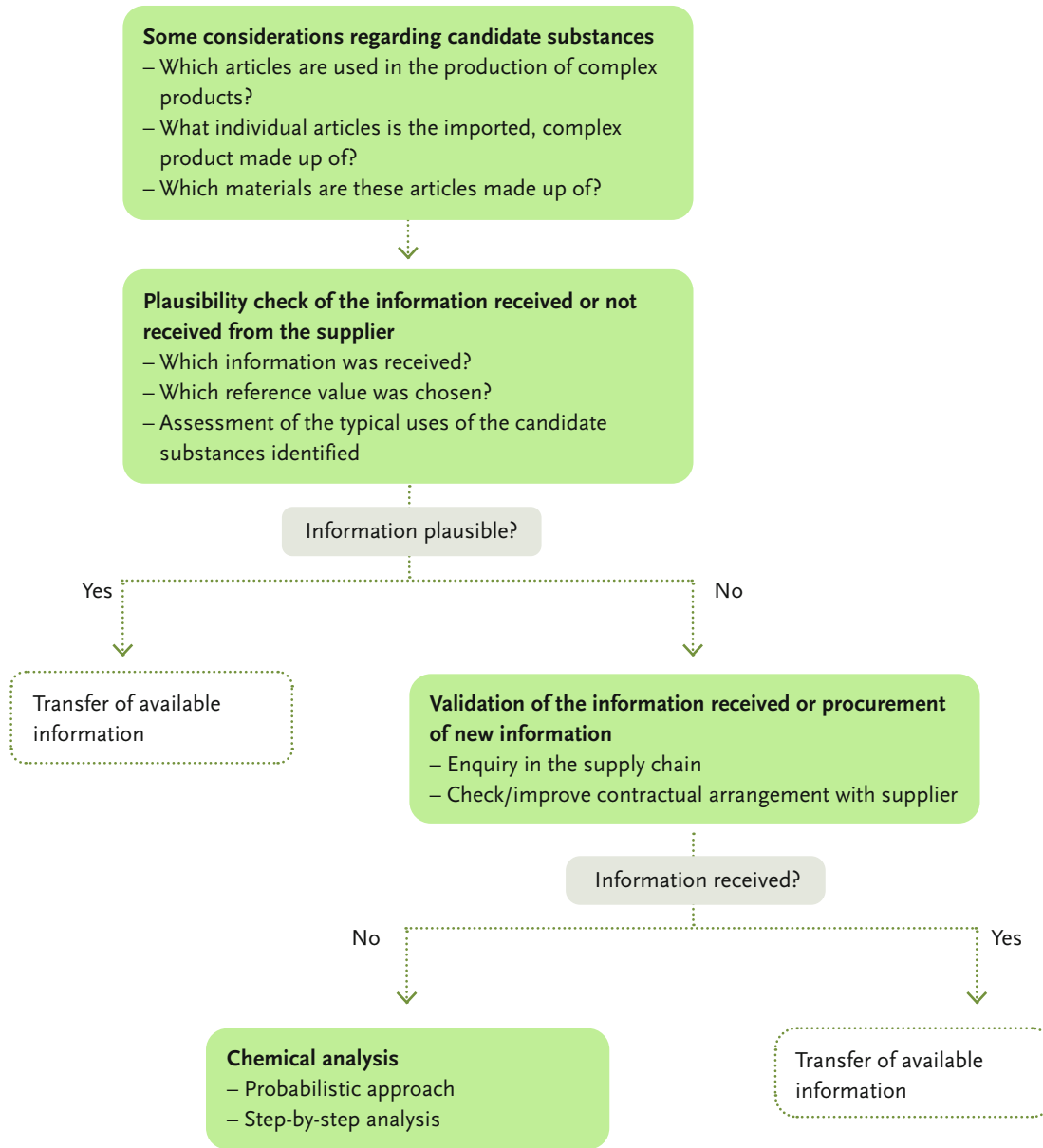


Fig. 6 Basic process to fulfil notification and information obligations for importers or producers of articles

However, in order to fully comply with the information obligations, one approach could be to approximate the individual article in the complex product on a step-by-step basis. One option would be to first analyse the complex product broken down by material and determine the concentration of candidate substances for the respective material, such as plastic (subdivided into rigid and soft plastics, if relevant), metal and ceramics etc. Another strategy for certain complex products could be to compile components with the same function and draw a preliminary conclusion about this group.

If the result of the analysis is that no SVHC over 0.1% was detected in the various materials, it is often also possible to make a statement regarding all articles that were compiled in this group. This group as a whole would no longer need to be taken into account for further considerations as regards potential information obligations.

If SVHC are detected as part of an analysis, this information could be passed on for all articles included in the group to be on the safe side.

In this case however, information on SVHC for articles from the group could potentially be passed on without the concentration actually exceeding 0.1% w/w in each individual article. This can cause problems with regard to providing correct information further down the supply chain. This approach should therefore be limited to very critical cases where it is not possible to make a statement on the individual articles without a considerable amount of effort. If a decision is made to take this approach, the reasons for this should be well documented.

Nevertheless, the objective of this approach should be to approximate the individual article within a complex product on a step-by-step basis in order to be able to ultimately make an authoritative statement on each individual article.

### Example

#### Plastic garden chair

A plastic garden chair cast in one piece is an individual article. Examples of candidate substances that may be present include plasticisers or flame retardants. If this is the case, a declaration must be given to the recipient stating that the concentration of a candidate substance present in the chair is >0.1%.

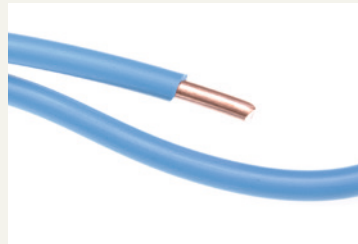


### Example

#### Sheathed cable

This generally involves an article consisting of two materials – the actual copper wire and PVC sheathing. During production, the melted plastic is sprayed on the wire, which means that the question of ‘PVC sheathing’ as an article in its own right does not arise. The reference for the concentration of plasticiser present in the PVC is therefore the wire with the plastic coating.

If the sheathing is manufactured separately as an article and is then pulled over a wire or cable (e.g. shrink-on tube), this is considered to be a composite product made of wire/cable and tubing.



#### Overview of possible approaches for an analysis:

- Complete analysis: All articles are examined for all candidate substances. This involves a lot of time and money.
- Probabilistic analysis: Only candidate substances likely to be present in the individual articles are analysed. It must be considered whether certain candidate substances could be present in an article based on the material properties and whether the use of the article renders the presence of such substances probable.
- Step-by-step analysis: Creation of groups in which articles are included, e.g. based on their material in combination with the probabilistic analysis.

## Example

### Bicycle

The situation is more difficult when considering a complex product (e.g. a bicycle) that consists of a large number of articles made of different materials. In this type of case, it is useful to identify the different articles and divide them into material groups to obtain an initial overview:

Plastics/rubber: Handle, tyre, tubing, rear light etc.

Metals: frame, handlebars, rim etc.

Rubber/plastic products have been produced as such and can be clearly defined or visibly distinguished. It is therefore possible to also draw conclusions about these articles (see Fig. 7).

The painted metal frame is an article. To determine whether a candidate substance is present, there are a number of considerations. There are two different materials present:

1. Metal, 2. Paint. If candidate substances are present, it is unlikely, in view of the material properties, that the same candidate substances will be present in both materials. A differentiated approach is therefore advisable, which will be explained using the example of the bicycle frame. The general considerations, however, can also be applied to the other articles in the figure.

For example, the metal frame (without paint) could contain the candidate substance lead.

In the following, however, the coat of paint will be considered. Here is a simple model calculation:

Assuming a frame with a total tube length of 2.5 m and a circumference of 10 cm, the surface area covered with paint is 0.25 m<sup>2</sup>. With an assumed thickness of this coat of paint of approx. 0.2 mm and a density of 2 g/cm<sup>3</sup>, the mass of the paint is approx. 100 g. With a frame weight of 2.9 kg, the paint content is approx. 3.5%.

Paints usually consist primarily of polymers (e.g. polyester), inorganic and organic pigments and dyes, additives and fillers. Any potential solvents should no longer be present in relevant quantity in the hardened product.

Close attention is therefore to be paid to the components of the paint which may be candidate substances. The following questions are to be considered here:

**Are pigments or dyes included in the candidate list? Are they used in these types of paints?**

**What additives are used in paints? Are they included in the candidate list?**

**Fillers are often inorganic or mineral substances. Are these kinds of substances included in the candidate list and are they also used for these applications?**

**Are concentrations of >0.1% to be expected for the individual substances with respect to the painted frame?**

The polymers present in the paint should be stable, inert and insoluble in water. In view of these properties, polymers, which make up a major proportion of the paint, are not to be expected as possible candidates. The question therefore remains as to whether there are still substances which could be present in the paint in relevant quantities from the other groups mentioned, giving rise to an information obligation. In our sample calculation above, this means that an analysis is not necessary if less than 3 g of a candidate substance is expected (<0.1% in the article painted frame).

In many cases, these kinds of questions can be answered theoretically, i.e. the presence of candidate substances can be ruled out with a high probability and without analysis.

If these questions cannot be answered theoretically, however, or there is no information available regarding whether the paint used may contain a candidate substance, an analysis should be conducted if there is any doubt.



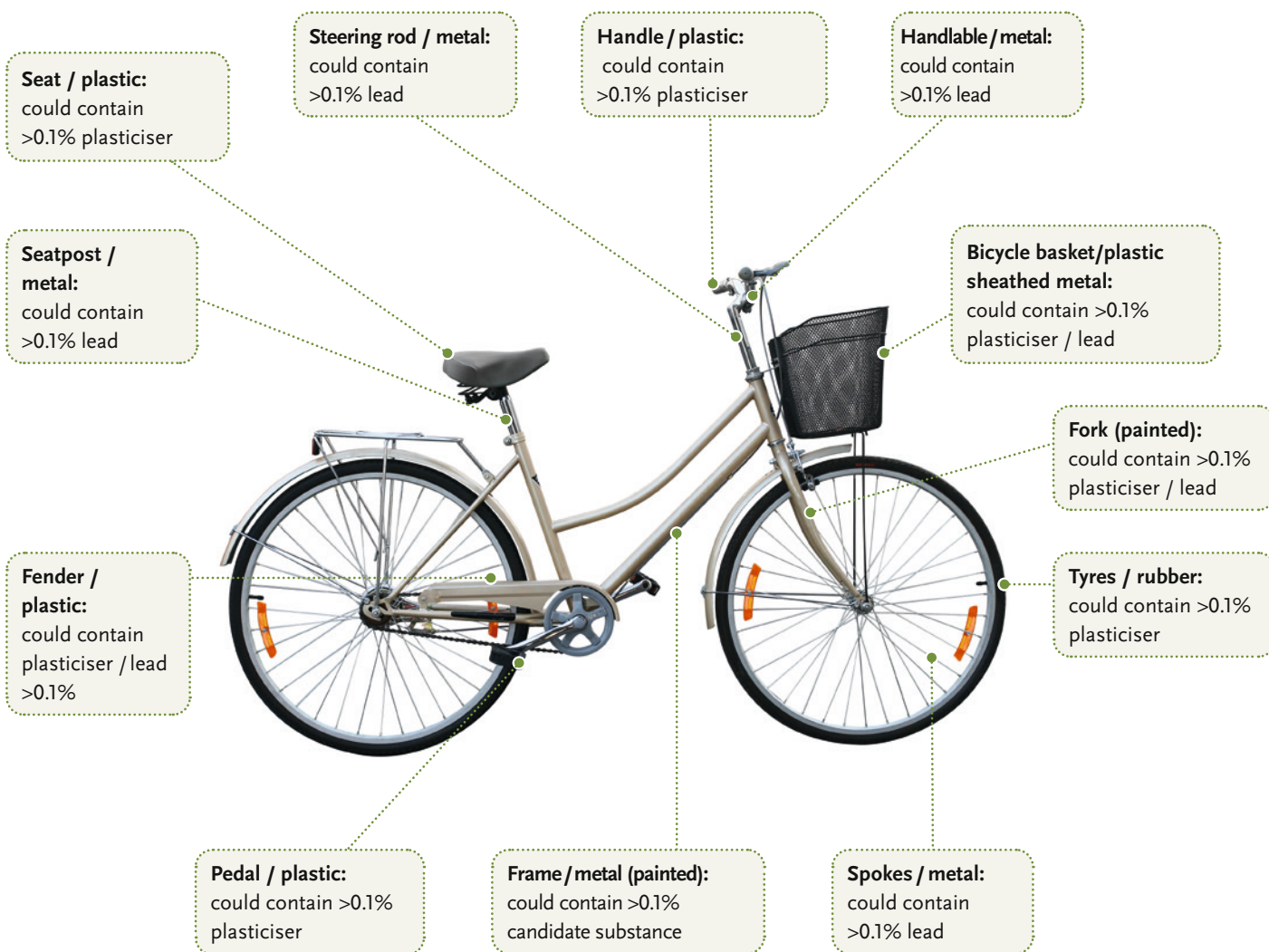


Fig. 7 Bicycle as an example of a complex product

## 7.6 Articles bonded with a SVHC containing adhesive

As described in Section 6.1.3, the individual article (and not the complex product) is the reference value for candidate substance content. In the case of painted articles, the total mass of the article and paint layer is relevant in order to check whether a notifiable candidate substance > 0.1% is present. This was explained based on the example of a painted bicycle frame in Section 7.5.

The following section looks at complex products where articles are bonded together by an adhesive containing an SVHC. For these products, the question arises under which conditions the SVHC in the adhesive is notifiable.

The information and notification obligations referred to in Articles 33 (1) and 7 (2) only apply to articles. First of all, therefore, the question arises as to whether the adhesive, which combines two articles, is to be deemed to be an article in the complex product. According to the guidelines on the requirements for substances in articles, the **adhesive is part of the articles combined in the complex product**, and not a substance or mixture as defined by REACH.

From the classification of the adhesive as part of the articles combined in the complex product follows with regard to the information and notification obligation: **For a candidate substance in the adhesive, the reference value is the total mass from the mass of the adhesive and the masses of the combined articles**. Therefore, in order to have a notifiable mass concentration, the following inequation must be fulfilled:

$$\frac{m_{\text{SVHC in adhesive}}}{m_{\text{adhesive}} + m_{\text{article 1}} + m_{\text{article 2}} \text{ etc.}} > 0.1\%$$

This approach is a pragmatic solution for a borderline case. Strictly speaking, assigning the adhesive to the individual article would only be possible with many complex assumptions that are more or less realistic or unrealistic, which would be difficult to convey. However, it should be noted that, in the case of a complex product

containing more than 0.1% SVHC in an article, this article forms the reference value (Section 6.1.3). Thus, for an SVHC in an article, the mass of the adhesive will not be taken into account even though the adhesive is considered to be a part of the article.

## Example

### Self-adhesive film

In the case of a self-adhesive film, the adhesive layer of the film is covered by paper (see Fig. 8). Neither the film nor the paper contain a candidate substance > 0.1%. However, the adhesive contains  $60 \text{ mg m}^{-2}$  of a candidate substance. Is there an obligation to inform the commercial recipient in accordance with Article 33 (1)?

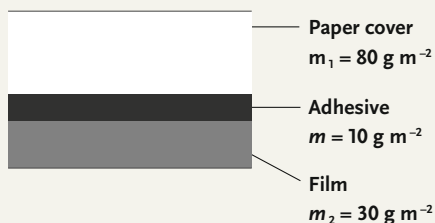


Fig. 8 Cross-section of a self-adhesive film

Both the film and the paper constitute articles as defined by REACH, with the adhesive being an integral part of the two articles. Therefore, the reference value for the candidate substance in the adhesive is the total mass from the mass of the adhesive, the film and the paper. The following applies to a self-adhesive film of  $1 \text{ m}^2$ :

$$\frac{m_{\text{SVHC in adhesive}}}{m_{\text{adhesive}} + m_{\text{article 1}} + m_{\text{article 2}}} = \frac{60 \text{ mg}}{10 \text{ g} + 80 \text{ g} + 30 \text{ g}} = \frac{0.06 \text{ g}}{120 \text{ g}} = 5 \times 10^{-4} = 0.05\%$$

The mass fraction of the candidate substance in the adhesive in relation to the total mass of adhesive, film and paper is 0.05%. Consequently, there would be no obligation to inform the commercial recipient in accordance with Article 33 (1).

## 7.7 Conclusion

In accordance with the interpretation of the CJEU, an object becomes an article for the purpose of the REACH Regulation as soon as it is produced and assumes a specific shape, surface or design that determines its function to a greater extent than the respective chemical composition. It does not lose this article property even if it is merged or combined with other objects in order to form a complex product with them. This means that even an article that is incorporated into a complex product retains its article status (unless it becomes waste or loses its shape, surface or design that determines its function to a greater extent than the respective chemical composition). It is irrelevant how the article is merged or combined with the other articles, i.e. whether it "only" screwed or connected to other articles or glued, soldered or welded onto the articles. Ultimately, the supplier must inform the recipient of each article incorporated into a complex product if the article contains a candidate substance > 0.1%. If information is passed along the supply chain as it should be, all parties involved will find this easy to do. As mentioned, there are however cases where this is not an easy task at all. In such cases, it is necessary to develop a strategy that ultimately enables one to fully comply with the respective information obligations without having to make a disproportionate amount of effort. Such a strategy is outlined in the previous chapters. In summary, the strategy is as follows:

1. Check with the supplier; where necessary, contractually oblige non-EU-based suppliers to pass on information regarding SVHCs
2. Validation and procurement of information; key word: probabilistic approach
3. In very difficult cases or in the case of highly fragmented complex products, a step-by-step approach beginning with a material analysis of previously defined groups of articles may be recommendable.

If this or another similar approach is taken, it is unlikely that you will be accused of violating your obligation to exercise diligence.

However, you are behaving culpably if you make no effort or only a very low amount of effort and consequently do not comply with your information obligations with regard to individual articles. In this case, you have acted negligently, which can be punished as an administrative offence or may result in corresponding damage to one's image.

The strategies presented do not represent any generally applicable criteria for the process, i.e. the questions concerning candidate substances in articles must always be answered on a case-by-case basis.

Each supplier should responsibly document the strategies applied and basic considerations so that he can justify his process if his recipient has doubts about his claims or in the case of monitoring. A strategy adapted to each individual case is an important step in achieving the goal of the REACH Regulation, namely to control the risks of substances of very high concern and create transparency regarding their use.

# Glossary

**Recipient of an article:** According to REACH (Art. 3 (35)), "an industrial or professional user, or a distributor, being supplied with an article, but does not include consumers".

**CLP Regulation:** Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) no. 1907/2006.

**EINECS** (European INventory of Existing Commercial Chemical Substances): EU inventory of existing substances containing around 100,000 substances. The list includes all substances deemed to be on the European market between 1 January 1971 and 18 September 1981 and were reported by the industry.

**Article:** According to REACH (Art. 3 (3))

'An object which during production is given a specific shape, surface or design which determines its function to a greater degree than does its chemical composition.'

**Mixture:** According to REACH (Art. 3 (2))

"Mixture or solution composed of two or more substances".

**Identified use:** According to REACH (Art. 3 (26)) "the use of a substance on its own or in a mixture, or a use of a mixture, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user."

**Supplier of an article:** According to REACH (Art. 3 (33)) "any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market."

**Downstream user:** According to REACH (Art. 3 (13))

"Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2 (7) (c) shall be regarded as a downstream user."

**PBT substances:** Substances with persistent, bioaccumulative and toxic properties.

**Substance:** According to REACH (Art. 3 (1))

"Chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition."

**SVHC** (Substances of Very High Concern): Substances with especially concerning properties.

**Use:** According to REACH (Art. 3 (24))

"Any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation."

**Consumer:** A definition of a consumer was not provided in REACH. A consumer is someone who is not a downstream user as stipulated in Article 3 (13), i.e. a natural person who uses substances or mixtures outside of their industrial or commercial activity.

**vPvB substances:** Substances with very persistent and very bioaccumulative properties.

# Literature and links

REACH-CLP-Biozid Helpdesk at the German Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin – BAuA)

<https://www.reach-clp-biozid-helpdesk.de>

Website of the European Chemicals Agency (ECHA)

<https://echa.europa.eu/de/home>

Guidance on the requirements for substances in articles

(all official languages of the EU)

<https://echa.europa.eu/de/guidance-documents/guidance-on-reach>

Candidate List of Substances of Very High Concern for Authorisation

Candidate List of Substances of Very High Concern for Authorisation

<https://echa.europa.eu/de/candidate-list-table>



## Legal note

### REACH: Info

#### Articles – Requirements for Producers, Importers and Distributors

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