Articles

Requirements for Producers, Importers and Distributors
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Imprint
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. In addition, companies that produce or supply articles have obligations to inform their recipients, who can be processors, distributors, 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 third, revised German edition. The brochure has been categorically updated and extended with information on the judgement of the Court of Justice of the European Union regarding SVHC in articles.

The following other brochures were published under the scope of the REACH info series:

REACH Info 1: Erste Schritte unter der neuen EU-Verordnung REACH
REACH Info 2: Besonderheiten bei Zwischenprodukten und Stoffen in Forschung und Entwicklung
REACH Info 3: Besonderheiten bei Polymeren und Monomeren
REACH Info 4: Neustoffe und REACH
REACH Info 5: Rechte und Pflichten des nachgeschalteten Anwenders unter REACH
REACH Info 7: Die sozioökonomische Analyse
REACH Info 8: Nächste Schritte unter der EU-Verordnung REACH
REACH Info 9: REACH und Recyling
REACH Info 10: Die Zulassung unter REACH
REACH Info 11: Expositionsabschätzung am Arbeitsplatz
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 the manufactured or imported substance is at least 1 tonne per year (t/a). In addition, substances, if they are contained in articles in the amount of 1 tonne per year and manufacturer or importer, and are intended to be released, must also be 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 1 tonne per year if it is not 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

In Article 3 (3) of the REACH Regulation, an article is defined as an object whose outer shape determines its function to a greater degree than its chemical composition. 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 article regardless of whether it is made of wood, metal or plastic. Its shape is what's decisive. On an individual basis, a table may also be chosen because of its material, but its function as a table is not affected.
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.

*Guidance on requirements for substances in articles
The table below provides several examples that were defined in one of the two categories at EU level. No final decisions were reached within the EU for examples flagged with an *). In these cases, the view of the REACH-CLP-Biozid Helpdesk was applied.

The table only provides an overview of the **basic differentiation** between a substance and an article. In the examples that follow, individual criteria that help differentiate between substances/mixtures and articles are explained.

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Classification</th>
<th>Material</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metal pipe</td>
<td>Article</td>
<td>Pen</td>
<td>Mixture (in a container)</td>
</tr>
<tr>
<td>Blasting abrasive</td>
<td>Substance or mixture *)</td>
<td>Printer/ink cartridge</td>
<td>Mixture (in a container)</td>
</tr>
<tr>
<td>Magnetic foils</td>
<td>Article</td>
<td>Candles</td>
<td>Substance or mixture *)</td>
</tr>
<tr>
<td>Aluminium foil</td>
<td>Article</td>
<td>Battery</td>
<td>Article</td>
</tr>
<tr>
<td>Wire</td>
<td>Article</td>
<td>Adhesive Tape</td>
<td>Article</td>
</tr>
<tr>
<td>Welded wire</td>
<td>Substance or mixture *)</td>
<td>Wet cleaning wipe</td>
<td>Mixture (on a carrier)</td>
</tr>
<tr>
<td>Metal balls (ball bearings)</td>
<td>Article</td>
<td>Metal bars</td>
<td>Substance or mixture</td>
</tr>
<tr>
<td>CD cases (plastic)</td>
<td>Article</td>
<td>Machine (oiled)</td>
<td>Article</td>
</tr>
<tr>
<td>Paper</td>
<td>Article</td>
<td>Car tyres</td>
<td>Article</td>
</tr>
<tr>
<td>Textiles</td>
<td>Article</td>
<td>Glow stick</td>
<td>Mixture</td>
</tr>
<tr>
<td>Polyester fibres</td>
<td>Article</td>
<td></td>
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<tr>
<td>Packaging</td>
<td>Article</td>
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</tr>
</tbody>
</table>
Example

One example of how complex differentiation is are filled **toner cartridges** for a laser printer. 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 be classified as an article.

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

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 it is more difficult or complicated, becomes an important criterion in the decision. If this is possible, and this must also be assumed in the case of toner which can also fulfil its function independently of the cartridge, this is a clear indication that it is not an article.

This system is more of a container that, on the one hand, holds the substance or mixture and, on the other hand, 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. The function of the toner independently 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.**
Another borderline case is the spray can, which may have a complex nozzle for even application of paint. Ultimately, this is also a container, similar to the case of the toner cartridge, whose main function is to hold the paint to be applied to an object using 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.

Conclusions for both examples

1. **Registration** of the substance(s) in the toner or the paint in accordance with Article 6 under the conditions specified there.

2. **Possible information obligation** in accordance with Article 7 (2) and Article 33 if SVHCs are contained in the material of the toner cartridge/spray can.

3. **Possible classification and labelling** of the contained mixture (by 1 June 2015 pursuant to the Dangerous Preparations Directive 1999/45/EC, then in accordance with the CLP Regulation).
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.

Regardless of whether a candle is a substance or a mixture, should the definition of an article be applied, it would not be an article with intentional release of substances in accordance with Article 7 (1) because the combustion products are not released intentionally but which 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 to sustain the combustion process. This is another criterion that supports the interpretation "candle = substance or mixture".

Import of an engine block whose movable parts are oiled: Does the lubricant used have to be registered when the engine block is imported?
An engine block is an article as defined in 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. As it can be assumed that the intention is not to release this oil (for more information, see chapter 4), it is not necessary to register the oil.

What needs to be considered 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, to protect against corrosion or for finishing. 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 form or shape.
Differentiating between articles and substances/mixtures

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 this, an aluminium bar is considered a substance while rolled or pressed products such as foils, sheets or profiles are seen as articles. Thus the parts of a bar must be registered as long as their quantity is at least 1 tonne per year and per manufacturer/importer (Article 6 of the REACH Regulation).

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.

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.

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.

When importing wire (exception: 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 which, however, is generally not the case for metals.

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

Blasting abrasives can be, e.g. metals or mineral materials. 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 abrasive were to be classified as an article, the shape of the particles (round, angular, raw, etc.) would be more important than its chemical composition.

**The following questions were used in decision-making by the REACH-CLP-Biozid Helpdesk.**

1. Are the form, shape, surface important for the effectiveness of the blasting abrasive?

2. Are the form, shape, 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 applicable?

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:
Form, shape, 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.
Differentiating between articles and substances/mixtures

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 (form, shape), 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 drying agents, e.g. that are included 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 included drying agents are not part of the article, in this case, camera or hand bag, they are substances or mixtures.

Silicon dioxide which is generally used as a drying agent must be registered pursuant to Article 6 if it is not a natural substance as defined in Article 3 (39) and the quantity does exceed the limit of one 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 with the European Chemicals Agency (ECHA).
4. Which obligations apply for 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. In the following decision-making tree, an overview of these obligations and conditions is shown. The REACH obligations are explained in detail for those affected in the following chapters.
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 for substances, namely substances themselves or for 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 contains 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 non-phase-in substance that is intended to be released from articles must be registered before the article is placed on the market.

For phase-in substances, the interim provisions in Article 23 apply if the substance was preregistered by the importer or producer of the article in accordance with Article 28.

Exemption
An exemption from registration of substances in articles is found in paragraph 6 of the same article. According to this, 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.
5.1 What does "release under normal or reasonably foreseeable conditions of use" mean?

The legal text 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 an article declared by its producers or importers. Such uses involving the release of the substance should be "reasonably foreseeable" in order to establish an 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. through warnings
- accidents

Upon closer inspection, there are only a small number of 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 called a carrier whose main function is to release the perfume.

The following examples help this issue further:

Is wear and tear of car tyres considered intentional release of substances as defined in Article 7 (1)?

When car tyres are subject to abrasion, this does not involve 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 articles themselves 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. The substances/mixtures can be washed off again at the end of the process. Is this considered 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. when 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). In actuality, the status of the substance changes under REACH when it is released. The “finish” substance becomes waste. Waste is exempt from obligations to register 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.

Article 7 (1) thus does not apply for wet cleaning wipes. The substances in the cleaning agent instead 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 Article 7 and 33 of the REACH Regulation

Notification obligations towards the ECHA arise for the 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 consumers in accordance with Article 33, however, to the latter only at their request.

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?

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 in Article 57 and is identified in accordance with Article 59 (1) if both the following conditions are met:

a) the substance is present in those articles in quantities totalling over 1 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).
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**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 a 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 of very high concern. In relation to the total quantity, it must be kept in mind that the substance quantities of differently affected articles must be added together when applicable. The producer or importer of the article is responsible for notification.

According to Article 7 (4), the following information must be forwarded 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 **information obligation** towards a recipient of an article in accordance with Article 33 also arises if a 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 provides the **recipient** with the information available to him that is sufficient for safe use of the article. This includes at least the name of the substance in question. He supplies the same information to the **consumer**, but only upon **request**.
6.1.2 How are substances of very high concern identified?

The criteria that characterise substances of very high concern are defined in Article 57 of the REACH Regulation. According to this, these substances are classified as carcinogenic, germ cell mutagenic or toxic for reproduction 1A or 1B. It 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) under the definition of substances of very high concern.

Substances with endocrine properties, i.e. properties that affect hormone balance and substances with properties similar to 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 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 apply.
To include a substance in the candidate list, a dossier must be generated that fulfils the requirements set forth in Annex XV of the REACH Regulation. 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 directly in the candidate list or following 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% 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 an article does not, as a general rule, lose its article character as a result of the incorporation ("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.
Fig. 3 Summary of the procedure to identify substances for the candidate list

*http://echa.europa.eu/web/guest/candidate-list-table
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 a SVHC, the producer or importer of this article informs the ECHA when both of the following conditions are met no later than 6 months after the substance is included in the candidate list:

The substance is contained in these articles at a level of more than 1 tonne per year and per producer or importer 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.
– For the tonnage of the candidate substance, its total quantity in all articles is used as a basis.
– To calculate the quantity threshold of the candidate substance of 1 tonne per year, only those articles in which the concentration is above 0.1% weight by weight are recorded.
– If an article contains several candidate substances, the calculation for every substance is performed separately and not as the total of all candidate substances.
6.1.5 Are there exemptions to the notification obligation for substances in articles?

According to Article 7 (3), the notification obligation set forth in Article 7 (2) can be omitted if the possibility of exposure of humans and the environment can be excluded. The previous chapter explained the definition of normal or reasonably foreseeable conditions.

A further exemption for the notification obligation to the ECHA is contained in Article 7 (6). According to this, 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) (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 exist for the supplier of an article in accordance with Article 33?

According to the REACH Regulation, the name of the substance must be communicated to the recipient as a minimum. In addition, however, all information sufficient for safe use of the article must also be provided.

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 case is shown by the example in the box below.

**Example**

When an article is processed, dust can be produced. Exposure of the recipient to this dust can, in the case of professional use, be prevented by technical equipment such as, e.g. an exhaust 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 exhaustion.

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 an article supplier has an information obligation in accordance with Article 33, he must provide the information to the recipient in a suitable form. However, the format and the channel are not defined. This makes it possible to provide the information on paper or electronically. It is not adequate to publish the information on the company's website because the provision of the information is considered an active process of "making it available to the recipient of the article".

What language must be used to pass on information in accordance with Article 33?
The REACH Regulation itself does not indicate which language the information has to be provided in. It is important, however, that the recipient can understand the information provided to him. As a result, the supplier of the article must use a language that he can assume his recipient can understand. This is usually the official language of the respective country. If, however, the supplier and recipient regularly communicate in a different language, the information may also be provided in this language.

On the other hand, the respective official language must be used for consumers in accordance with Article 33 (2).

From what quantity does information need to be passed on to the recipient in accordance with Article 33?
The obligation to pass on information is only dependent on the concentration of the SVHC in the article. This means that, independently of the annual tonnage, the information obligation always applies starting from a concentration of more than 0.1% weight by weight.

Do the notification obligations set forth in Article 33 also apply for "old articles", i.e. for 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 a 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, the supplier must pass on the information required in Article 33 to the recipient.
Who is responsible in the article supply chain 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 SVHCs are contained in an article, 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 research on whether SVHCs are present in an article 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 him.

6.1.7 How can the consumer obtain information on SVHCs in an article?
According to paragraph 2 in Article 33, a consumer also has the right to request information about the SVHCs that appear on the candidate list 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 a SVHC is contained in an article, 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 he also has to obtain the relevant information.

If a consumer asks a question about the presence of SVHCs of the supplier or producer of the article, he 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 Obligation to notify in accordance with Article 40 of the CLP Regulation

The importer or producer of an article also has a notification obligation to the ECHA if his article contains a substance that is required to be registered. This affects in particular 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 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 is required to provide the ECHA with the following information as long as 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**

**Article 40 of the CLP Regulation**

(1) Any manufacturer or importer, or group of manufacturers 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 of 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 in (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. Within the EU, there have been varying interpretations with regard to the reference for an article in cases where an article is incorporated into another 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 believe that in cases where a product is incorporated into another 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 more complex product. In recital 53 of the judgement made by the CJEU it is stated in this context that "... a manufactured object meeting the criteria laid down in Article 3(3) of the REACH Regulation does not cease to be an article when it is assembled or joined with other objects in order to form with them a complex product. In such a situation, that manufactured object remains an ‘article’ within the meaning of that provision."

In brief, this is referred to as the principle

"Once an Article – Always an Article" ¹

The interpretation of the principle "Once an Article – Always an Article" is explained in detail in the "Guidance for suppliers of articles" of the supporter states mentioned².

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¹ Often abbreviated as 1O5A
² Guidance provided by member states Germany, Denmark, France, Belgium and Sweden as well as Norway in 2013

www.reach-clp-biozid-helpdesk.de/de/Downloads/Fachbeitraege/Leitfaden%20f%C3%BCr%20Lieferanten%20von%20Erzeugnissen_de.pdf?__blob=publicationFile
Some examples of individual articles are listed below that must also be even consulted for calculating the SVHC concentration even if the respective articles are combined with one or more other articles. Furthermore, this means that information must be passed on, specifying the individual article that contains a candidate substance greater than 0.1 percent by weight.

The following are examples of individual articles:
- belt buckle
- bicycle grip
- shoe soles
- computer housing

The principle "Once an Article – Always an Article" offers a variety of significant advantages with regard to the transfer of articles:
- Basic objectives such as the protection of human beings and the environment as well as transparency in the supply chain are achieved.
- The producer of a complex product may pass on directly the information obtained on individual articles (without additional calculations).
- Consumers who call upon their right to information in accordance with Article 33 (2) of the REACH Regulation obtain 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 a product or not.
- If the information available on candidate substances in the individual articles is not adequate for imported complex products, making a chemical analysis necessary, the analysis of the individual articles may be easier than one for the complex product.
- EU-based producers and importers of articles are subject to the same obligations. The importer does not profit 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 players involved along the supply chain are also informed that the continued availability of the article is subject to a certain amount 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 therefore not simply "disappear" from the market without warning.
7.2 Satisfying the registration 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.

Under certain conditions, however, producers of complex products or importers 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, the supplier from outside of the EU is not willing to or able to provide the information required.

The following describes a possible procedure from the point of view of the German REACH-CLP-Biozid Helpdesk for article producers or importers to fulfil the notification or information obligations with respect to articles. This means that, on the basis of the principle "Once an Article – Always an Article", the individual article is used as the reference value and not the assembled article.
Fig. 4 Information flow for candidate substances in a supply chain within the EU. Substance manufacturers and formulators indicate these in the safety data sheets (SDS) when they are present.
7.3 Individual considerations regarding candidate substances

To even be in the position to comply with the information obligations in accordance with Article 7 (2) and Article 33 of the Reach Regulation with reference 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 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 (probability approach) and how plausible information is on SVHC in the supply chain.

In this context 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 German REACH-CLP-Biozid helpdesk has drawn up a list of examples of typical uses for the candidate substances identified to date. This can be found using the link3 below. A use specified in this list for a certain substance may, for example, in the event of doubt justify further research up to 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.

3 www.reach-clp-biozid-helpdesk.de/de/REACH/Kandidatenliste/Kandidatenliste-Verwendung/Kandidatenliste-Verwendung.html
7.4 Production of articles

The question about the concentration of candidate substances in articles is variably 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 handle", to the purchaser 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. This is important as there will probably be a delay in all importers and suppliers practically implementing the judgement made by the CJEU regarding complex products.

7.5 Import of articles

An importer of a complex product or an EU producer of a complex product that imports individual built-up articles from outside of the EU can, in contrast, be presented 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 on SVHC. 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 due 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 is a range of situations that can occur in the course of this:

a.) Information on the concentration of candidate substances >0.1% is provided. 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 on to the recipient of the article.

b.) Information on the concentration of candidate substances >0.1% is provided. The information is **not trustworthy** or plausible. Further action is required, e.g. 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 there are actually no candidate substances present in the article or that the concentration was wrongly calculated with reference to the complex product. But no information may also mean that the supplier himself does not have any such information or does not comply with the contractual agreement. In this case, the importer should take action.

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**2. Step-by-step analysis or of the complex product**

An analysis is necessary if the supplier of the article or of the complex product 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 that may also consist of a great number of very fragmented articles, it can be very difficult or more laborious in individual cases to state the concentration of candidate substances for each of these articles.

However, in order to fully comply with the information obligations, an 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 (where relevant, separated into rigid and soft plastics), 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.
Individual considerations regarding candidate substances

- Which articles are used in the production of complex products?
- The imported complex product is made up of which individual articles?
- Which materials make up these articles?

Plausibility check of the information received or not received from the supplier

- Which information was provided?
- Which reference was chosen?
- Assessment of the typical uses of the candidate substances identified

Information plausible?

Yes
- Pass on available information

No
- Validation of the information received or procurement of new information
  - Enquiry in the supply chain
  - Check/improve contractual arrangement with supplier

Information received?

No
- Chemical analysis
  - Probability approach
  - Step-by-step analysis

Yes
- Pass on available information

Fig. 5 Basic process to fulfil notification and information obligations for importers or producers of articles
If the result of the analysis is that no SVHC was detected in the different materials, as a general rule a statement can also be made regarding all articles that were included 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 would possibly 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 finally make an authoritative declaration on each individual article.

Possible approach for an analysis at a glance:

- Complete analysis: All articles are examined for all candidate substances. This involves a lot of time and money.
- Probability analysis: Only those 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 the different articles are included, e.g. based on their material in combination with the probability analysis.
**Example**

**Plastic garden chair**
A plastic garden chair cast in one piece is an individual article. Candidate substances that may be present are, for example, 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**

**Insulated 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 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 complex product made of wire/cable and tubing.

**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: grips, tyre, hose, rear light, etc.
- Metals: frame, handlebars, rim, etc.

In this way, rubber or plastic articles produced as such are clearly defined or more specifically, the scope of these is discernibly outlined. It is therefore possible to also draw conclusions about these articles (see Fig. 6).

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.

No candidate substances are currently expected in the metal frame (without paint).
This means that the **coat of paint** must primarily 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 m². With an assumed thickness of this coat of paint of approx. 0.2 mm and a density of 2 g/cm³, the mass of the paint is approx. 100 g. With a frame weight of 2.9 kg, the percentage of paint present is approx. 3.5%.

In general, paints primarily consist of polymers (e.g. polyester), inorganic and organic pigments and dyes, additives and fillers. Possible solvents should no longer be present in the hardened product in relevant quantities.

Close attention is therefore 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 kinds 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, such 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. 6  Bicycle as an example of an assembled article

- **Saddle/plastic:** Could contain >0.1% plasticiser
- **Handlebar/metal:** Currently no candidate substances to be expected
- **Grip/plastic:** Could contain >0.1% plasticiser
- **Handlebars/metal:** Currently no candidate substances to be expected
- **Seat post/metal:** Currently no candidate substances to be expected
- **Splash guard/plastic:** Could contain >0.1% plasticiser
- **Bicycle basket/plastic unsheathed metal:** Could contain >0.1% plasticiser
- **Forks (painted):** Could contain >0.1% plasticiser
- **Tyres/rubber:** Could contain >0.1% plasticiser
- **Pedal/plastic:** Could contain >0.1% plasticiser
- **Frame/metal (painted):** Could contain >0.1% candidate substance
- **Spokes/metal:** Currently no candidate substances to be expected
7.6 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 obtains 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 the shape, surface or design that determines its function to a greater extent than the respective chemical composition). How the article is merged or combined with the other articles, so whether it is, for example, "only" screwed or connected to other articles or stuck, soldered or welded onto the articles is irrelevant. Ultimately, the supplier must inform the recipient of each article incorporated into a complex product if a candidate substance >0.1% is contained in the article. 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 commit non-EU-based suppliers to pass on information regarding SVHC
2. Validation and procurement of information; key word: probability approach
3. In very difficult cases or in the event of very fragmented complex products, a step-by-step approach beginning with a material analysis of previously defined groups of articles can be recommended

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 valid 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 one of the goals of the REACH Regulation, namely to control the risks of substances of very high concern and create transparency regarding their use.
Glossary

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


**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.

**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.

**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 industry.

**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".

**Mixture:** According to REACH (Art. 3 (2)), "a mixture or solution composed of two or more substances".

**Non-phase-in substance:** Substance that is not described by the definition of a phase-in substance.

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

**Phase-in substance In accordance with REACH (Art. 3 (20)), a substance which meets at least one of the following criteria:

a) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);
b) it was manufactured in the Community, or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004, on 1 January 2007 or on 1 July 2013, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided that the manufacturer or importer has documentary evidence of this:

c) it was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004, on 1 January 2007 or on 1 July 2013, by the manufacturer or importer before the entry into force of this Regulation and it was considered as having been notified in accordance with the first indent of Article 8 (1) of Directive 67/548/EEC in the version of Article 8 (1) resulting from the amendment effected by Directive 79/831/EEC, but it does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this, including proof that the substance was placed on the market by any manufacturer or importer between 18 September 1981 and 31 October 1993 inclusive

**Substance:** In accordance with REACH (Art. 3 (1)), "a 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".

**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".

**SVHC:** Substances of very high concern

**Use:** In accordance with 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".

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

**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".
**Literature and links**

REACH-CLP-Biozid Helpdesk at the German Federal Institute for Occupational Safety and Health  
(Bundesanstalt für Arbeitsschutz und Arbeitsmedizin – BAuA)  
www.reach-clp-biozid-helpdesk.de

Website of the European Chemicals Agency (ECHA)  
http://echa.europa.eu

Guidance on the requirements for substances in articles (all official languages of the EU)  

Candidate List of Substances of Very High Concern for Authorisation  
http://echa.europa.eu/web/guest/candidate-list-table
Imprint

REACH Info 6
Articles – Requirements for Producers, Importers and Distributors

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