



Guidance on requirements for substances in articles

1.0 Introduction

A company has the role of an article producer, if it produces articles within the EU, regardless of how it is produced and where the article is placed on the market. An article importer is any company located inside the EU which imports articles from countries which are located outside the EU. In article supplier is a company which produces, imports or distributes articles and/or places them on the EU market. Retailers are also article suppliers.

Non-EU producers of articles may appoint "Only Representatives" to fulfill all obligations of the importers of their articles into the EU. In this case, Only Representatives shall fulfill all obligations for substances in articles, including pre-registration and registration of substances with an intended release and notification of Substances of Very High Concern on the so-called "candidate list".

This guidance mainly describes how a company can check whether it has to fulfill any requirements under REACH regulation. Please note that if article producers use substances and preparations (bought on the EU market) in the production process of the article, they also have to fulfill downstream user requirements. If the article producer also is the importer of substances/preparations into the EU, he is also a substance importer and may have to fulfill a number of other REACH requirements for these substances, including registration requirements under Article 6 of REACH, unless as indicated above his supplier outside the EU has appointed an only representative to fulfill the importer obligations.

The main objectives of this guidance are to:

- Assist the REACH actors in deciding whether or not they are manufacturers or importers of substances (on their own or in preparations) or article suppliers

- Assist article suppliers (article producers, article importers and/or distributors/retailers of articles, as well as only representatives of non-EU companies exporting articles to the EU) in deciding if they have to fulfill registration, notification and/or communication requirements related to substances in their articles

2.0 What is an article under REACH

"Article means 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;" (REACH, Article 3(3)).

In a general understanding, an article is an object composed of one or more substances or preparations given a specific shape, surface or design. It may be produced from natural materials, such as wood or



wool, or from synthetic ones, such as polyvinyl chloride (PVC). Substances or preparations may be added to give an article its special properties. Most of the commonly used objects in private households and industries are articles, e.g. furniture, clothes, vehicles, books, toys, kitchen equipment, and electronic equipment.

An article is to be understood as the article *as produced or imported*. It may be very simple, like a wooden chair but could also be rather complex, like a computer, consisting of several parts, which are also considered articles when produced or imported. It may be particularly difficult to decide if an object is an article or if it is a substance or preparation when assessing different stages in raw materials processing. Furthermore, when substances or preparations are enclosed in an object it may be difficult to decide if they are to be considered an integral part of an article (like e.g. the liquid in a thermometer) or if they are not an integral part of an article (for example an aerosol in a spray can, ink in a printer cartridge). In these cases, these are classified as “Borderline cases”, detail will be explained in later part of this guidance.

2.1 The function of an object

The function of an object, which may or may not be an article, is determined by what its producer / supplier wants it to be used for and what the person acquiring it expects it to do. For many objects there is no doubt about what their function is, for example the function of scissors is to cut. The function is thus **either obvious or could be evidenced by the object’s labels, use instructions** etc. If it is difficult to decide whether or not an object is an article it may be necessary to further analyze what its function is: The function refers to the basic principle determining the use of the object. It may be helpful to define the result of using an object to identify its function and pay less attention to the quality of the result. For example, the principle behind a printer cartridge is to bring ink onto paper. A higher degree of technical sophistication of the object ‘printer cartridge’ may *improve* the functioning and the quality of the result but it does not *change* the function as such. For these reasons, 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 determining the quality of the result.

2.2 The shape, surface and design of an object

The elements **shape, surface** and **design** represent the physical appearance of an article 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 outmost layer of an object. Design means the arrangement of the ‘elements of design’ in such a way as to best accomplish a particular purpose. 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. An object may be built up with a high level of sophistication of these characteristics. Nevertheless, characteristics simply *improving* the function of an object but not as such *changing* the function should not be overestimated for the reasons explained in section 2.1.

2.3 Distinguish borderline cases

An object may consist of

- A special container or a special carrier, which is normally a solid material and may be constructed as very simple or highly sophisticated objects and
- Solid, liquid or gaseous substance(s) and/or preparation(s), which could be (integral) part of an article.

For determining whether the chemical content of an object is an integral part thereof (and therefore the object as a whole is an article as defined under REACH) or if it is a substance / preparation for which the rest of the object functions as container, a closer examination is necessary.

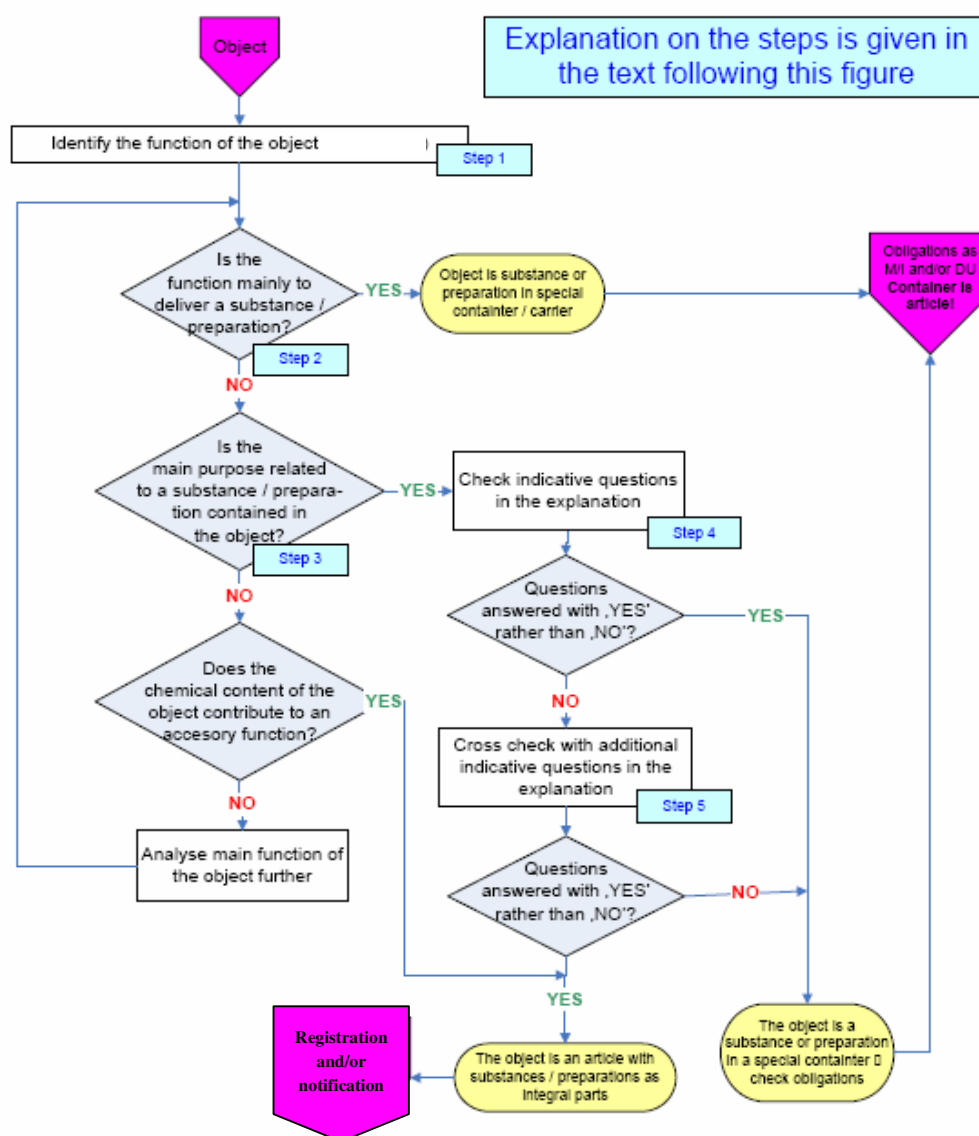


Figure 1 Deciding on borderline between substances/preparations in special containers /carrier materials or as integral part of articles (source from ECHA)



2.3.1 Explanation to the workflow:

Step 1: Define the function of the object.

Note that the degree of technical sophistication of an object's shape, surface or design may make it difficult to decide on what is more relevant for the proper functioning of the article. Even though these elements may improve the quality of the object, they frequently do not determine the function of the object. Therefore, the shape, surface or design should not be overestimated, as they are often not more decisive for the function of the whole item than the chemical composition of the contained substances/preparations.

Step 2: If the function of the object is mainly to deliver a substance/preparation, then this substance/preparation and its chemical composition is generally more important for the function than the container that delivers the substance/preparation. Therefore, the chemical composition of the substance/preparation determines the function of the object to a greater degree than its shape, surface or design, and the object is a substance/preparation in a special container or on a special carrier material. The container or carrier material functions as 'packaging' for the chemical content and may be constructed in a quite sophisticated way to control or target its 'delivery'. However, it is the substance/preparation that matters most when the actual function takes place 'outside' the object, even though the container may be very important for the quality of the function and the convenience of handling the object. If this consideration gives a clear answer, there is no more need to go through the further steps.

Step 3: If the main purpose of the object is not related to the substance/preparation under consideration but to another function, then the object should be analyzed on the basis of its main function. This is e.g. the case for a perfume in a perfumed textile, e.g. a towel. Here, the main function is not releasing the perfume but to dry a person. Therefore, the further analysis needs to focus on whether the towel as such is a preparation or an article. If the result of this analysis is that the main object is an article, the substance/preparation referred to above may still have as an accessory function an intended release (e.g. releasing perfume from a perfumed towel).

Step 4: If the main purpose of the object is related to the substance/preparation under consideration but there are still doubts on whether the object as such is a substance/preparation or an article, the following questions may lead to clarification:

Question 4a: If the substance/preparation were to be removed or separated from the object and used independently from it or changed from the object to a similar type of object, would the substance/ preparation still be capable in principle (though perhaps without convenience or sophistication) of carrying out the intended purpose of the substance/preparation?

Question 4b: Does the object act as a container or carrier for release or controlled delivery of the substance/preparation or its reaction products?

Question 4c: Is the substance/preparation predominantly consumed during the use phase of the object or eliminated or in any other way outside the object at the end of useful life, i.e. before disposal?

If you can answer these questions with 'yes' rather than 'no', then the object should be regarded as a special container / special carrier material with substances / preparations contained within. This means that the substances as such or in the preparation may have to be registered under Article 6 of REACH and that the container / carrier material itself is an article and obligations under Article 7(2) and Article 33 need to be complied with.

If step 4 gives a clear answer, there is no more need to go to step 5. In case of doubts on answering the questions 4a and 4b, it is also recommended to think of other ways how the function can be achieved to decide if this is more dependent on chemical or on physical properties.

Step 5: If the answers to step 4 are predominantly no, you can use the following questions to crosscheck whether the object should indeed be considered as an article and not as a substance/ preparation in a special container. Please note that these questions should not be used as stand-alone questions before having gone through steps 1 to 4.

Question 5a: If the substance/preparation were to be removed or separated from the object or exchanged for a similar type of substance/preparation, would the object be unable to fulfill its intended purpose?

Question 5b: Is the main purpose of the object other than to deliver the substance/preparation or its reaction products?

Question 5c: Is the object normally discarded with the substance/preparation at the end of useful life, i.e. at disposal?

If you can answer these questions with 'yes' rather than 'no', then the function of the object is likely to be determined by the physical properties shape, surface and design, than by the chemical composition. The object is then regarded as an article and its chemical content as an integral part thereof. In this case it must be checked if obligations under Article 7 and Article 33 apply.

2.3.2 Requirements for objects which are substances/preparations in containers

The described concept of substances/preparations in a container vs. article and the existence and application of clear rules for that definition may reveal that the status of some objects under REACH may differ from a company's current understanding of an object as an article. In particular, substances as such or in preparations which are contained in a special container or in a special carrier material need to follow the requirements for substances/preparations, which may include e.g.

- Registration in accordance with Article 6 (and not 7)
- Labeling in accordance with Directive 67/548/EEC
- Obligation to notify the Agency on the classification of the substance, in accordance with Article 113
- Safety data sheet in accordance with Article 31
- If the substances are of very high concern and included in Annex XVI of REACH, authorization of the use in accordance with Title VII
- General restriction on the use in accordance with Article 68(2) and Annex XVII

3.0 Substances intended to be released from articles

Registration of substances in articles is required when all conditions listed under Article 7(1) are fulfilled:

- The substance is intended to be released under normal or reasonably foreseeable conditions of use; Thus the release of the substance carries out a function of the article
- The total amount of the substance present in all articles with intended release produced or imported by one actor exceeds 1 tonne per year;

If the substance has already been registered for that use a registration is not required (However, a pre-registration is recommended). As a general rule, 'intended release' relates to a function of an article. This means if the substance were not released, the respective function (which in most cases is not the main, but an accessory function) would not be achieved. In case of scented articles for example, the fragrance substances need to be inhaled in order for the article to be smelled. Substance which are released because of ageing of articles, because of wear and tear or as a result of accidents, are not intended releases, as the release as such does not provide a function in itself.

3.1 Screening at article level - checking the total tonnage of articles

If the total volume of all articles with intended release of substances produced or imported by one actor is equal to or remains under 1 tonne per year, the volume of substances intended to be released will definitely also be below 1 tonne per year. Thus, registration of substances in the articles will clearly not apply. If the total volume of all articles with intended release exceeds 1 tonne per year, the assessment

should be continued.

3.2 Screening at preparation level

If the total volume of all substances/preparations contained in all produced or imported articles with intended release remains less than 1 tonne per year, also no further action needs to be taken. A first screening can be performed if either the volumes of substances/preparations in the articles with intended releases or the volumes of articles placed on the market are available.

3.3 Identification of substances intended to be released

First and foremost, the substance identities and their amounts/concentrations in preparations intended to be released should be requested from the suppliers. If you include substances as such into articles, you should ask your supplier for the identity of these substances if it is not obvious from a safety data sheet. If you include preparations into articles, you should ask your supplier for the identity of those substances, which are contained in the preparation above the critical level. If you import articles with intended release, ask respective information from your non-EU supplier.

For the purpose of identifying whether or not a registration is needed and for pre-registering, in the first instance it is sufficient to know the CAS or EINECS/ELINCS number of the substances. Communication on substance identities and quantities may be hindered by confidentiality concerns. Therefore, it is essential that only the necessary information is requested. Furthermore, it may be helpful to tell the suppliers why the information is needed, which may be unknown, particularly by non-EU article suppliers. Only if it is not possible to obtain the substance identity via supply chain communication, other approaches may be used. It may be possible to identify the substance(s) via a combination of knowledge of the article (databases, sector publications etc.) and chemical analysis.

4.0 Tasks and Obligations

Four types of requirements exist for producers, importers and other suppliers of articles: to register (1) or notify (2) substances contained in articles to the Chemicals Agency, to communicate specific information related to the content of some specific substances to the customers (3) and to comply with any community wide restriction (4).

4.1 Registration requirement

A registration of substances in articles is obligatory for an article producer or importer only if the following conditions are met:

- The substances are intended to be released from the produced or imported article(s) during normal

and reasonable foreseeable conditions of use

- The total amount of the substance present in the articles with intended releases produced and/or imported by that actor exceeds 1 tonne per year per producer or importer.

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 more than one type of article with intended release is produced/imported, the quantities of that substance in all articles with intended releases have to be summed up. The amounts of the same substance produced or imported as such or in preparations do not have to be taken into account, as they would be covered by registration obligations under Article 6 of REACH. Even if the above criteria are met for a substance in an article, the substance does not have to be registered by the article producer or importer if it has already been registered for that use. If an article producer or importer has to register a substance, he should also make a pre-registration in order to benefit from the later registration deadlines of the phase-in scheme. According to Article 7(5), the Agency may decide that an article producer or importer must submit a registration for any substance contained in an article if the amount of the substance exceeds 1 tonne per year and if there is a suspicion that the substance is released from the article resulting in risks to human health or the environment. This may apply to any substance which has not yet been registered for that use under Article 6 or Article 7.1.

4.2 Notification requirement

Notification of substances in articles is required when all conditions of Article 7(2) are met:

- The substance is included in the candidate list for authorization (Article 59(1)) and
 - The substance is present in all articles produced or imported by one actor in an amount totaling over 1 tonne per year (per producer or importer)
 - The substance is present in articles above a concentration of 0.1% weight by weight (w/w)

If, however, one or both of the following conditions are met, no notification is required:

- The producer or importer can exclude exposure of the substances to humans or the environment during normal or reasonable foreseeable conditions of use including disposal (Article 7(3)).
- The substance has already been registered for that use according to Article 7(6)

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). Only substances with specific properties can be identified as substances of very high concern on the candidate list for authorization. The properties are defined in Article 57 and include substances which are: carcinogens, mutagens or toxic to reproduction (CMRs category 1 and 2), persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) or for which there is evidence for similar concern. Inclusion of substances in the



candidate list is preceded by a formal procedure. The obligation to notify substances in articles also applies to packaging materials, which may be produced or imported separately as packaging of imported goods. Packaging is to be assessed separately from any object it contains.

A notification is not required for a substance in articles which have been produced or imported before the substance has been included on the candidate list for authorization.

5.0 Packaging and Containers

Substances, preparations and articles can be contained inside of packaging. This packaging, be it a carton, a plastic wrapping or a tin can is considered as article under REACH. Similarly, the cartridge of a toner is regarded as an article under REACH. The packaging material does not belong to the substance/preparation or article being packaged. Producers/importers of packaging or of packaged substances, preparations or articles have to fulfill the same requirements for that packaging as for any other article. Packaging with different functions needs to be considered separately (e.g. if an article is directly wrapped in plastic and then packed in cardboard boxes, the plastic and the cardboard box should be considered separate articles.)

Normally there is no intended release from packaging materials. There may be exemptions, e.g. packaging releasing corrosion inhibitors. In this case the release is intended (the function is to prevent corrosion) and constitutes an accessory function of the article (the main function is to protect the object contained inside the packaging from any damage during transport and storage).