ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE IN A NUTSHELL

Requirements for substances in articles

The document aims to explain in simple terms the main requirements for substances in articles

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European Chemicals Agency

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

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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 (EEA, but henceforth referred to simply as "EU")[1], 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 EU may use this Guidance in a Nutshell to understand the requirements for substances in articles the importers of their articles in the EU have to fulfil.

2. Essential to understand

2.1 What is an article?

Most of the commonly used objects in private households and industries are themselves articles (e.g. one-piece plastic spoons, injection-moulded garden chairs), or incorporate articles (e.g. sofa, vehicle, clock, electronic equipment). 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 properties other than chemical characteristics. **Shape** means the three-dimensional form of an object, like depth, width and height. **Surface** means the outermost layer of an object. **Design** means the arrangement or combination of the "elements of design" in such a way as to best accomplish a particular purpose of the object, taking into account amongst others the safety, utility/convenience, durability, and quality.

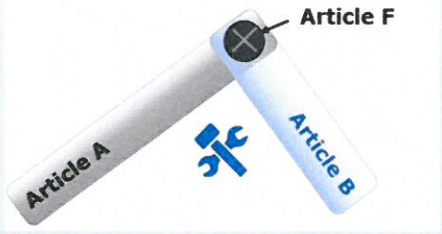
The term "**function**" in the article definition should be interpreted as meaning the intended purpose for which an object is to be used. In this sense, for example, the function of a printer cartridge is to bring ink/toner onto paper, and the function of a battery is to provide electric current.

Articles that are assembled or joined together remain articles, as long as they keep a special shape, surface or design, which is more decisive for their function than their chemical composition, or as long as they do not become waste[2].

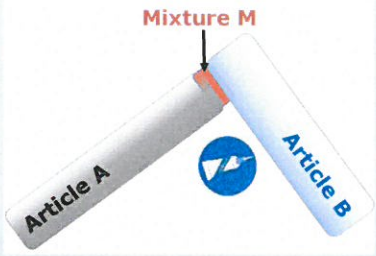
In this guidance and in the full *Guidance on requirements for substances in articles*, the term "**complex object**" refers to any object made up of more than one article. In complex objects, several articles can be joined or assembled together in various manners. For example, they can be mechanically assembled or joined using substance(s)/mixture(s) as shown in Figure 1. The question whether a complex object itself may fulfil the definition of article turns solely on a determination according to the criteria laid down in the article definition.

[1] The European Economic Area is composed of Iceland, Liechtenstein, Norway and the European Union Member States.

[2] "Waste" as defined in the Waste Framework Directive (Directive 2008/98)



A) Articles mechanically assembled (i.e. articles assembled without the incorporation of substance(s)/mixture(s))
Example(s): pair of (metallic) scissors, foldback clips



B) Joining together two or more articles using substance(s)/mixture(s)
Example(s): block of sticky notes, glued chip in a bank card, unpainted bicycle frame formed by welding together multiple steel tubes.

Figure 1: Types of complex objects

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 accessory function that is not directly linked to the main function. A scented children's toy, for example, is an article with intended release of substances, because fragrance substances contained in the toys are released with the intention to make the article more attractive by providing a pleasant smell.

2.3 What are Candidate List substances ?

Candidate List substances are substances of very high concern (SVHCs), because of their 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" (Candidate List)[3] available in the ECHA Website[4]. Substances are included on this Candidate List after it has been agreed according to a formal procedure that they fulfil the criteria for being SVHCs.

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

A company is an **article producer** if it produces articles within the EU, regardless of how the articles are produced and whether they are placed on the market. Irrespective of the production process, companies producing articles within the EU may have obligations for the substances contained in their articles.

3.2 Companies importing articles

Companies located inside the EU can import articles from outside the EU either to supply them to their customers, for further processing, or own final use. These companies may also have obligations for the substances contained in the articles imported, as companies producing these articles within the EU.

[3] In the remainder of this document "Candidate List" means "Candidate List of Substances of Very High Concern for Authorisation".

[4] https://echa.europa.eu/candidate-list-table

3.3 Companies supplying articles

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

Please note that companies producing, importing and supplying articles may also have other roles and thus have further obligations under REACH than those outlined in the present Guidance in a Nutshell. 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.

Moreover, Appendix 1 of the full *Guidance on requirements for substances in articles* outlines the main REACH processes or activities that may affect producers, importers and suppliers of articles.

4. What are the obligations for substances in articles under REACH?

The following table outlines the registration (Article 7(1)), notification (Article 7(2)) and communication (Article 33) obligations for substances in articles.

Table 1: Obligations for substances in articles

Obligation	Registration of substances in articles	Notification of substances in articles	Communication of information on substances in articles
legal basis in REACH Regulation	Article 7(1)	Article 7(2)	Article 33
actors concerned	article producers and article importers	article producers and article importers	article suppliers
substances concerned	substances intended to be released from articles	substances included in Candidate List of Substances of Very High Concern for authorisation	substances included in Candidate List of Substances of Very High Concern for authorisation
tonnage threshold	1 tonne per year	1 tonne per year	-
concentration in article threshold	-	0.1% (w/w)	0.1% (w/w)
exemption from obligation possible on the basis of:			
substance already registered for that use (Art. 7(6))	yes	yes	no
exposure can be excluded (Art. 7(3))	no	yes	no

The flowchart below (Figure 2) gives an overview of the major steps involved in identifying obligations for substances in articles and directs the reader to the relevant corresponding sections in the full Guidance.

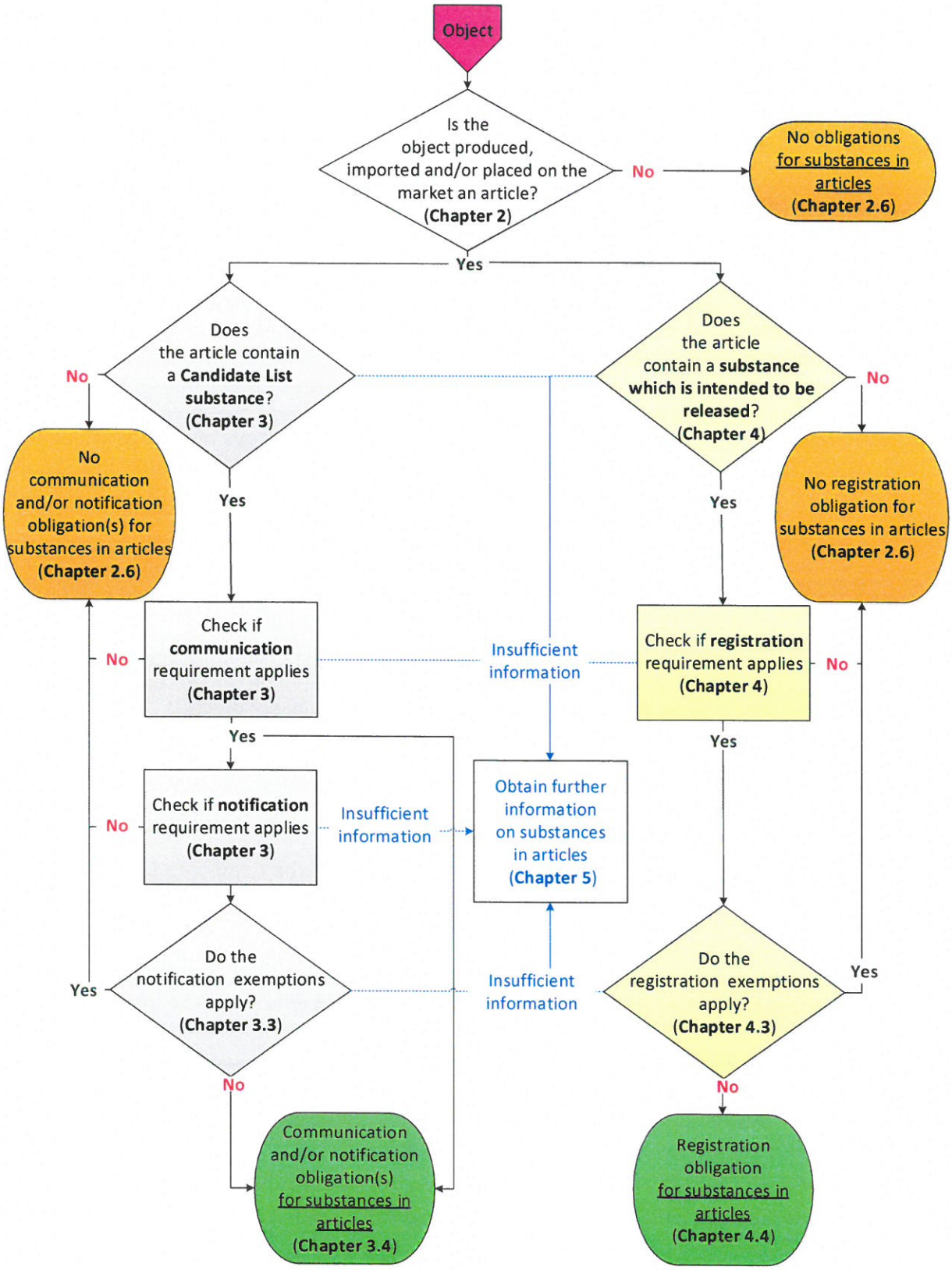


Figure 2: General processes for identifying obligations for substances in articles according to Articles 7 and 33

4.1 Requirements for Candidate List substances in articles

4.1.1 Communication of information on substances in articles

Any supplier of an article containing a substance has to provide to the recipient of the article (Article 33(1)) or to a consumer (Article 33(2)) relevant safety information, available to him, when both the following conditions are met:

- The substance is included in the Candidate List (see section 2), and
- The substance is present in articles produced and/or imported above a concentration of 0.1% (w/w),

The information is to be provided **to the recipient**[5] of the article **when the article is supplied** for the first time after the inclusion of the substance into the Candidate List and **to the consumer upon request** by that consumer, within 45 calendar days of that request and free of charge.

If no particular information is necessary to allow safe use of the article containing a Candidate List substance, e.g. when exposure can be excluded at all life cycle stages of the article including disposal[6], **as a minimum the name of the substance in question has to be communicated** to the recipients of the article or to consumers. The information provided should make it clear that the substance is on the most recent update of the Candidate List and that this is the reason for giving the information.

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

- The Candidate List substance concentration threshold of 0.1% w/w applies to every article supplied. This threshold applies to each article of an object made up of more than one article, which were joined or assembled together (complex objects);
- There is no tonnage trigger for these obligations;
- A distributor supplying articles to consumers does not comply with his communication obligation toward a consumer upon request, just by referring the consumer to his own supplier, or the producer/importer of the articles;
- The communication obligations arise from the presence of the Candidate List substance in the article. These obligations apply regardless of whether or not the supplier is aware of the presence of the substances. Therefore, it is in the interests of the supplier to seek information on the presence of Candidate List substances;
- The communication of information at the request of a consumer is independent of whether the article was purchased by that particular consumer.

4.1.2 Notification of substances in articles

Notification is the submission of specific information on a substance and its uses in articles, as well as the use of the article 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 (see section 2), and
- The substance is present in articles produced and/or imported above a concentration of 0.1% (w/w), and

[5] The term "recipients" refers to industrial or professional users and distributors, but not to consumers
[6] It is recommended to document the reasons that lead to the conclusion that no information other than the substance name only is necessary to be communicated to allow the safe use of the article (see sub-section 2.6 of the full Guidance).

- 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 for the producer/importer.

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 during the service life of the articles and the waste stage);.
- The substance has already been registered for that use (i.e. the use of the substance in the article) by the company or another company;
- The articles have only been produced and/or imported by the producer/importer before the substance was included in the Candidate List.

The substance concentration threshold of 0.1% (w/w) applies to each article as produced or imported. This threshold applies to each article of a complex object. An importer of a complex object is importer of the various articles the complex object is made from, and must therefore have the necessary information for each one of them for the purpose of being able to comply with notification obligations. Section 3.2.2 of the full *Guidance on requirements for substances in articles* gives further details and scenarios regarding who is responsible to notify each of the articles in a complex object. It contains illustrative scenarios for objects assembled, joined or coated in the EU and for imported complex objects.

A notification of substances in articles shall be made at the latest 6 months after it has been included in the Candidate List.

4.2 Requirements for substances intended to be released from articles

4.2.1 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, and
- 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 or are not released at all, 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 of the substance in the article) by another company.

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

A correct, consistent and well documented decision as to what is an article under REACH is a key issue, when determining your role and duties as producer, importer and supplier of articles.

In many cases applying the REACH definition of an article (see section 2.1 is straightforward. The decision on whether an object is an article or not can then directly be made by comparing the importance of physical and chemical characteristics for achieving the object's function, i.e., following steps 1 and 2 in the workflow illustrated in Figure 3. However, in cases where it is not possible to unambiguously conclude whether the object fulfils the REACH definition of an article or not, a more in-depth assessment is needed.

Before proceeding with this assessment, it needs to be judged whether the object contains a substance or mixture that can be physically separated from the object (e.g. by pouring or wringing out/ see step 3). Depending of this reasoning, the assessment may consist on answering a series of questions under steps 4 and 5 or under step 6. Those answers may enable to conclude on the article status of the object.

One outcome of this process can be that the object is a combination of an article (functioning as a container or a carrier) and a substance/mixture, such as a printer cartridge or a wet cleaning wipe. It is to be noted that an importer or supplier of such an object is also considered to be an importer or supplier of a substance/mixture. As such he might also have obligations other than those of importers and suppliers of articles. This means that substances in a container or on a carrier material might e.g. have to be registered, or be supplied with a safety data sheet. Importers and suppliers of a combination of an article and a substance/mixture, therefore have to separately check if obligations for the article apply and if obligations for the substance/mixture apply.

The assessment on whether an article should be considered an "article with intended release of a substance/mixture" or not, as defined in section 2.2 is strongly recommended to be done at step 2, before proceeding with the next steps.

Steps 3 to 6 were developed to support a more in depth assessment for certain large (sub)groups of objects with common features. Note that they do not cover all possible objects, therefore they may not allow reaching a final conclusion for a particular object under assessment. In such cases, the assessment needs to take into account other specific considerations that will allow answering the question in step 2 of the workflow.

Each of the steps is described in more detailed in section 2.3 of the full *Guidance on requirements for susbtances in articles*.

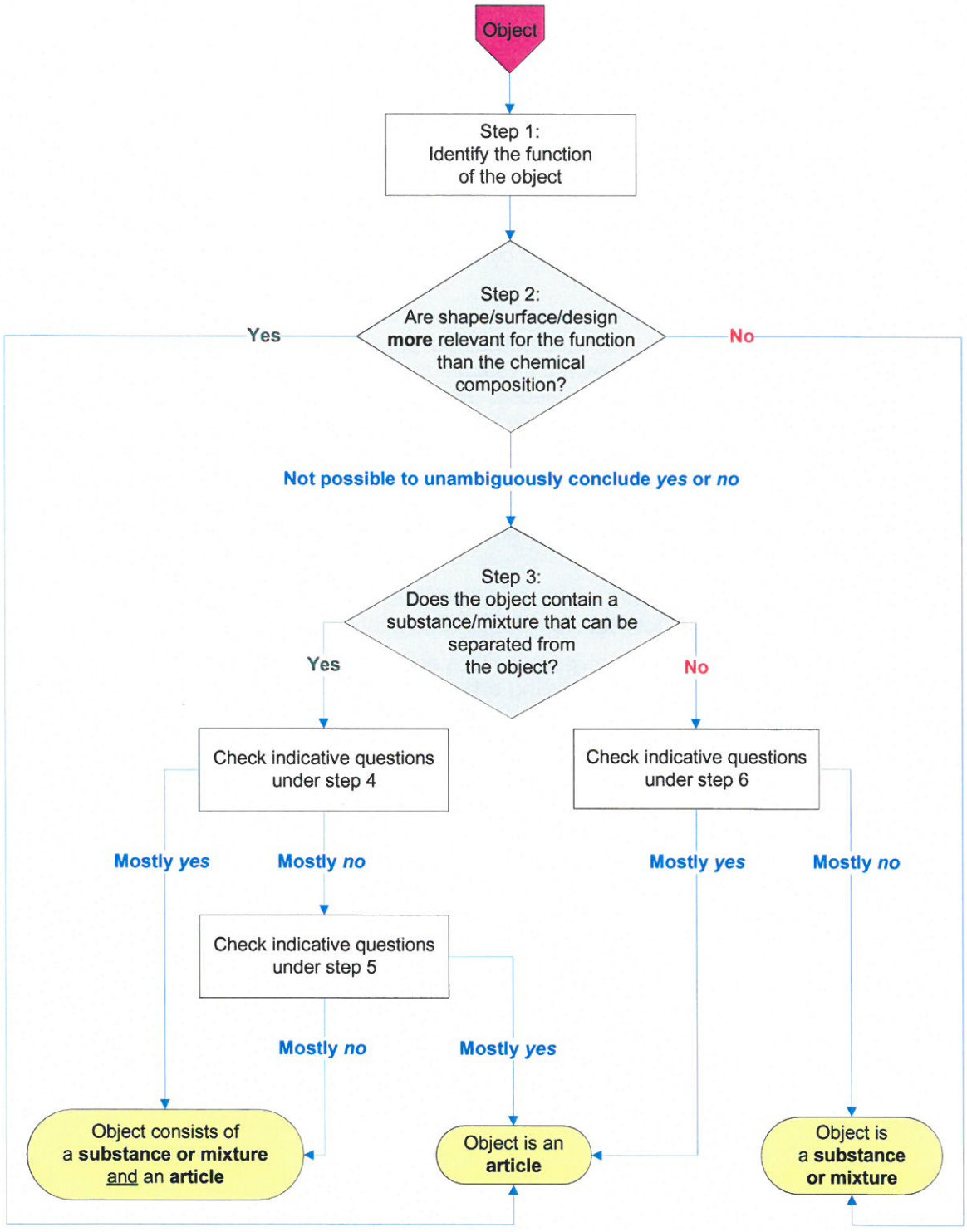


Figure 3: Flowchart illustrating decision-making on whether an object is an article or not

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.

If the main function of an object is to deliver a substance or mixture, then the object is usually to be seen as a combination of an article and a substance/mixture. 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 a children's toy was given as an example of this in section 2.2). In contrast, the release of a substance, because of ageing of articles or of wear and tear, or as an unavoidable side-effect of the functioning of the article, is generally not considered as an intended release. A release as such does not provide a function in itself.

An intended release of a substance from an article has 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 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 the concentration and the tonnage of a Candidate List substance in articles

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

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

Table 2 illustrates several scenarios on how to determine the concentration of a Candidate List substance (weight by weight (w/w)) in an article.

Table 2: Scenarios illustrating how to determine the concentration of a Candidate List substance (w/w) in articles

Scenario	Calculation of the concentration of a Candidate List substance (w/w)	Example(s)
I. Article made from a Candidate List substance as such or in a mixture	The concentration is calculated over the total weight of the article, i.e. dividing the weight of the Candidate List substance in the article by the total weight of the article.	Plastic article made from a mixture (e.g. injection moulded chair, plastic print for a t-shirt) containing a Candidate List substance.
II. Candidate List substance as such or in a mixture used for joining two or more articles (complex object)	The concentration of the Candidate List substance is calculated over the total weight of the complex object, i.e. by dividing the weight of the Candidate List substance in the complex object by the total weight of the complex object.	See Figure 1 B).
III. Candidate List substance in coatings		Examples of coating mixtures: paint, lacquer, varnish, functional coating
III. A) Fully coated article	The concentration of the Candidate List substance in the (fully/partially) coated article is calculated over the total weight of	

Scenario	Calculation of the concentration of a Candidate List substance (w/w)	Example(s)
III. B) Partially coated article	the coated article, i.e. dividing the weight of the Candidate List substance in the coated article by the total weight of the article	
III. C) Coated complex object	The concentration of the Candidate List substance is calculated over the total weight of the complex object, i.e. dividing the weight of the Candidate List substance in the coated complex object by the total weight of the coated complex object.	
IV. Very complex objects (combinations of simpler complex objects plus further articles)	The calculation rules set out for scenarios I to III above apply for each article or simpler complex object.	Sofa, bicycle, mobile phone, car and aircraft.

One of the conditions of the **notification obligation** is the 1 tonne threshold per actor per year for the Candidate List substance present in all articles produced and/or imported in a concentration above 0.1% w/w.

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

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

   The calculation of the concentration of the Candidate List substances in articles or complex objects is done as described in Table 2.

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

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

If the total amount of the Candidate List substance present in all articles produced and/or imported, which contain more than 0.1% w/w of that substance, exceeds 1 tonne per actor per year, the producer/importer has the obligation of submitting a notification of substance in articles to ECHA for that Candidate List substance.

5.4 Determining whether exemptions from notification obligation apply or not

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

(a) exemption based on exclusion of exposure and
(b) exemption for substances already registered for that use.

According to Article 7(3), notification is not required if the producer or importer of articles can exclude exposure to humans or the environment during normal or reasonably foreseeable

conditions of use[7], including disposal[8]. A producer/importer wanting to demonstrate exclusion of exposure has to ensure that the SVHC on the Candidate List does not come into contact with humans or the environment. All exposure routes in all life cycle stages have to be considered (service life of the article and waste stage) when assessing the exclusion of exposure.

According to Article 7(6) a notification of a substance in articles is not required if the substance has already been registered for that use. This refers to any registration of that use of the substance in the same supply chain or any other supply chain, i.e. for this exemption from notification to apply, the registrant does not necessarily need to be in the same supply chain as the potential notifier. A substance has already been registered for a particular useif two conditions are fulfilled:

- The substance is the same as the substance already registered;
- The use is the same as the use described in a registration of the substance, i.e. the registration refers to the use in the article.

The substance information in the **ECHA's dissemination portal**, which can be accessed via the ECHA website: http://echa.europa.eu/information-on-chemicals, will normally not be sufficient on its own to conclude on the sameness of two uses for the purpose of establishing whether exemption for substances already registered for that use applies.

Note that it might require more resources and be more difficult to properly assess and document exclusion of exposure or to find out if the substance is already registered for the use, than to prepare and submit a substance in articles notification. A justification of the applicable exemption should be documented so that it can be presented to enforcement authorities on request.

Further considerations on the applicability of the exemptions from substance in articles notification obligations are provided in section 3.3 of the full Guidance.

6. How to comply with the duty to communicate information on substances in articles

EU producers and importers of articles and all actors in the supply chain are required to communicate down the supply chain on the presence of the Candidate List substances (above 0.1% w/w). The information communicated should be sufficient to allow safe use of the articles they place on the market. While industrial/commercial actors in the supply chain should get this information as a matter of course, consumers have to request the information. It is recommended to always provide an answer to a consumer request, even if there are no Candidate List substances present in the article.

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

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

Furthermore, the supplier should consider recycling and disposal of the articles as well as foreseeable misuse of articles, in particular, by consumers.

[7] The terms "normal conditions of use" and "reasonably foreseeable conditions of use" are explained in section 5.2.
[8] The term "disposal" here also covers the waste stage. This stage, as part of the life cycle of a substance, needs to be considered in the exposure assessment to demonstrate "exclusion of exposure".

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

All actors receiving information on the presence of the Candidate List substances and on safe use must pass on any relevant information to the next actor in the supply chain, or to consumers upon request, taking into account the expected uses and conditions of use of the article placed on the market.

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

REACH does not specify a particular format for providing information on substances in articles. You must choose the most appropriate format for provision of information, depending on the content and the addressee of the information (e.g. industrial or professional users, consumers).

Standard answering letters might be a suitable medium to inform consumers, whereas a professional or industrial user might be better informed through separate use instructions. Among several possible formats, there are also IT systems or tools available to facilitate communication throughout the supply chain and to consumers.

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. However, we recommend you 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 explanations of the concepts and principles introduced by the present document, as well as examples.

Companies producing, importing or placing articles on the market do not always have the information in house which is necessary to establish whether they are subject to substances in articles obligations. Identifying substances in articles and quantifying their amounts is in many cases only possible if the respective information is made available by the actors in the supply chain. **Supply chain communication** is therefore the most important and efficient way of gathering the information needed in order to identify and comply with your obligations under REACH. Chemical analysis, although helpful in certain situations (e.g. obtain and confirm information needed for compliance), may yield ambiguous results and/or be very costly and are thus not recommended as the preferred instrument for obtaining information.

Section 5 of the full *Guidance on requirements for susbtances in articles* provides general advice, for producers, importers and other suppliers of articles on performing their duties for obtaining and then evaluating the information needed to comply with their substance in articles obligations. This is particularly relevant when information has not been made available to the supplier through the supply chain as a matter of course. Appendix 5 in the full Guidance complements that general advice for complex objects.

EUROPEAN CHEMICALS AGENCY
ANNANKATU 18, P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU