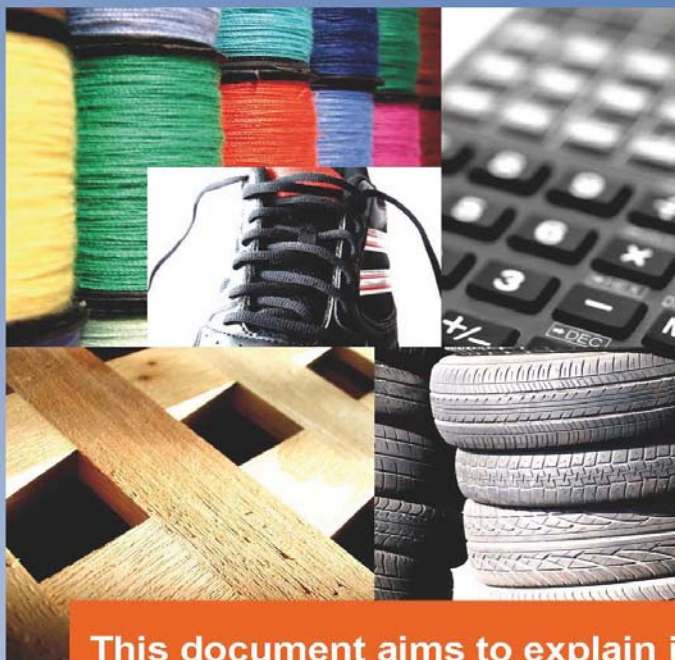


*Guidance in a Nutshell*

# Requirements for Substances in Articles



**This document aims to explain in simple terms the main requirements for substances in articles.**

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## 1. INTRODUCTION

This Guidance in a Nutshell explains in brief the provisions of Regulation (EC) No 1907/2006 (REACH Regulation) that apply to substances in articles.

This Guidance in a Nutshell is aimed at managers and decision-makers of companies producing, importing and/or supplying articles in the European Economic Area<sup>1</sup> (EEA), particularly if they have little experience with chemicals regulatory affairs. Reading this document will allow them to decide whether they need to read the full [Guidance on requirements for substances in articles](#) or not, in order to identify their obligations under REACH concerning substances in articles.

Companies located outside of the EEA may use this Guidance in a Nutshell to understand the requirements for substances in articles the importers of their products in the EEA have to fulfil.

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<sup>1</sup> The European Economic Area is composed of Iceland, Liechtenstein, Norway and the 27 EU Member States.

## 2. ESSENTIALS TO UNDERSTAND

### 2.1 What is an article?

Most of the commonly used objects in private households and industries are articles, e.g. furniture, clothes, vehicles, books, toys, and electronic equipment. An article may be very simple, like a wooden chair, but it could also be rather complex, like a computer.

The REACH Regulation defines an article as “an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition”.

In this regard, the shape, surface and design of an object represent its physical appearance and can be understood as other than chemical characteristics. **Shape** means the three-dimensional form of an object, like depth, width and height. **Surface** means the outermost layer of an object.

**Design** means the arrangement of the ‘elements of design’ in such a way as to best accomplish a particular purpose. For example, the design of a textile may be determined by the twist of fibres in the yarn, the weave of threads in a fabric and the treatment of the surface of the textile.

The term “**function**” in the article definition should be interpreted as meaning the basic principle determining the use of the object rather than the degree of technical sophistication. In this sense, for example, the function of a printer cartridge is basically to bring ink onto paper, and the function of a battery is to provide electric current.

### 2.2 What is an intended release of substances from articles?

Substances may be intended to be released from articles in order to provide an “added value”, where this accessory function is not directly linked to the main function. Scented children’s toys, for example, are articles with intended release of substances, because fragrance substances contained in the toys are released in order to provide an added value, namely a pleasant smell.

### 2.3 Are there substances which are of particular concern?

There are certain substances which are of particular concern, because they may have very serious effects on human health and the environment. These substances can be found in the “Candidate List of Substances of Very High Concern for Authorisation” in the [ECHA Chem section of the ECHA website](#). Substances are included on this candidate list after it has been agreed by a formal procedure that they fulfil the criteria for being substances of very high concern.

If a substance listed on the candidate list is contained in articles, this may trigger additional obligations for companies producing, importing and supplying these articles.

### 3. WHO MAY HAVE OBLIGATIONS FOR SUBSTANCES IN ARTICLES UNDER REACH?

#### 3.1 Companies producing articles

Articles can be produced from components which are already articles themselves, and also from substances or mixtures of substances that are transformed into articles or incorporated in articles during the production process. Irrespectively of the production process, companies producing articles within the EEA may have obligations for the substances contained in their articles.

#### 3.2 Companies importing articles

Companies located inside the EEA can import articles from outside of the EEA either to supply them to their customers, or for the production of new articles. These companies may have the same obligations for the substances contained in the articles imported as companies producing these articles within the EEA.

#### 3.3 Companies supplying articles

Companies placing articles on the market in the EEA may also have to fulfil certain requirements for substances in articles. This is irrespective of whether they produce these articles themselves or whether they purchase them (inside or outside of the EEA). In this regard, retailers are also supplying articles and may have obligations for the substances contained therein.

**Please note that companies may also have obligations other than those for substances in articles, which are outlined in the present Guidance in a Nutshell.** Therefore, in general, companies are advised to identify their obligations by running the [Navigator](#) on the ECHA website. The Navigator helps industry to determine its obligations under REACH and find the appropriate guidance on how to fulfil these obligations.

## 4. WHAT ARE THE OBLIGATIONS FOR SUBSTANCES IN ARTICLES UNDER REACH?

### 4.1 Registration of substances in articles

Registration is the submission to ECHA of a technical dossier with information on the properties of a substance and, if required, a chemical safety report documenting the chemical safety assessment for this substance. Registration of a substance in articles is mandatory for an **article producer or importer** only if the following two conditions are met:

- The substance is intended to be released from the produced and/or imported articles during normal or reasonable foreseeable conditions of use.
- The total amount of the substance present in all articles produced and/or imported, from which the substance is intended to be released, exceeds 1 tonne per year.

For the second condition the amounts intended to be released as well as the amounts which are not (intended) to be released need to be taken into account. Furthermore, if different types of article with intended release are produced and/or imported, the quantities in all articles with intended release have to be summed up.

If the above conditions are not met, ECHA may still decide that an article producer or importer must submit a registration for any substance in an article, if the amount of the substance exceeds 1 tonne per year and there is a suspicion that the substance is released from the article resulting in risk to human health or the environment.

In any case, the substance does not have to be registered by the article producer or importer, if this substance has already been registered for that use (i.e. the use by which the substance is included in the article) by another company.

### 4.2 Notification of substances in articles

Notification is the submission of specific information on a substance and its uses in articles to ECHA. Notification of a substance in articles is required by an **article producer or importer** when all of the following conditions are met:

- The substance is included in the candidate list of substances for authorisation (see section 2).
- The substance is present in articles produced and/or imported above a concentration of 0.1% (w/w).
- The total amount of the substance present in all articles produced and/or imported, which contain more than 0.1% (w/w) of the substance, exceeds 1 tonne per year.

If, however, any of the following conditions are met, no notification is required:

- The producer/importer can exclude exposure of the substances to humans or the environment during normal or reasonably foreseeable conditions of use including disposal (i.e. it can be demonstrated that no exposure occurs at all life-cycle stages of the substance).
- The substance has already been registered for that use (i.e. the use by which the substance is included in the article) by another company.
- The articles have only been produced and/or imported by the producer/importer before the substance was included in the candidate list of substances for authorisation.

The substance concentration threshold of 0.1% (w/w) applies to the article as produced or imported. It does not relate to the homogeneous materials or parts of an article, as it may in some other legislation, but relates to the article as such (i.e. as produced or imported)<sup>2</sup>.

A notification of substances in articles shall be made at the latest 6 months after it has been included on the candidate list of substances for authorisation, but only starting from 1 June 2011.

### 4.3 Communication of information on substances in articles

Suppliers of articles containing a substance included in the candidate list of substances for authorisation in a concentration above 0.1% (w/w) have to provide relevant safety information about this substance available to them to the recipients of these articles. If no particular information is necessary to allow safe use of the article containing a substance from the candidate list, as a minimum the name of the substance in question has to be communicated to the recipients. The information is to be provided to the recipients automatically, i.e. directly after the substance is included in the candidate list. Note that the term “recipients” refers to **industrial or professional users and distributors**, but not to consumers.

Information available to the article supplier necessary to ensure safe use of an article has to be provided also to **consumers** upon request. Consumers have to be provided with this information within 45 days of the request, free of charge.

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

- There is no tonnage trigger for this obligation (i.e. it also applies below 1 tonne per year).
- A packaging is always to be treated as an article separate from the contents of the packaging. Therefore, the obligation to communicate information on substances in articles also applies to packaging materials.

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<sup>2</sup> [Dissenting views](#), questioning the application of the 0.1% threshold to the entire article have been notified by six Member States (Austria, Belgium, Denmark, France, Germany and Sweden) and publication of this part of the guidance document was not endorsed by these Member States.

- The substance concentration threshold of 0.1% (w/w) applies to the article as supplied. Like in the context of substance notification, it does not relate to the homogeneous materials or parts of an article, but to the article as such<sup>3</sup>.
- The obligation also applies to articles which were produced or imported before the substance was included in the candidate list and are supplied after the inclusion. Thus, the date of supply of the article is the relevant date here.

The following table compares the registration, notification and communication obligations for substances in articles.

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

**Table 1: Main obligations for substances in articles.**

## 4.4 Compliance with restrictions for substances in articles

The use of particular substances in certain articles is restricted under REACH. Therefore, companies have to make sure that the articles they produce or import are compliant with the restrictions outlined in the REACH Regulation. Details on compliance with restrictions are given in chapter 13 of the [Guidance for downstream users](#).

<sup>3</sup> [Dissenting views](#), questioning the application of the 0.1% threshold to the entire article have been notified by six Member States (Austria, Belgium, Denmark, France, Germany and Sweden) and publication of this part of the guidance document was not endorsed by these Member States.

## 5. PRACTICAL GUIDANCE TO IDENTIFY REQUIREMENTS FOR SUBSTANCES IN ARTICLES

This section aims to provide particular support in identifying the requirements for substances in articles described in section 4.

### 5.1 Deciding whether an object is an article or not

Producers and importers of articles have duties less frequently under REACH compared to substance manufacturers and importers of substances or mixtures as the first group may be exempted from registration in different circumstances (e.g. if the substance has been registered for that use). A correct, consistent and well documented decision as to what is an article under REACH is therefore a key issue.

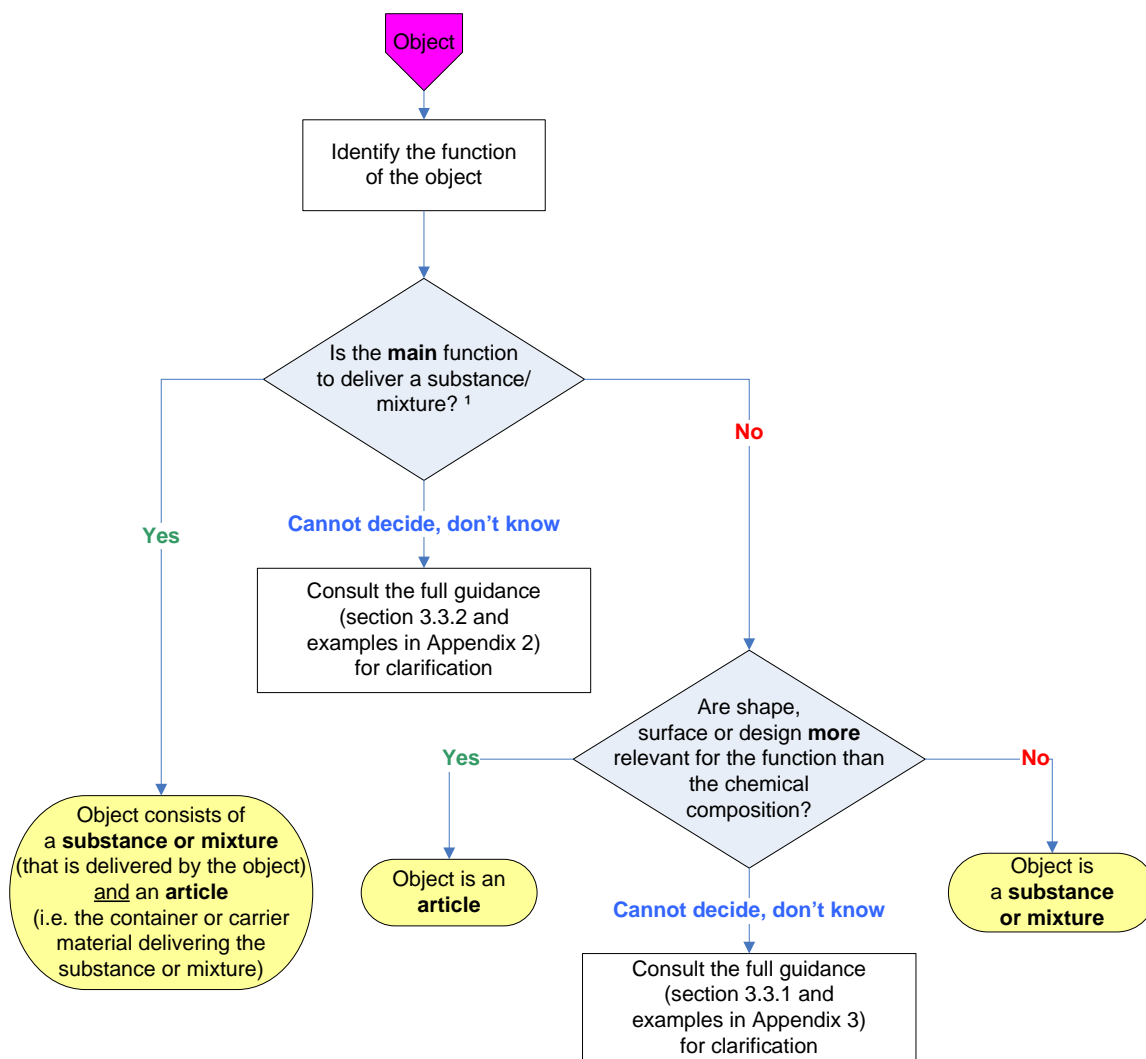
The decision as to whether an object is actually an article can however be difficult in certain “borderline cases”. Two types of borderline cases are distinguished:

- raw materials and semi-finished products that are further processed to final articles.
- objects containing substances/mixtures, or objects carrying substances/mixtures on their surface.

The transition point of raw materials and semi-finished products from substances/mixtures to articles during processing is to be determined by comparing the importance of physical and chemical characteristics for achieving the object’s function. If you can unambiguously conclude that the shape/surface/design are more relevant for the function than the chemical composition, the object that you are assessing is an article. If the shape, surface or design is of equal or less importance than the chemical composition, it is a substance or mixture. In case of doubt, you may use the indicative questions given in section 3.3.1 of the full [Guidance on requirements for substances in articles](#) in order to better determine whether or not the raw materials or semi-finished products constitute an article.

Concerning the second type of borderline case, a main principle to be followed is that if an object merely acts as a container or carrier material to deliver a substance or mixture (such as a spray can with a mixture in it, a printer cartridge, a pen, a cleaning tissue containing chemicals, a printer ribbon or a carbon paper with ink, etc.) then the object is to be seen as an article with a substance/mixture enclosed in it. Importing such an object would mean that the importer might not only have the obligations of importers of articles (see section 4), but also the obligations of importers of substances/mixtures (these are explained in detail in the [Guidance on registration](#)).

Opposite to this there are cases where a substance/mixture is to be seen as an integral part of an article like the liquid in a thermometer, where the thermometer and the liquid within it together form an article.



<sup>1</sup> In answering this question, consider the object as a whole, including a potential chemical content (like e.g. in a battery or a thermometer).

Figure 1: Flowchart illustrating decision-making on whether an object is an article or not.

## 5.2 Deciding whether a substance release is intended or not

If a substance is intended to be released from an article, it may have to be registered under REACH. It is therefore essential to establish whether the release of this substance from articles is intended or not, in order to identify the possible obligation to register this substance in articles.

As explained in section 5.1, if the main function of an object is to deliver a substance or mixture, then the object is to be seen as an article with a substance/mixture enclosed in it. This delivery of a substance/mixture is not to be regarded as an “intended release” from articles under REACH.

Thus, a substance is intended to be released from articles if it fulfils an **accessory function** which would not be achieved if the substance were not released

(fragrance substances in children's toys were given as an example of this in section 2.2). Consequently, substances that are released because of ageing of articles, because of wear and tear or as an unavoidable side-effect of the functioning of the article, are generally not intended releases, as the release as such does not provide a function in itself.

An intended release of a substance from an article has furthermore to occur under **normal or reasonably foreseeable conditions of use**. This means that the substance release has to occur during the service life of the article. Hence, a substance release during the production or disposal phase of the article's life cycle is not an intended release. Similarly, a release in an accident or due to any form of misuse which is not in accordance with the use instructions or functionality of the article, does not occur under normal or reasonably foreseeable conditions of use and is therefore not considered to be an intended release.

### 5.3 Determining whether cut-offs for requirements for substances in articles are exceeded or not

The requirements for substances in articles may apply if the amount of a substance in articles produced and/or imported or its concentration in these articles exceeds specific thresholds. For this reason it is necessary to obtain (qualitative and quantitative) information on the composition of articles imported, as well as on substances and mixtures that are included in articles during production.

Identifying and quantifying substances in articles or mixtures is in many cases only possible if the respective information is made available by the actors in the supply chain. **Supply chain communication** is therefore the most important and effective way of gathering the information needed in order to identify ones obligations under REACH. In this regard, establishing communication standards for the supply chain is an important task for the private sector in order to facilitate the implementation of REACH.

Information needed to identify and comply with requirements for substances in articles can often be derived from **standard information** that is obtained from suppliers based in the EEA. Suppliers of substances or mixtures, for instance, have to provide their customers with safety data sheets, or, where a safety data sheet is not required, with available and relevant safety information and details on regulatory requirements (need for authorisation, restrictions imposed). Suppliers of articles must provide available and relevant safety information as well, provided that the articles supplied contain a substance included in the candidate list of substances for authorisation in a concentration above 0.1% (w/w).

Importers of substances, mixtures and articles will not necessarily receive comparable standard information from their non-EEA suppliers. In this case and whenever standard information received from suppliers in the EEA is not sufficient to check compliance with REACH, companies have to obtain the necessary information by **pro-active requests** in the supply chain. To avoid requests having to be passed up complex supply chains via several distributors, the producers of articles, formulators and manufacturers of substances could be identified and addressed directly to obtain the information required. Furthermore, it may be helpful to tell the suppliers why the information is needed, which may be unknown, particularly to non-EEA suppliers.

In many cases, however, the exact composition of articles or mixtures is not needed to clarify whether requirements for substances in articles have to be fulfilled. Certainty in particular that no notification or communication obligations for substances in articles apply can also be achieved by **excluding or limiting the presence of substances** that are on the candidate list of substances for authorisation. Suppliers could for example provide certificates which guarantee that certain substances are not used in the manufacture of their products or remain below certain concentrations in their products. A different approach would be to include respective criteria in supply contracts excluding or limiting the presence of certain substances in the products to be supplied. Accordingly, requests in the supply chain should wherever possible also be targeted and e.g. aim at excluding or limiting the presence of certain substances instead of asking for the exact composition of articles or preparations, which is more often confidential information.

Substances contained in articles or mixtures can also be identified and their concentrations quantified by applying analytical methods. However, **chemical analyses** may yield ambiguous results, and be very costly and time consuming. They should therefore be considered only as the last resort to obtain the information necessary to identify obligations under REACH, i.e. only if other approaches to obtain information such as publicly available databases or branch knowledge fail or become too complicated.

## 5.4 Determining whether a substance is already registered for a use or not

A registration or notification of a substance in articles is not required, if the substance has already been registered for that use (i.e. the use by which the substance is included in the articles) by another company. This is the case, if two conditions are fulfilled:

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

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

A potential registrant or notifier of a substance in articles would also have to check if the use in question by which the substance is included in his articles is the same as one of the uses described in a registration of this substance that was already made. For this he has to describe the process by which the substance is included in the articles, and into which type of article. This use description should be in line with the use descriptor system explained in [chapter R.12 of the Guidance on information requirements and chemical safety assessment](#). To come to a conclusion on whether the substance is considered as registered “for that use” or not, he has to compare this use description with those uses already registered for the substance.

Where the provision of a safety data sheet is required, once a substance has been registered, information on the uses it has been registered for are communicated down the supply chain. Please note that the complete set of registered uses may not be identified in a safety data sheet for a mixture, as these are more specific than those for the single substances. Such standard information on registered uses, however, will normally not be communicated along the supply chain for non-dangerous substances or mixtures, nor for articles.

In most cases, if you need to find out for which uses a substance has been registered, you will have to ask other actors up your supply chain. Alternatively you could identify and ask a manufacturer or importer of that substance from any supply chain for the uses he has registered this substance for, or whether he has registered it for a particular use. A good way to identify manufacturers and importers of a substance is to launch a corresponding request within the Substance Information Exchange Forum for this substance (SIEF), provided that you have pre-registered the substance.

## 6. HOW TO COMPLY WITH THE DUTY TO COMMUNICATE INFORMATION ON SUBSTANCES IN ARTICLES

REACH does not specify a particular format for providing information on substances in articles. You must choose a format that will ensure that the recipient can readily become aware of the information. The information could for example be included in already existing documents, such as instructions for use.

In order to determine what safety information shall be provided to the recipient of an article, or to a consumer requesting this, the article supplier has to consider how the article is used, which exposures and risks could arise and which information, in particular on risk management, is required for the user of the article to ensure safe handling. Assessing and communicating on safe use under REACH in general means addressing the life-cycle of a substance from the stage of the respective actor. Article suppliers should hence consider the service life of the article as well as appropriate instructions for its disposal. Specific storage or transport conditions should also be considered, where relevant for safe use of the article.

## 7. WHERE TO FIND FURTHER GUIDANCE

This Guidance in a Nutshell should provide you with the decision-making aids necessary to identify possible obligations under REACH concerning substances in articles. If your case, however, is particularly complex you may want to consult the full [Guidance on requirements for substances in articles](#) in order to conclude on whether the requirements for substance on articles apply or not.

The full guidance document provides more detailed examples and explanations of the concepts introduced by the present document. Additional insight might be gained particularly by reading the following parts of the full guidance document:

- Section 2.8 gives recommendations for record-keeping.
- Aspects related to the chemical analysis of substances in articles as well as recommendations for the planning of a testing strategy are described in section 5.
- Appendices 2 and 3 contain detailed examples of both types of borderline cases mentioned in section 5.1 of the present document.

# Guidance in a Nutshell

## Requirements for Substances in Articles