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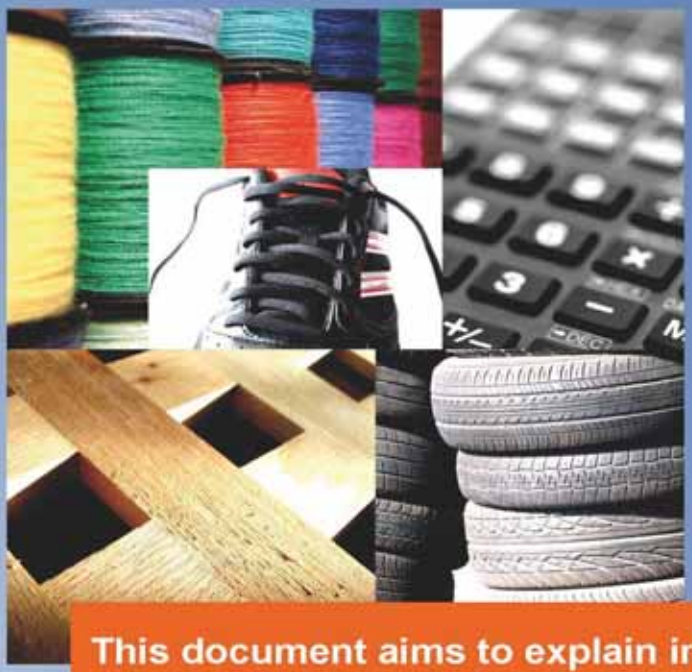
*Guidance in a Nutshell*

# 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[1] (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.

[1] The European Economic Area is composed of Iceland, Liechtenstein, Norway and the 27 European Union 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 laptop 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 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 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" (Candidate List)[2] in the ECHA Chem section of the ECHA website. Substances are included on this Candidate List after it has been agreed according to a formal procedure that they fulfil the criteria for being substances of very high concern.

[2] In the remains of this document "Candidate List" means "Candidate List of Substances of Very High Concern for Authorisation"

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 into articles during the production process. Irrespective 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 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 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 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.

## 4.2 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).
- The substance is present in articles produced and/or imported at a concentration of above 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 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 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 the article as produced or imported. In practice, however, companies may already be collecting information not only on the whole article but also on parts thereof. Companies may, on a voluntary basis, prepare their notification to ECHA on this basis.

A notification of substances in articles shall be made at the latest 6 months after it has been included on the Candidate List, 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 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” here 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 also to be provided to **consumers** upon request. Consumers have to be provided with this information within 45 days of their 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).
- Packaging is always to be treated as an article separate from the contents of the package. Therefore, the obligation to communicate information on substances in articles also applies to packaging materials.
- The substance concentration threshold of 0.1% (w/w) applies to the article as supplied as is the case in the context of substance notification. In practice, however, companies may already be collecting information not only on the whole article but also on parts thereof. Companies may, on a voluntary basis, follow this approach

- 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.

**Table 1:** Main 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 | yes | yes | no |
| exposure can be excluded | no | yes | no |

## 4.4 Compliance with restrictions for substances in articles

The use of particular substances in certain articles is restricted under REACH (Annex XVII). 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.

# 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.

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. 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.

This assessment consists in answering a series of indicative questions given in section 2.4 of the full Guidance on requirements for substances in articles. From the answers to these questions it can be deduced whether the object in question is an article or not. In an initial step 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). Which set of indicative questions is to be answered in order to be able to conclude on the article status of the object will depend on this reasoning. Figure 1 illustrates this decision making process and refers to the corresponding steps in section 2.4 of the full Guidance on requirements for substances in articles.

An outcome of this process can be that the object is a combination of an article (functioning as a container or a carrier material) 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.

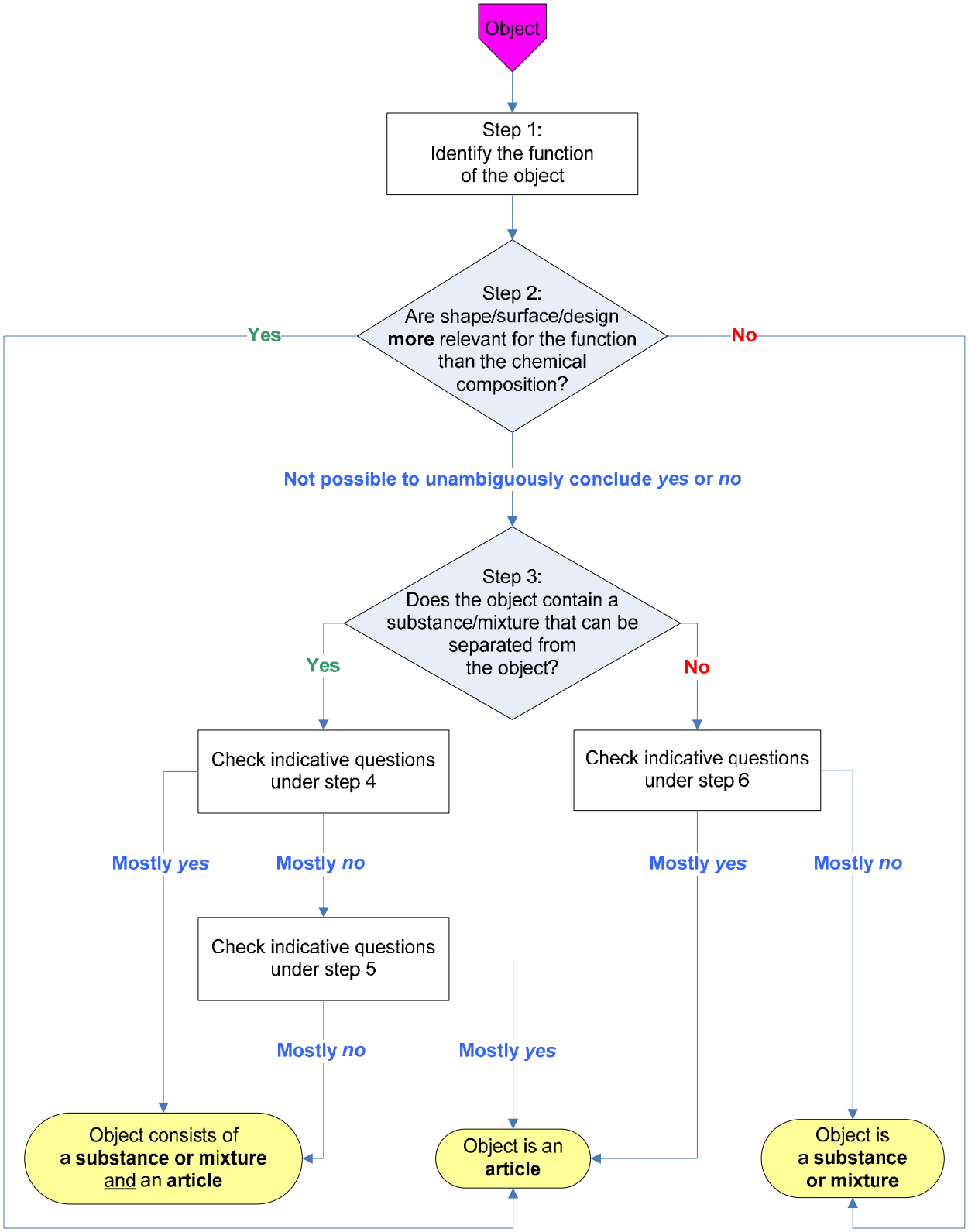


**Figure 1:** **Flowchart illustrating decision-making on whether an object is an article or not**

## 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.

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 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 **standardized 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 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.

Whenever the information received is not sufficient to check compliance with REACH, companies may consider obtaining 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 potentially 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. 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 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 mixtures, which is more often confidential information.

Substances contained in articles can be identified and their concentrations quantified by applying analytical methods. If other approaches to obtaining information fail or become too complicated, conducting **chemical analyses** may thus be an option to obtain information on the composition of articles. Although chemical analyses may be helpful in certain situations, it is to be noted that they may yield ambiguous results and/or be very costly and are thus not recommended as the preferred instrument for obtaining information.

The success of a company in obtaining information on substances in articles will largely depend on whether it has a quality management system in place or not. Quality management systems can include product tests performed in-house, supplier audits and third party certifications. Normally these measures are routinely performed to achieve improvements in processes and products as well as customer satisfaction. If such routines are already in place, less effort will be needed to obtain the required information on substances in articles, whether this is done through communication in the supply chain or by means of chemical analyses.

## 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 of the substance 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 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 of the substance 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 function of the substance in the article (e.g. pigment, flame retardant), 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. Please note that (due to the generic architecture of the use descriptor system) using only the elements of the use descriptor system to describe a substance will not be sufficient to conclude on the sameness of two uses for the purpose of establishing whether an exemption on the basis of Article 7(6) applies. Therefore, the use in question has to be described more in detail than just by using elements of the use descriptor system. To come to a conclusion on whether the substance is considered as registered "for that use" or not, the potential registrant or notifier has to compare the description of his use 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 relevant uses it has been registered for are communicated down the supply chain. Such standardized 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 want 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 or joined the SIEF as a data holder.

## 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 information is readily available to the recipient of the article or the consumer. The information could for example be included in already existing documents, such as instructions for use.

In order to determine what safety information must 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 2.5 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 5.2.
- Appendices 1 and 2 contain detailed examples of assessments of the article status of different objects.

Guidance in a Nutshell
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**European Chemicals Agency** Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu | info@echa.europa.eu