Guidance on requirements for substances in articles

May 2008

Guidance for the implementation of REACH

LEGAL NOTICE

PREFACE

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 fulfil registration, notification and/or communication requirements related to substances in their articles

The meeting of the REACH Member State Competent Authorities (REACH-CA meeting) of 19-20 December 2007 could not reach consensus on some elements of this guidance on requirements for substances in articles and the Commission decided to transfer the finalised text, being endorsed by the majority of Member State Competent Authorities, to ECHA for publication. The positions were maintained at the REACH-CA meeting of 27-28 March 2008. Hence ECHA sought the advice of its Management Board in its meeting of 23-24 April 2008. At this occasion the majority of the members of the Management Board supported the publication of the guidance document in its current state. However, dissenting views with regard to the application of the 0.1 % threshold were upheld by a significant number of Management Board Members and have been notified to ECHA in writing by 6 Member States (Austria, Belgium, Denmark, France, Germany and Sweden). In line with the consultation procedure on guidance (MB/30/2007 final dd. 29/02/2008) a reference to the notified dissenting positions has been added to the relevant parts of the guidance document.

This guidance document is part of a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving all stakeholders: Member States, industry and non-governmental organisations. These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/reach_en.asp). Further guidance documents will be published on this website when they are finalised or updated.

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1].

[1] Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006); amended by Council Regulation (EC) No 1354/2007 of 15 November 2007 adapting Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), by reason of the accession of Bulgaria and Romania (OJ L 304, 22.11.2007, p. 1).

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ABBREVIATIONS

/y	Per year
CAS	Chemical Abstract Service
CMR	Carcinogenic, mutagenic and toxic for reproduction
Conc.	Concentration
DU	Downstream User
EIF	Entry Into Force
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ELVs	End of Life Vehicles
ES	Exposure Scenario
eSDS	Extended Safety Data Sheet
ESIS	European chemical Substances Information System
EU	European Union
F	Formulator
GC-MS	Gas Chromatography – Mass Spectrometry
GHS	Globally Harmonised System for Classification & Labelling
ID-no	Identification number
ID number	Identification number
IUPAC	International Union of Pure and Applied Chemistry
M	Manufacturer
M/I	Manufacturer/Importer
PBT	Persistent, Bioaccumulative and Toxic
P/I	Producer/Importer
Prep.	Preparation
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RIP	REACH Implementation Project
RMM	Risk Management Measures
RoHS	Restriction of the Use of certain Hazardous Substances in Electrical and Elec-

	tronic Equipment
SCCNFP	Scientific Committee on Cosmetic Products and Non-food products intended for Consumers
SDS	Safety Data Sheet
SIEF	Substance Information Exchange Forum
SMEs	Small and Medium-Sized Enterprises
Subst.	Substance
SVHC	Substances of Very High Concern
TGD	Technical Guidance Document
Vol	Volume
vPvB	very Persistent and very Bioaccumulative
WEEE	Waste Electrical and Electronic Equipment
w/w	Weight per weight

1 GENERAL INTRODUCTION

This guidance interacts with several other REACH guidance documents. As a general principle, the current document will not repeat what is in other guidance documents, unless found absolutely necessary for the purpose of this guidance. Consequently, there are several references to other guidance documents and tools, which can be found (now or in the near future) on the web-site of the European Chemicals Agency: http://ec.europa.eu/echa/.

1.1 Who is this guidance for?

This guidance document is addressed to producers, importers and suppliers of articles located in the EU as well as only representatives of non-EU suppliers of articles.

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

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. An article supplier is a company which produces, imports or distributes articles and/or places them on the EU market. Retailers are also article suppliers. Further explanation and the definitions of these roles are included in Appendix 1 of this guidance.

Non-EU producers of articles may appoint "Only Representatives" to fulfil all obligations of the importers of their articles into the EU. In this case, Only Representatives shall fulfil all obligations for substances in articles, including pre-registration and registration of substances with an intended release (Article 7(1)), notification of Substances of Very High Concern on the so-called "candidate list"[2] under Article 7(2), provision of information under Article 33 and ensuring compliance with any restrictions in Annex XVII. Details on the role and obligations of Only Representatives can be found in the Guidance on registration and Guidance on data sharing.

This guidance mainly describes how a company can check whether it has to fulfil any requirements under Article 7 and Article 33 of REACH.

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 fulfil downstream user requirements. Support is provided in the Guidance for Downstream Users. If the article producer also is the importer of substances/preparations into the EU, he is also a substance importer and may have to fulfil 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 fulfil the importer obligations.

[2] Explained further in Section 2.2.

In general, companies are advised to identify their roles and check their obligations by running the **Navigator** on the web-site of the European Chemicals Agency, where other final guidance documents can also be found.

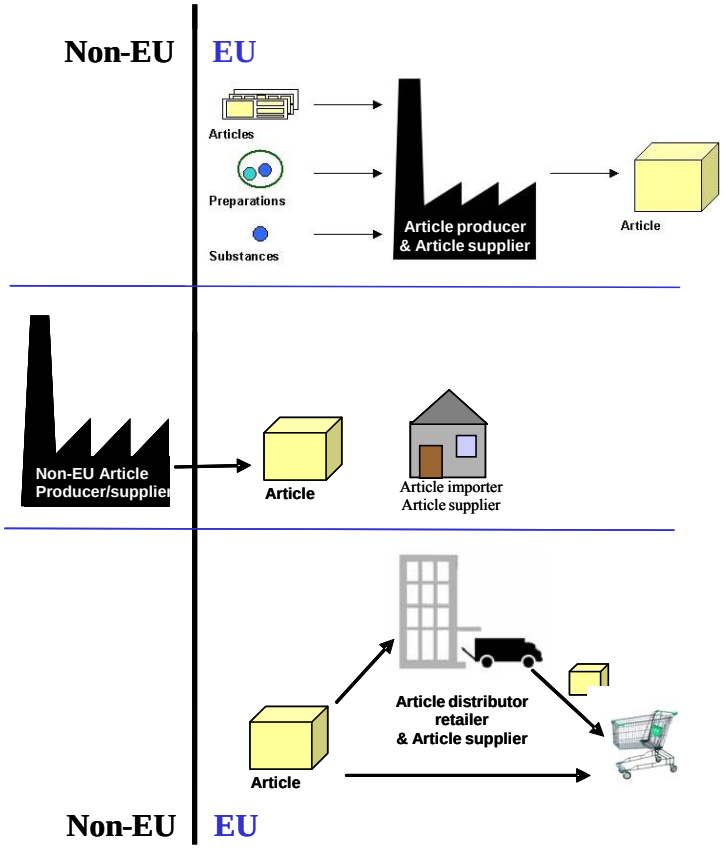

Figure 1 Article suppliers: producers, importers and distributors of articles

When determining if and which requirements apply, the first step is to check whether the produced or imported objects are considered articles or substances/preparations under REACH.

1.2 Why this guidance is needed and how to use it

The specific aim of this guidance is to assist suppliers of articles in assessing which requirements have to be complied with related to the production, import and supply of articles. It provides guidance for answering the following questions:

- Do I need to pre-register and register substances under REACH?
- Do I need to notify substances in articles under REACH?

It guides article suppliers (including producers and importers) to answer the question:

- Do I need to forward information on substances in the articles to my customers?

The workflow in Section 6.1 directs the user of the guidance to the chapters which are relevant in relation to these requirements.

However, it is advised to first read the general guidance on issues relevant for all actors covering:

- Overview of requirements for substances in articles and related requirements (Chapter 2)
- Guidance on what is considered to be an article (Chapter 3)
- Communication about substances in the supply chain (Chapter 4).
- Chemical analysis as an option to identify and quantify substances in articles (Chapter 5)

The Appendices provide further information and examples.

2 REQUIREMENTS FOR SUBSTANCES IN ARTICLES UNDER REACH

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). These obligations only apply under certain conditions, which are specified in Article 7, 33 and the entries in Annex XVII of REACH. Article suppliers, which are only supplying (i.e. not themselves producing or importing the articles), only have to comply with Article 33.

The following parts of REACH are of particular relevance for producers, importers and other suppliers of articles:

- **Article 3(3): Article definition.**
- **Article 7: Registration and notification of substances in articles.** Defines under which circumstances article producers and importers are to register or notify (see sections 2.1 and 2.3).
- **Article 23, 28-30: Deadlines for pre-registration and registration of *phase-in substances* and participation in Substance Information Exchange Fora (*SIEF*).** Article producers and importers who have to register substances intended to be released should make a pre-registration to benefit from the transitional provisions for phase-in substances.
- **Article 57 and 59:** Criteria for substances of very high concern (SVHC) and procedure for how they are placed on the *candidate list*.
- **Article 33: Duty to communicate information on substances in articles.** Producers, importers and other suppliers of articles containing substances on the candidate list may have to forward required information available to them down the supply chain (Article 33(1) and to consumers on request (Article 33(2)).
- **Annex XVII** listing the conditions of restrictions, which may pertain to certain substances in produced and imported articles.

Substances being (an integral) part of imported articles cannot be subject to authorisation. *However, if an EU-based producer of an article incorporates a substance as such or in preparation into the article, that use of the substance may have to be authorised (if the substance is listed in REACH Annex XIV).* If such a substance is acquired from the EU market, the supplier has to give this information in section 16 of the safety data sheet or via information according to article 32. If the article producer imports such substances himself, he has to apply for an Authorisation for continued use. Details on the Authorisation procedure, notifying the use of authorised substances etc. can be found in the Guidance for Downstream Users (Chapter 12 on authorisation), Guidance on Annex XIV inclusion (substances subject to authorisation) and the Guidance on authorisation application.

As already noted, producers of articles using substances/preparations may also have other importer and/or downstream users obligations under REACH.

In general, it may be helpful for article producers/importers/suppliers to understand more of the overall legislative system, e.g. to understand the possibilities of obtaining information in the supply chain and to get a full overview of their REACH obligations. Please refer to the web-site of the

European Chemicals Agency (http://ec.europa.eu/echa/) for further general information on REACH and the roles and obligations of the various actors.

2.1 Registration according to Article 7(1) (and 7(5))

A **registration** (Article 7.1) 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[3].

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 (Article 7(6)). Guidance on this is provided in Chapter 9.

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 (see Section 2.5 and the Guidance on pre-registration and Guidance on registration for further information). It will be further explained in Section 2.5, why a producer/importer who thinks that the substance intentionally released from his article will at a later stage be registered for his use (and therefore he will at that point in time be exempted from registration via Article 7(6)), should also seriously consider pre-registration.

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 (see Chapter 9).

[3] Example: If a company X imports three articles A, B, and C with 60 tonnes of the substance present in each but: in article A, the substance is not intended to be released, in article B, 40 out of 60 tonnes are released under normal conditions and in article C 10 out of 60 tonnes are released under normal conditions, the company X will need to register the total volume of the substance in article B and C: 120 tonnes, i.e. in the 100-1000 tonnes band.

2.2 Notification according to Article 7(2)[4]

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

- The substance is included in the candidate list[5] for authorisation (Article 59(1)) and
  - The substance is present in all articles produced or imported by one actor in an amount totalling 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) (see Chapter 9).

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 authorisation. 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 (see Guidance on Annex XIV inclusion).

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 authorisation.

2.3 Obligations according to Article 33[4]

The aim of Article 33 is to ensure that sufficient information is communicated with articles to allow their safe use.

Producers, importers and other suppliers of articles containing substances of very high concern (SVHC) included on the candidate list for authorisation in a concentration above 0.1% (w/w) have to provide respective information available to them to the recipients[6] of the articles and as a mini-

[4] Dissenting views (http://reach.jrc.it/docs/guidance_document/dissenting_en.pdf), questioning the application of the 0.1 % threshold to the entire article have been notified by 6 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] A separate list will be established according to the procedures of Article 59 with substances which are identified as candidates for the authorisation procedure. This list will be published on the website of the European Chemicals Agency.

[6] Note that the term "recipients'' does not include consumers under REACH.

mum the name of the substance. This information is to be provided 'automatically' (Article 33(1). NB! There is no tonnage trigger for this obligation (i.e. it also applies below 1 tonne/a) and the obligation cannot be exempted neither via Article 7(3) (exclusion of exposure) nor via Article 7(6) (already registered for that use).

Information available to the article supplier necessary to ensure safe use of an article has to be provided also to consumers upon request (Article 33 (2)). Consumers have to be provided with information within 45 days of the request, free of charge.

As for the article 7(2) requirements, the substance concentration threshold of 0.1 % (w/w) applies to the article as produced, imported or supplied.

For example, if imported buttons for jackets contain such substance in concentrations of 0.5% (w/w), this needs to be communicated to the recipient. If these buttons are imported as part of jackets the concentration of the substance in relation to the imported article (the jacket) will probably be lower than 0.1% (w/w) and in that case no information would have to be communicated.

The obligation to forward available information on substances of very high concern on the candidate list also applies to packaging materials. This packaging material is always a separate 'article'. Thus, if the imported buttons or the imported jackets were packaged in plastic packaging material, the content of such substances in this packaging material would have to be assessed separately.

The obligation to provide available information on substances of very high concern to the recipients of the articles applies as soon as a substance has been included on the candidate list for authorisation. The obligations also apply to articles which were produced or imported before the substance was included on the candidate list and are supplied after the inclusion. Thus, the date of supply of the article is relevant.

2.4 Restrictions

Restrictions (Annex XVII): The content of substances in articles can be restricted or banned under the restrictions procedure. Article producers and importers have to follow the conditions outlined in Annex XVII of REACH from June 1, 2009. Until then, the directive on marketing and use of dangerous substances (76/769/EC) is still in force. Details on compliance with restrictions are given in the Guidance for Downstream Users (Chapter 13). Further detailed guidance will not be given in this guidance document.

2.5 Timelines under REACH

Substances intended to be released from articles under normal or reasonably foreseeable conditions of use are to be registered under Article 7(1) by the same dead-lines that apply to substances as such or in preparations to be registered under Article 6. Also, the same distinction between phase-in substances and non-phase-in substances applies[7].

[7] Phase-in substances are defined in Article 3(20) as substances meeting one of the following criteria (simplified, for details see legal text or Guidance on Registration, Section 1.7.1): a) listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) or b) manufactured in the EU but not placed on the market since June 1, 1993 or c) substance is a no-longer polymer. All substances not meeting these criteria are non-phase-in substances. For further information, please consult the Guidance on Registration.

The obligation to register substances in articles applies from 1 June 2008. However, for pre-registered substances the transitional registration deadlines of the phase-in scheme apply. Phase-in substances can be pre-registered[8] in the period between 1 June and 1 December, 2008.

NB! Important in relation to Article 7(6). At the time of pre-registration, few substances will already have been registered. Therefore, a producer/importer of an article with an intended release of substances should seriously consider pre-registering. If he does not pre-register and if the substance has not (yet) been registered for his use, he has to cease his production/importation until he has made a registration as his substances would be considered a non-phase-in substance, or until someone else registers his use (which may take several years)! Please note that the pre-registration dossier is a rather limited dossier.

An article producer/importer who has pre-registered will become member of the Substance Information Exchange Forum (SIEF) for that substance. This may assist in finding another actor who registers the use in the article and thereby trigger that the article producer/importer can use the Article 7(6) exemption. Otherwise, the article producer/importer will himself have to register. Further guidance on 'registered for that use' is given in Chapter 9 of this guidance. Note that becoming a SIEF member may entail obligations related to data sharing. Information on SIEFs can be found in the Guidance on data sharing.

A non-phase-in substance intended to be released from articles has to be registered after 1 June 2008 and before the article is placed on the market. An inquiry has to be made to the Agency to identify if information is available on the substance that could be shared.

A notification of substances in articles shall be made at the latest 6 months after it has been included on the candidate list for authorisation but only starting from 1 June 2011. Information on substances on the candidate list contained in articles is to be forwarded to the recipients of article directly after a substance is included in that list. The candidate list will be updated continuously when substances have been identified as meeting the criteria of Article 57. Table 1 summarises the deadlines relevant for article suppliers.

[8] Separate guidance is available on pre-registration and data sharing.

Table 1 Timelines for article suppliers

Potential obligations for article suppliers	**Time**
Start of obligation to register non-phase-in substances and phase-in substances which have not been pre-registered, if conditions of Article 7.1 are met	From 1 June 2008
Pre-registration of phase-in substances if they need to be registered according to Article 7.1 or according to Article 6 (e.g. substances imported in preparations)	1 June 2008 – 1 December 2008
Participation in SIEFs (potential registrants according to Article 6 and 7.1)	1 June, after pre-registration[9]
Communication regarding substances on the candidate list in articles according to Article 33	After publication of candidate list (first list expected autumn 2008 / beginning 2009)
Notification of substances in articles according to Article 7.2	6 months after substance is included in candidate list. No notification required before 1 June 2011
Registration of pre-registered phase-in substances • in amounts ≥ 1000 tonnes per year or more, • in amounts ≥ 1 t/a if the are known carcinogens, mutagens or reprotoxic substances (category 1 and 2) and • in amounts ≥ 100 t/a substances if they are classified with R50/53[10]	By 30 November 2010
Registration of pre-registered phase-in substances in amounts between 100 and 1000 tonnes per year	By 31 May 2013
Registration of pre-registered phase-in substances between 1 and 100 tonnes per year	By May 2018

2.6 Other relevant legislation

The restrictions on the marketing and use of certain dangerous substances and preparations[11] in the Annex I of Directive 76/769/EEC will be repealed on 1 June 2009 and included in Annex XVII of the REACH: "Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles". This means that existing restrictions, such as the ban of certain azo-colorants in textiles, will continue to apply.

Other legislation concerning restrictions, reducing the use of or the risks from hazardous substances in articles still apply separately from REACH. Examples are the General Products Safety Directive 2001/95/EEC and product specific legislation such as Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS), Directive 88/ 378 on toys or Directive 2000/53/EC on End of Life Vehicles (ELVs). A list of relevant legislation is provided in Appendix 7 of this guidance.

[9] After pre-registration is accepted access to a dedicated website for the same pre-registered substance is granted; SIEFs must be formed by pre-registrants themselves.

[10] Provided as harmonised classification in Annex 1 of Directive 67/548/EEC or as result of self-classification.

[11] consolidated text: CONCLEG: 1976L0769 – 16703/2004

2.7 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 fulfil 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[12] 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). For further guidance see Chapter 3.

2.8 Documentation

There are no specific record-keeping requirements for Article 7 or Article 33 of REACH for article suppliers except for those needed when registration, notification or communication are required. However, article suppliers may also be suppliers and users of substances or preparations and in relation to these roles shall assemble and keep available relevant information for at least 10 years (Article 36 of REACH).

Article suppliers should consider documenting the results of their compliance checking, even when it has been identified that no obligations under REACH exist. Documentation facilitates demonstrating REACH compliance towards customers and (inspecting/enforcing) authorities.

It is recommended that each producer/importer establishes routines to ensure high quality documentation. Possible approaches could be:

- Article suppliers with implemented management systems could incorporate REACH conformity as a criterion – with clear indications of how conformity will be secured and documented.
- Article suppliers without a management system may follow a kind of "good practice for supplying articles", which could be developed by the respective industrial associations. This might include:
  - Following the workflows of this guidance
  - Describing whether registration/notification or communication on SVHC is required
  - Supporting documents including letters from suppliers, certificates, results of analysis etc.

[12] Known cases of packaging material from which substances or preparations are released are metal wrapping containing anti-corrosion agents.

3 DECIDING 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. In order to determine whether or not an object fulfils the definition of an article under REACH sometimes a deeper assessment of an object's function and its properties is needed.

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[13]. 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, the elements of the article definition in the sections below should be looked at in more detail, including the essential and decisive elements of the article definition. Appendices 2 and 3 contain examples of borderline cases illustrating the decision making process.

3.1 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 of brooms is to sweep, the function of a radio is to receive and amplify the programme of the radio station etc. 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 analyse 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.

Further considerations on the function of articles are given in Section 3.3.2.

[13] Dissenting views (http://reach.jrc.it/docs/guidance_document/dissenting_en.pdf), questioning the application of the 0.1 % threshold to the entire article have been notified by 6 Member States in writing (Austria, Belgium, Denmark, France, Germany and Sweden) and publication of this part of the guidance document was not endorsed by these Member States.

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.

3.2 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 3.1.

3.3 Workflow for deciding if an object is an article or not

The workflow provides guidance on deciding if an object is an article or not. It assists in deciding if an object is an article or not in particular when there are doubts concerning:

1) The borderline in the sequence of processing natural or synthetic materials to final articles, in particular deciding on 'semi-finished products'

2) The borderline between substances/preparations in special containers / on special carrier material and substances/preparations being (integral) parts of an article

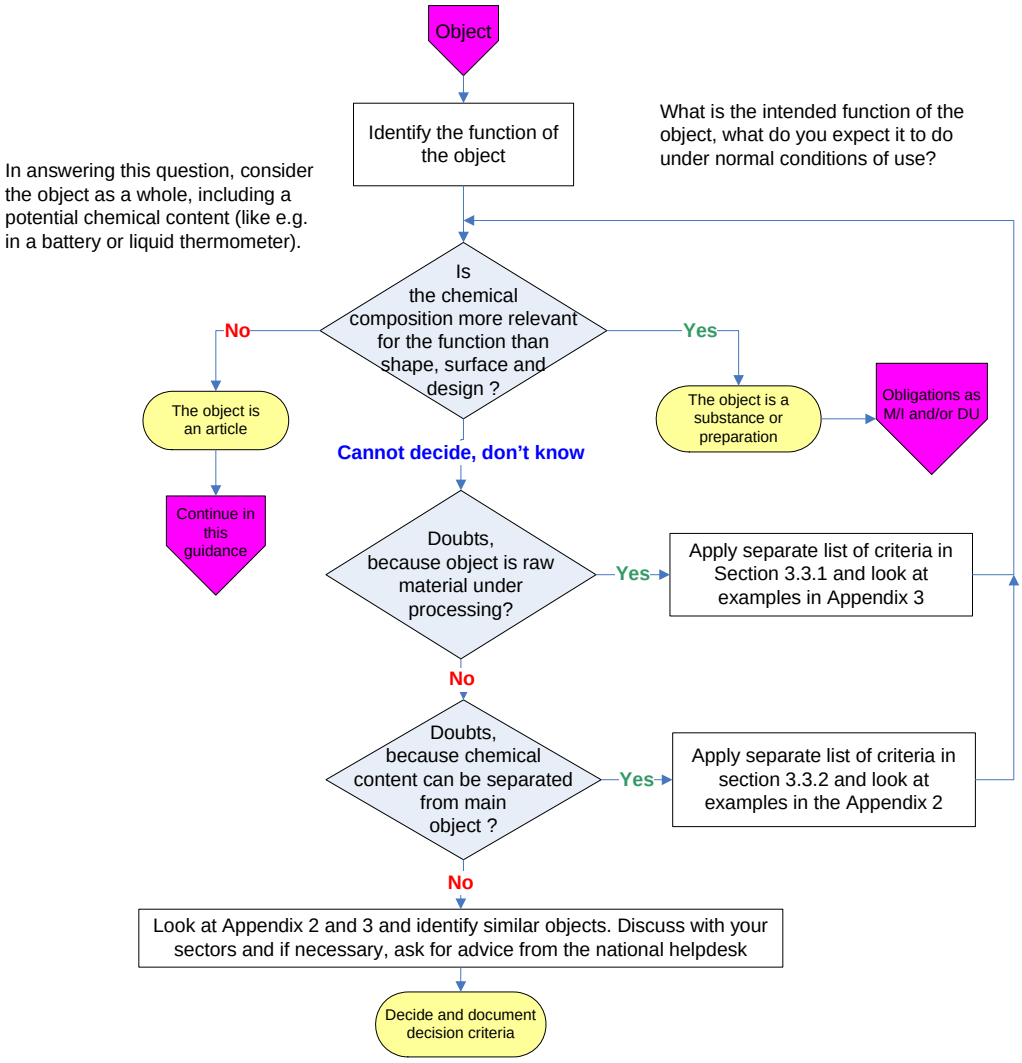

Figure 2 Decision taking on the article definition

3.3.1 Borderline in the sequence of processing natural or synthetic materials to final articles

When materials are processed, there is a certain point in the processing, where they change from being a substance/preparation to being an article. In some cases there may be doubts on when exactly this transition occurs. The following approach should be seen as decision help in support of the application of the article definition when deciding on these types of cases. The following steps may be taken:

As a general principle, the article definition should be applied, which is a two step process:

1. Determine the function(s) of the material by assessing the technical features of the material in relation to the intended function by the seller as well as the buyer of the material.
2. Decide on what is more relevant for the function, the shape/surface/design or the chemical composition

If you can unambiguously conclude that the shape/surface/design are more relevant for the function than the chemical composition, the (form of the) material 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 preparation.

In this respect it is however always important to recall the basic requirement given in the definition of an article, cf. Art. 3(3), that the shape, surface or design of the material in question must be deliberately determined and given during production.

If you are in doubt, you may use the following indicative questions in order to better determine whether or not the material is an article. These questions can only be used to support the evaluation of the importance of the chemical composition versus the shape/surface/design in relation to the function and thus facilitate the application of the article definition to raw materials.

Not all questions may apply to all raw materials and processes and the weight of evidence of the answers to the questions may vary from case to case. It is also possible that some answers are contradictory. In concluding whether the raw material is an article or not, the various relevant indications should be considered and not only one question or consideration.

- Does the material in question have a function other than being further processed?
  If the material predominantly has other functions (i.e. end-use functions), then this may be an indication that it is an article according to the definition of REACH.

- Does the seller place the material on the market and/or is the customer mainly interested in acquiring a material because of its chemical composition or its shape/surface/design?
  If the material is mainly put on the market or acquired because of its shape/surface/design, this is an indication that the material is an article.

- After which processing step is the function determined to a larger degree by the shape/surface/design (e.g. polymer pellet is converted to film)?
  A comparison of the material's properties and general shape before and after the different processing steps may be helpful to identify the transition point.
  'Light processing' such as drilling, grinding or bending may improve or modify a material's shape, surface or design for carrying out a function and is thus frequently applied to materials which are already articles.

- Does the chemical composition of the material as such remain similar in the next processing steps as a change may indicate the material being a preparation?
  The fact that the chemical composition of a raw material is significantly changed, e.g. additives are added to a polymer, may be an indication that the material is still a preparation. It should be noted however that the fact that a given material in itself does not change its chemical composition and properties cannot be used as an indication of the material being an article. Surface treatment of raw materials which are articles may result in a change in its overall chemical composition, however not in the status of the material being an article. Examples are printing onto the surface, painting, applying coatings, etc. Some finishing other than surface treatment may change the chemical composition, but not the status of the material being an article, e.g. dyeing of fibres.

Examples are given in Appendix 3.

3.3.2 Borderline between substances/preparations in special containers / on special carrier materials and substances/preparations being (integral) parts of an article

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.

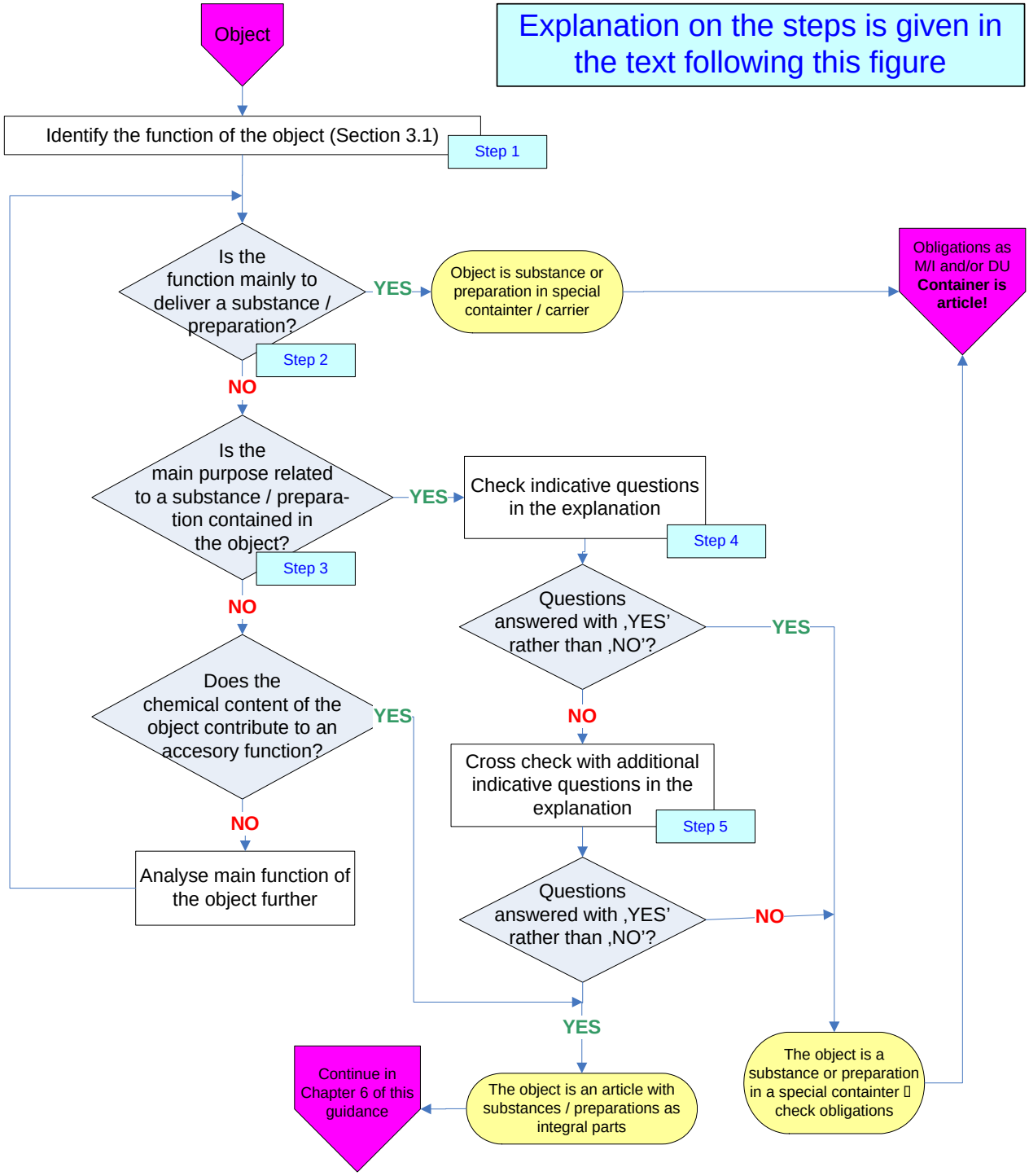

Figure 3 Deciding on borderline between substances/preparations in special containers / carrier materials or as integral part of articles

M = manufacturer of substances; I = importer of substances; DU = downstream user

Explanation to the workflow:

Step 1: Define the function of the object in line with section 3.1.

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 analysed 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 [14]?

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[15] under Article 6

[14] Function as described in section 3.1.

[15] Registration would be required by the article supplier only if the object is imported and the substance amounts contained exceed 1 t/a.

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.

Example 1 Substances / preparations in a container - Toner Cartridge

Example: Toner cartridge Answering the above indicative questions: 4a) if the toner was moved from the cartridge, it would still be possible to bring it to paper, although with a loss of quality and convenience; 4b) the function of the cartridge is to hold the toner in place inside a printer and it controls the speed and mode of release; 4c) the cartridge is disposed of without the toner, which is consumed during the useful life of the cartridge. The answers to the questions allow the conclusion that a toner cartridge is a special container containing a preparation.

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 cross-check 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 fulfil 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.

Example 2 Substances/preparations on a carrier material - wet wipes

Example: Wet wipe with a cleaning liquid in it The function of wet cleaning wipes is to remove dirt from surfaces. The cleaning effect could generally be achieved by using the same preparation with another type of wipe (e.g. a normal household wipe). This is in principle a clear result. However, if in doubt, one could also ask the question the other way round and compare whether the wipe alone would achieve the same result. In this case it is considered that it would be easier to achieve the desired result with the same preparation and another type of wipe rather than with the dried wipe or with another substance (e.g. water only). Therefore, cleaning wipes should in general be considered as a special carrier material containing a preparation.

Example 3 Substances/preparations as integral part of an article

Examples: Thermometer Answering the above questions: 5a: The empty thermometer would fail to show the temperature; thus the object would no longer be useful. 5b: The main function of the thermometer is to show the temperature, this is not a delivery of a substance or preparation. 5c: The thermometer is normally disposed of together with its chemical content. In conclusion, answering these questions leads to the conclusion that a thermometer (including the liquid it contains) is an article.

3.3.3 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)
- Labelling 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, authorisation of the use in accordance with Title VII
- General restriction on the use in accordance with Article 68(2) and Annex XVII

Please refer to the Navigator on the web-site of the European Chemicals Agency to identify all relevant requirements (http://ec.europa.eu/echa/).

The definition of the status of objects under REACH does not affect legislation which is not based on the REACH definition of articles.

4 INFORMATION VIA THE SUPPLY CHAIN

For article suppliers, communicating with the suppliers is the most important and efficient way to gather information on substances contained in their articles. Communication along the supply chain is one of the core instruments to ensure controlled use of substances. As stated also in the introductory clauses to REACH (the recitals), communication on substance hazards and risks as well as advice to control risks, is an important purpose of REACH. Identifying substances in articles and quantifying their amounts in order to assess whether or not these may pose a risk 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 way of gathering the information needed. This is due to the fact that chemical analysis, although a possible way to identify and quantify constituents of substances, preparations or articles, is time consuming, costly and difficult to organise. However, supply chains may be complex and non-EU companies may not be prepared to provide the information. Article importers may have to inform their suppliers outside the EU of the requirements of REACH and make special arrangements to receive information. Establishing communication policies and standards for substances in articles is an important task for private sectors in order to facilitate the implementation of REACH.

Information needed to check whether or not the requirements of REACH Article 7 apply can relate to the identity of substances as well as to the amounts/concentrations in the article itself or in preparations used in its production.

The communication of the information related to substances contained in articles according to Article 33 shall enable safe use of the article and should consider the entire life cycle of the article. What information is actually needed depends on a case-by-case assessment and is explained in the respective sections in this guidance.

Only representatives responsible for the importer requirements on behalf of non-EU article producers/suppliers have to comply with the obligations of Article 7 as well as Article 33 when these apply. Thus, they will be responsible for the upstream communication with the non-EU supplier on behalf of the importers.

4.1 Obtaining standardised information from suppliers

EU suppliers of substances (on their own or in preparations) have to communicate information according to Article 32 or via safety data sheets. Article suppliers (producers/importers/distributors) normally have no legal obligation to communicate information on substances contained in their articles apart from the obligation in Article 33 under REACH[16].

Some information needed to comply with Articles 7 and 33 can be derived from safety data sheets or Article 32-information[17] of substances or preparations[18] which have been used to manufacture an

[16] However care must be taken as decisions made in relation to the definition of an object being a substance/preparation in a container which then may require classification and labelling as well as safety data sheets.

[17] Information according to Article 32 is required for substances as such or contained in preparations which are subject to authorisation or restrictions when no safety data sheet is required. Furthermore, it may be required if for such substances (other) specific risk management measures need to be communicated. Further information is provided in the Guidance for Downstream Users.

article. This information is either required to be provided, e.g. if an article producer uses the substance or preparation in his production, or could be requested from the actors up the supply chain and normally contains information on:

- The registration numbers of the substance(s), as such or in a preparation, if registered (when substance volume ≥ 1 tonne per year and per manufacturer/importer) in section 1 or in section 3 of the safety data sheet or as Article 32-information.
- The identity of the manufacturer/importer/distributor responsible for placing the substance/preparation on the EU market in section 1 of the safety data sheet or as Article 32-information
- The chemical names and identification numbers of the substances in section 1 and/or 3 of the safety data sheet or as Article 32-information
- Concentration ranges of dangerous substances in the preparation in section 3 of the safety data sheet
- The classification of the dangerous substance(s) and information on authorisation and restriction where applicable in section 2 or 3 of the safety data sheet or as Article 32-information
- Important and common use(s) of the substances in section 1 of the safety data sheet
- Exposure Scenarios if the substance volumes exceed 10 tonnes per year and per manufacturer / importer including the identified use(s) for which the substances have been registered. Exposure scenarios describe how a substance is used during its life-cycle and recommend how to control exposure of humans and the environment. These exposure scenarios cover the incorporation of the substance in the article and the resulting life-cycle stages of the substance, including the service life of the article and the waste life-cycle stage, as relevant. Therefore the information they contain can be useful to prepare the information to be provided to customers to allow safe use of the article (See also Guidance on information requirements and chemical safety assessment).

As previously noted, an article producer importing substances (on their own or preparations) has registration obligations for these substances. This way he will generate relevant information for those substances in case they are incorporated into an article.

Article suppliers acquiring articles within the EU will normally receive the relevant information for substances in those articles.

Article importers will not receive any comparable standardised information together with the imported articles. In order to be able to check compliance with REACH, they therefore have to generate information and communication should be initiated with the non-EU suppliers as soon as possible.

4.2 Requesting non-standardised information up the supply chain

In many cases either no or insufficient information will be supplied to article producers, importers and other suppliers to check if the requirements of Article 7 and 33 apply to them and to implement

[18] A safety data sheet is required for substances and preparations which are classified as dangerous as well as under certain other circumstances apply (see REACH article 31). However, frequently safety data sheets are also supplied for non-classified substances and preparations.

the necessary steps for achieving compliance. In these cases, active requests for information on the identity of substances and on the concentrations/amounts contained in preparations or articles will need to be made. It is acknowledged that supply chains are complex and that confidentiality or supply contracts may to a large extent hinder communication. Furthermore, enquiring substance identities and/or contents will need time and resources.

EU producers, importers and other EU-suppliers of articles can take similar steps to obtain information. Table 2 shows which actors in the supply chain have what type of information on substances and their amounts in the article. Normally only the direct supplier is known to the article producer or importer, thus requests may have to be forwarded up the supply chain.

It is important to keep in mind, which actors in the supply chain have what information on substances as such, in preparations and in articles and what information they are required to forward to their customers and what could be provided voluntarily. The following table gives an overview.

Table 2 Availability of information in the supply chain

Information REACH Actor	Relevant information that must be provided 'automatically' for non-classified substances / preparations	Relevant information that must be provided 'automatically' if substance / preparation is classified	Relevant information that may be provided on a voluntary basis
Substance manufacture / importer (registrant)	Substance name (label) If non-classified SVHC on candidate list → Article 32-information: registration number, specific risk management information	Substance name, registration number, classification, relevant registered uses	Information on the identification of a substances, e.g. composition, impurities etc. All registered uses
EU supplier of preparations	Name of preparation and contact information (label). If SVHC(s) on candidate list are contained above cut-off limits in Article 14: registration numbers and specific risk management information	If above cut-off limits of Article 14: name and registration number of classified substances and SVHC on the candidate list, their concentration ranges in the preparation, risk management measures, relevant uses of the preparation	Identity of suppliers of substances and preparations used to produce the preparation. Exact amount of substances and preparations in the preparation
EU article producer (uses substances / preparations)	If SVHC(s) on candidate list in concentrations above 0.1%, sufficient available information to enable safe use	If SVHC(s) on candidate list in concentrations above 0.1%, sufficient available information to enable safe use	Identification and amounts of substances / preparations included in the article and the identity of their suppliers
Article distributor / retailer	If SVHC(s) on candidate list in concentrations above 0.1%, sufficient available information to enable safe use	If SVHC(s) on candidate list in concentrations above 0.1%, sufficient available information to enable safe use	Identity of article producer
Only representative or article supplier outside the EU	If SVHC(s) on candidate list in concentrations above 0.1%, sufficient available information to enable safe use	If SVHC(s) on candidate list in concentrations above 0.1%, sufficient available information to enable safe use	Identity of article producer

Producers, importers and only representatives of articles with intended release of substances may have to register these substances; including non-classified substances. They need to know the identity and amount/concentration of all substances intended to be released from that article as well as the total amount contained in that article and all other articles intentionally releasing that substance

(See also Section 2.1). In order to benefit from the deadlines for phase-in substances, pre-registration is required (see further details in section 2.5).

Producers and importers of all articles, including those with intended release, need to know if and in what concentrations substances on the candidate list for authorisation are contained in the article.

- Article producers using substances and preparations as well as articles for their production, will receive respective information in safety data sheets, as Article-32-information or accordance with Article 33(1) from their EU suppliers. Information on the exact concentration / amount may have to be requested.
- Importers of articles and only representatives will not automatically receive this information but have to actively ask for it.

For obtaining information through supply chain communication, various approaches can be taken:

1) Information can be requested for specific articles produced and on a case-by-case basis. Normally this would be done when there is a clear idea that requirements would apply and what type of information would be needed. This communication would most likely be direct (phone, meeting) and supported by letters or questionnaires.

2) Information can be requested in a standardised form (e.g. questionnaire) from all actors up the supply chain. The request should be targeted using cut-offs for amounts and specifying what information is needed and what isn't. This request could be used e.g. to identify the registered uses of substances/preparations used in the article or to find out, whether or not certain substances are used at all.

3) To avoid complex communication via several actors, the suppliers could be identified individually to obtain information.

4) Excluding the use of substances is another way of 'obtaining' information on the non-existence of substances in articles. This exclusion could be done 'top down', when suppliers provide certificates that substances are not used or remain under certain concentrations in articles. Another option is to include respective criteria in supply contracts 'bottom up'.

Which option is the most effective and works best will depend on the specific cases and further types of communication may be necessary.

Suppliers of preparations and articles are not required to provide information on non-dangerous substances or on precise amounts used therein. They may also be reluctant to invest their resources or may themselves have suppliers which are not willing to co-operate. Sometimes it is possible to rephrase or target an information request in a way that suppliers can answer it without having to disclose confidential business information or to be involved in extensive communication.

There may however be cases where supply chain communication will not be successful. In these cases other means of identifying the substance(s) may be used, such as a combination of publicly available information in databases, branch knowledge and conclusions from chemical analysis.

5 CHEMICAL ANALYIS OF SUBSTANCES IN ARTICLES

Theoretically, 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 analysis may thus be a 'last resort' for checking/fulfilling REACH obligations in relation to the identity and the content of substances in an article. Chemical analyses may yield ambiguous results and/or be very costly and is thus, as already indicated in Chapter 4 not recommended as the preferred instrument for obtaining information. Difficulties related to chemical analysis of substances will be faced relating to the following issues and have to be kept in mind in case chemical analyses are conducted:

- Sampling of articles: articles may be very complex and composed of different parts and materials. It is therefore difficult to create a sample that represents the article for the analysis
- Extraction of substances from the article: substances which are included in the article matrix may have to be extracted from it.
    i. This may result in chemical reactions that could 'create' substances which do not exist in the article
    ii. The extraction may not be exhaustive, thus the full content of substances in the matrix may not be obtainable
    iii. In case substances intended to be released are extracted, they cannot always be distinguished from substances which are not intended to be released and are part of the article matrix
- Analytical methods: various methods are available to screen for the existence and identify different substances in a sample.
    i. Measurements in most cases will identify the chemical compounds/components in the sample but not necessarily 'the substance', which has originally been used to produce the article. Note that substances may consist of several compounds/components (see Guidance on substance identification).
    ii. The analysis may show the existence of certain elements (e.g. halogens) or the molecular weight rather than substances.
    iii. If a high variety of different substances are contained, several analyses may be needed to identify all substances, and it is particularly difficult to assign an appropriate method if it is not clear what is being looked for.
    iv. The quantification of substances requires additional measurements

Chemical analyses have to be planned carefully taking into account what information can be obtained with which methods. If an analysis is carried out, a strategy should be developed in collaboration with experienced laboratories and based on available methods. The testing strategy and interpretation of results should take into account any other available information from e.g. industry sec-

tor organisations, research institutions and/or accredited chemical analysis laboratories on the article which is being analysed[19].

5.1 Chemical analysis in the context of substance registrations

If substances are intended to be released they can in principle be separated from the article without extraction or special methods, so taking respective samples for chemical analysis should normally be possible.

The following steps are proposed, if analysis is regarded as necessary and helpful:

- Consult experts or sector information sources to narrow down which substances to look for (both with regard to the tonnage threshold and groups of substances). Specific requirements to substances in articles are often linked with standard methods for analytical control of compliance (see Appendix 5).
- Develop a strategy for testing as a tiered process, i.e. broad screenings, narrow screenings and identification by e.g. semi-quantitative methods
- Identify from which part of the article to sample: Separated liquids, gases or powders, extracts from article matrix or other types of sample from the article
- Perform the chemical analysis for the identification of substances

The results of the analysis will frequently not enable the full identification of the substances which have originally been used and which may or may not have already been registered for that use in the article. This is particularly the case for multi-constituent substances and substances of unknown or variable composition (UVCBs), as it cannot be seen which compounds have been constituents of multi-constituent substances or have been impurities etc. Thus, the results obtained from chemical analysis may differ from the exact identity of substances that were originally used for producing the article.

It may be possible to combine the results of an analysis with other knowledge on the article to reach conclusions on the identity of substances intended to be released.

Only if the 'original' (registered) substances intended to be released from the article cannot be determined, the article producer/importer should identify all compounds as 100% pure substances and register those, for which the tonnage threshold is exceeded. This may signify that the article producer/importer has to register a substance 'for the first time' (and therefore cannot apply Article 7(6)).

[19] It should be noted that there are no formal requirements on methods and/or laboratories to use. It is up to the producer/importer/supplier judge the appropriateness.

Example 4 Identification of substances intended to be released - fragranced T-shirt

Example: Fragranced T-shirt

A screening for organic compounds could be performed using e.g. GC-MS. The screening procedure would cover a scan of a broad range of organic compounds in order to get an overview of the number and amount of different compounds. The result of the screening would be a list of substances and their concentration range contained in the gas sample. Depending on the total amount of released substances, further information on concentrations may need to be generated by further, targeted analysis for single components.

5.2 Chemical analysis of substances on the candidate list for authorisation[20]

The identity of substances on the candidate list for authorisation will be known to any actor via the web-site of the European Chemical Agency. Thus, the gathering of information from suppliers or, as a last resort, chemical analyses can in principle be targeted at those substances on the candidate list which are suspected to be present in the article.

Sampling of articles may cause the difficulties mentioned in the introduction to this chapter. Similarly, extraction of substances will usually be necessary, which may cause the ambiguities discussed. It is important to involve respective laboratories and experts to conduct and interpret the analysis. The following general approach is proposed to identify whether or not substances of very high concern on the candidate list are contained in articles:

- Narrow down the range of SVHC on the candidate list which could be present in the article and thus have to be analysed by applying common knowledge about what could possibly be present in the article (e.g. if a gas is included in the candidate list, it can be excluded as present in many articles), by collecting information from sector publications, product standards etc. The content of several SVHC can probably be excluded by this step.
- Consider whether more than 0.1 % could be present in the article. Note that 0.1% (w/w) corresponds to 1 gram/kg or 1000 ppm. Trace amount would therefore not normally exceed this concentration.
- Exhaust options for obtaining information via the supply chain for suspected SVHC.
- Only as a last resort, conduct targeted analysis to identify whether or not suspected SVHC are present

If it is identified that the concentration is above 0.1 %, it is relevant to identify the total amount (to check whether notification under Article 7(2) is required). If the supply chain communication cannot assist with obtaining the information necessary, the following steps could be carried out for the identified SVHC:

- If the concentration has been established with high certainty, it is straightforward to calculate the total amount by multiplying amount of article with the concentration. Note that amounts have to be summed up if several articles are imported/produced that contain the same substance
- If it is just known that the concentration is above 0.1%, some calculations could be made based on worst-case assumptions about the maximum possible concentration.

[20] Dissenting views, questioning the application of the 0.1 % threshold to the entire article have been notified by 6 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.

- Only conduct chemical analysis if there is still doubt about whether the tonnage could be above 1 tonne/a.

The analytical limit of detection of the SVHC, i.e. the lowest concentration of a substance which can be accurately measured in the analysed material should be at least 0.05% when technically and economically feasible.

High competence in analytical chemistry is needed, and the analysis needs to be carefully planned on a case-by-case basis to obtain a sufficiently reliable result. Branch organisations, research institutions and/or accredited chemical laboratories should be consulted.

6 REGISTRATION AND OR NOTIFICATION REQUIREMENTS

The workflow in this section guides you through the basic questions to find out which requirements apply in relation to the article in question. It should be noted that an article could contain substances intended to be released (which may or may not be listed on the candidate list for authorisation) and substances on the candidate list for authorisation which are not intended to be released. Both the content of substances on the candidate list for authorisation and the intended release of substances is to be considered. This also applies to packaging materials produced or imported together with articles.

6.1 Workflow on identification of potential requirements related to articles

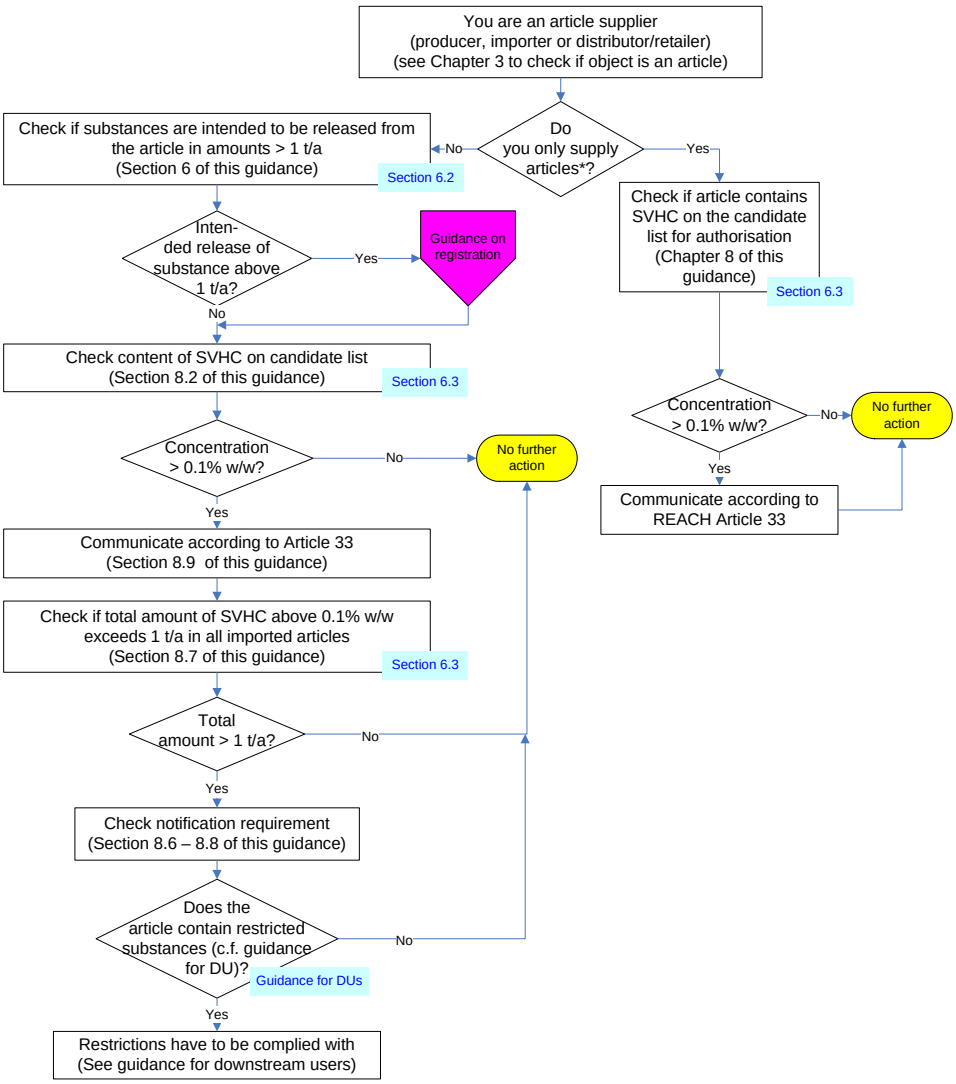

Figure 4 Identification of requirements for substances in articles

SVHC = substance of very high concern; w/w = weight per weight; t/a = tonnes per year; DU = downstream user

** "Do you only supply articles?" You should answer yes to this question if you only supply articles. If you also import or produce articles you should answer no.*

6.2 Substances intended to be released from the article

The intended release of substances as such or in preparations from an article normally applies to an accessory function of an article. In contrast, if the main function of an object is to release substances or preparations, as it is the case e.g. for pens, then the object is in most cases a "substance / preparation in a special container / on a special carrier material" and not an article with an intended release (c.f. Section 3.3.2).

If an article has an accessory function, which is achieved through the release of substances or preparations during normal and reasonably foreseeable conditions use (e.g. a scented eraser) then the release is to be regarded as intended. Consequently for these substances registration requirements under Article 7(1) of REACH have to be checked (see Chapter 7).

Example 5 Example - releases from a scented eraser

An eraser (rubber eraser) consists of an elastic material (rubber or resin components) and additive agents such as fillers and polishing materials. Fragrance substances can also be added to provide an accessory function of a good smell.

The fragrance substances only fulfil their function if they can be inhaled and thus it is intended that they are released.

6.3 Substances on the candidate list for authorisation

For any imported or produced article, it should be checked whether or not substances on the candidate list for authorisation are contained in concentrations triggering notification and communication requirements under REACH (i.e. >0.1% (w/w)). Substances are included on the candidate list for authorisation after it has been agreed by a formal procedure that they fulfil the criteria of Article 57 of REACH (substances of very high concern – SVHC). The candidate list for authorisation will be published on the Agency's website. This list will be updated every time a decision on inclusion of a substance has been taken. Explanation for decision-making is provided in Chapter 8; examples are given in Appendix 4.

6.4 Time of checking compliance

The time at which the article producer and importer checks compliance with the requirements of Article 7(1) is relevant with regard to the consequences and options he has available (see Table 1). Potential registrants should preferably pre-register between June 1 and December 1 2008 and explore the option that other registrants in the SIEF include his use in their registration dossier (see also Section 2.5). If an article supplier identifies a registration requirement after 1 December 2008 for substances in articles he has been producing or importing already, he cannot submit a pre-registration any more and is required to submit a registration immediately / before he produces or imports the article.

If an article producer or importer intends for the first time, after 1 December 2008, to produce or import an article with intended release of substances / preparations, or for the first time in doing so exceeds the threshold of 1 t/a for the substances intended to be released, he may submit a pre-registration even though the deadline has expired, if he can prove that he manufactures or imports the substance(s) he needs to register for the first time (Article 28 of REACH).

7 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[21]; thus the release of the substance carries out a function of the article
- The total amount of the substance present in all articles[22] with intended release produced or imported by one actor exceeds 1 tonne per year;

If the substance has already been registered for that use (see Chapter 9) a registration is not required (However, a pre-registration is recommended as explained in section 2.5).

As a general rule, 'intended release' relates to a function of an article[23]. 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. Further explanation of the term intended release can be found in Appendix 1 of this guidance.

7.1 Workflow on checking if registration is required

The following is a tiered checking, aiming at quickly identifying cases in which registration is not required, with as little information as possible. However, it may be more efficient to perform the steps in a different sequence, e.g. if certain information is available. Sections 7.2 and 7.3 describe an initial assessment, which is based on:

- The total volume of the articles with intended release produced or imported
- The total or the maximum volume of the substances/preparation incorporated in the article with intended release

If the need to register cannot be excluded, the substances intended to be released have to be identified in order to:

- check if any of the substances are exempted from registration
- check whether the substances have already been registered for that use (Chapter 9)

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[21] The terms normal and reasonably foreseeable conditions of use and intended release are further explained in Appendix 1

[22] This means for determining the tonnage threshold, also the amounts a substance that are not intended to be released need to be considered. Furthermore, the amount of that substances should be accumulated for all produced/imported articles with intentional release of that substance. See also section 2.1.

[23] Article 7(1)(b) states that "the substance is intended to be released under normal or reasonably foreseeable conditions of use." Both of conditions must be met. Thus, a release in an accident which is not intentional, does not trigger Article 7(1), even if it is, in some sense, reasonably foreseeable.

- pre-register, join a Substance Information Exchange Forum (SIEF) and participate in joint registrations
- determine the total amount of each identified substance in the articles with intended release.

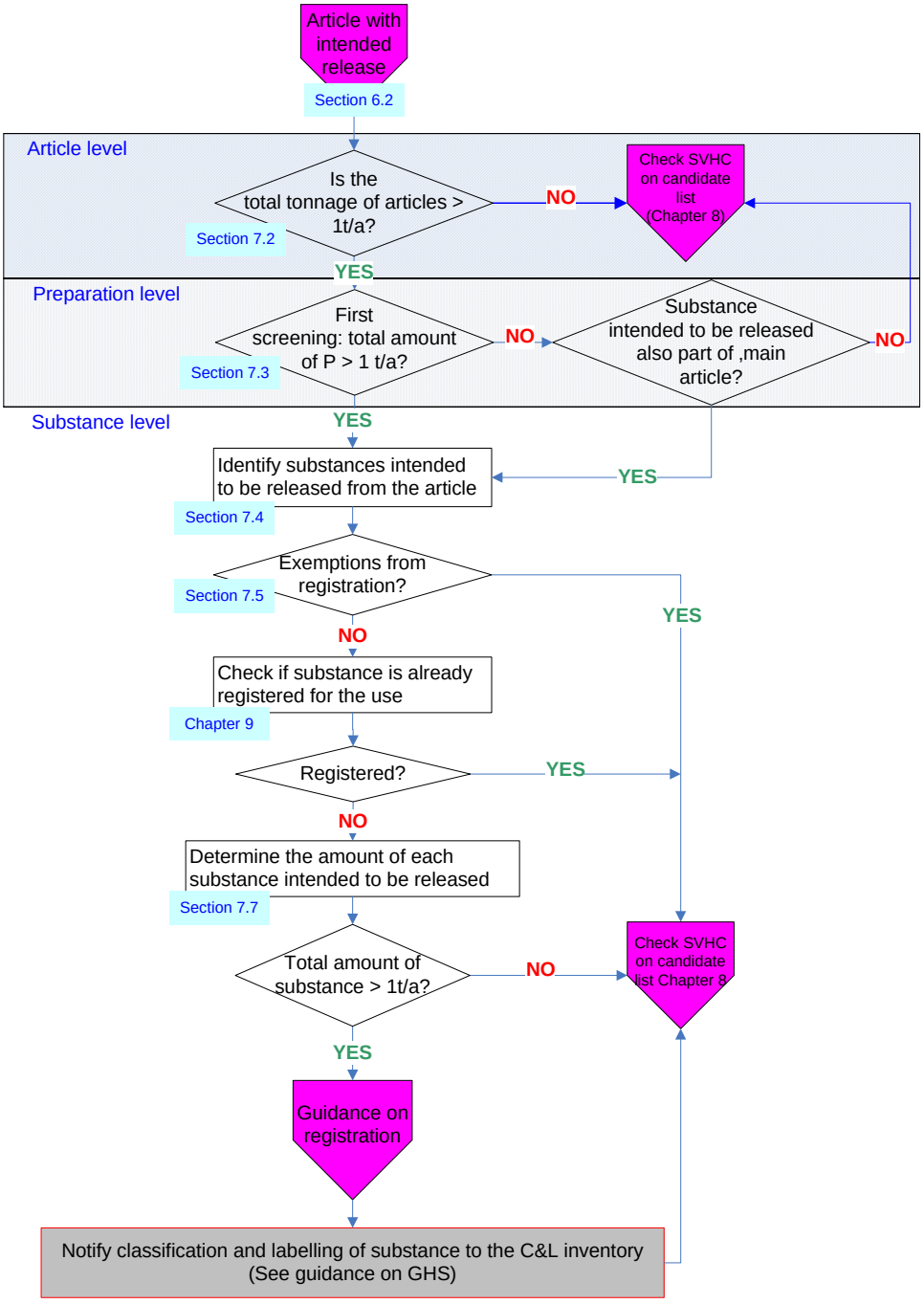

Figure 5 Workflow for checking if registration is required

P = preparation; SVHC = substance of very high concern; t/a = tonnes per year; GHS: Globally Harmonised System for Classification & Labelling

7.2 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.

7.3 Screening at preparation level

If the total volume of all substances/preparations contained in all produced or imported articles with intended release remains under 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.

7.3.1 Volume of substances/preparations in articles is known

If the volumes of the substances/preparations intended to be released and incorporated in those article are known, they can be summed up and compared to the tonnage threshold. These amounts are known to those articles producers who include them into the article.

The amount of substance/preparation released can be estimated by weighing an article before and after the release. This value can be used for a decision only if it can be excluded that further non-released substance/preparation is remaining in the article. In many cases it will be possible to exclude (substance function, properties and common sense) that a substance that is intended to be released from an article is also part of the matrix of that article. For example a fragrance in a scented eraser is intended to be released from it but would not be expected to be part of the rubber matrix of the eraser.

The critical market volume of the articles potentially causing a registration of substances intended to be released can be estimated as follows:

Based on the maximum content of a preparation in an article which is intended to be released, the maximum amount of articles that can be placed on the market without triggering registration obligations can be determined by a simple backwards calculation:

$$\mathrm{Vol}_{\mathrm{article}}\ [\mathrm{t/a}] < \frac{1[\mathrm{t/a}]}{\max\ \mathrm{Conc}_{\mathrm{preparation}}\ \mathrm{in\ article}[\%]\cdot 0.01} \qquad \text{or}$$

$$\mathrm{Number}_{\mathrm{article}}\ [\mathrm{number/a}] < \frac{1[\mathrm{t/a}]}{\max \mathrm{Conc}_{\mathrm{preparation}}\ \mathrm{in\ article}[\mathrm{t/article}]}$$

$\mathrm{Vol}_{\mathrm{article}}$ = tonnage of articles produced / imported
$\mathrm{Number}_{\mathrm{article}}$ = number of articles
$\mathrm{Conc}_{\mathrm{preparation}}$ in article = maximum weight percentage of the preparation in the article

Example 6 Preparation intended to be released - smelling eraser

Example: An eraser contains a preparation with several fragrant substances which are intentionally released.

Assumption: The maximum content of the fragrant preparation, which consists of several substances, in the eraser is 20% by weight of the eraser (1) or given as 2 g fragrant preparation per eraser (2). The producer/importer of the eraser does not produce or import other articles. It can be excluded that the fragrant substance is part of the article matrix.

The maximum amount of the article not triggering the registration obligations is estimated:

(1) $Vol_{article}$ [t/a] < $\frac{1[t/a]}{20\% \cdot 0.01}$ = 5 t eraser/a

(2) $Number_{article}$ [number of erasers/a] < $\frac{1[t/a]}{2\,g/eraser}$ = 500,000 erasers/a

Conclusion: The estimation shows that as long as the article is produced or imported below 5 tonnes per year or the number of erasers is below 500,000 per year, the amount of the fragrant preparation contained in the eraser remains under 1 tonne per year and thus none of the substances contained in the preparation will exceed the threshold of 1 tonne per year.

This is a minimum estimate based on the content of a preparation in one article as it was assumed that other articles were not produced or imported. However, care has to be taken if more articles, from which the same substance is intended to be released, are produced or imported. In that case, the amounts from all these articles must be summed up.

7.3.2 Volume of articles is known

If the market volume of the articles is known, the critical concentrations of substances in the preparations intended to be released can be derived as follows:

Knowing the total market volume of the article and the maximum amount of the preparation included in the article (assuming that only one preparation with the specific substance is used and in one article only), the concentration limit, below which registration is not necessary, can be calculated for the substances:

$$\text{Max. conc. of substance in preparation [\%]} < \frac{1[t/a]}{Vol_{article}[t/a]\,x\,Conc_{preparation}[\%]/100}\ x100$$

$Vol_{article}$ = tonnage of articles produced / imported
$Number_{article}$ = number of articles
$Conc_{preparation}$ = maximum weight percentage of the preparation in the article

Information requests up the supply chain can then be focused on substances exceeding the concentration calculated to be critical.

Example 7 Substance intended to be released - smelling eraser

Example: A smelling eraser contains a mixture of fragrances that are released during use.

Assumption: The eraser consists of maximum 15% fragrances. An importer sells 30 tonnes of these erasers on the European market every year: The importer of the eraser does not import or produce other articles. He imports 4.5 t/a fragrances (30 t/a eraser x 15/100)

Maximum concentration of substance in the fragrance [%] $< \frac{1[t/a]}{4.5[t/a]} = 22\%$

Conclusion: This means that registration is not necessary for substances contained in the fragrance below 22% by weight. As this may not apply to all substances in the fragrance, further information has to be sought. The supplier of the eraser can be asked by the importer whether the concentration of 22% is exceeded for any of the substances used in the fragrance, or any specifically know substance.

If the first screening shows that the threshold volume for registration is exceeded, the identification process as described below should be followed.

7.4 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 (see section 7.3). If you import articles with intended release, ask respective information from your non-EU supplier. An overview of information availability in the supply chain is provided in Chapter 4.

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 is it 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 (see Chapter 5).

7.5 Checking whether the substances are exempted from registration

A number of substances are exempted from registration and thus also do not have to be registered if they are intended to be released from articles. The substance identities including CAS or EINECS numbers are compared with the exemptions from registration. The Navigator on the Agency website should be used to check if any exemption applies and a registration under 7(1) therefore would not be required.

7.6 Checking for existing registration for that use

Guidance on checking if a substance is already registered for a use is given in Chapter 9. However, before December 2008, it is very unlikely that a phase-in substance has been registered. Thus respective checking only makes sense from 2009. This means that you should pre-register any substance intended to be released, which you already use or import in your articles, if you want to continue supplying these articles (see also section 2.5).

7.7 Total amount of each substance intended to be released

If you have identified that a substance may need to be (pre-)registered, you have to collect further information on amounts to determine if / which tonnage threshold is exceeded and if so, for the pre-registration you need to know the tonnage band of registration (see Table 1). Therefore, if you plan to find other SIEF members that would register your use before you are obliged to do it (see also Section 6.4), you only need to identify the tonnage band, not the exact amount.

To identify the total amount of a substance intended to be released, you have to sum up all amounts of that substance in all articles with intended release of that substance produced/imported within one calendar year. Note that not only the amounts intended to be released but the total amount in the articles needs to be considered and that all imported/produced articles releasing that substance must be considered.

The best and most efficient method to identify the amounts and concentrations of substances as such or in preparations is to communicate with the suppliers. To target requests, different methods or starting points may be chosen depending on the type of information available:

- The total volume of the articles placed on the market is known and the concentration ranges of substances in the preparations intended to be released or part of the article have been obtained from e.g. supply chain, product specifications (on specific content in specific articles) or classification thresholds.
- The exact concentration of the substance in the article can be obtained from e.g. mass balance (article producers), information through the supply chain, branches etc. or quantitative chemical analysis.

It may be helpful to structure the information collection based on the different life-cycle stages of the substances intended to be released in order to target the requests in the supply chain.

Table 3 Requests for information in the supply chain

Item	Available information	Cut-off, targeting	Remarks
Article with intended release of preparation	Amount of articles produced / imported. Amount of substance/preparation intended to be released in the article	Targeting requests upstream → identification of concentrations of substances in the preparations which would not lead to exceeding the annual tonnage threshold	Note that amounts in all articles have to be summed up!
Formulator of preparation intended to be released and his suppliers	Concentration of dangerous substances in the preparation, as well as concentration of preparations the formulator has bought for use in his preparation	Substances below the concentrations communicated by the supplier. Requests for substances in the preparation should be in the way: Which non-classified substances are contained in concentrations > xyz % and what is the upper concentration range.	If preparations are used in the preparation, the identification of substances may be quite complex. Targeting information requests is particularly important due to confidentiality.
Substance manufacturer / importer (M/I)	Substance identity and composition	Should only receive requests on substance identity for which registration is required	If possible, the M/I should be identified in person in order to cooperate further on information on substance identity

If the substances intended to be released are also part of the article matrix, these amounts have to be identified as well (not included in the table).

If requesting information in the supply chain is impossible, chemical analysis may be conducted to quantify the amounts of the identified substances (see Chapter 5.1).

7.7.1 Calculation of the total amount of a substance intended to be released contained in articles

If the maximum content (whether or not it is intended to be released) of a preparation in an article and the maximum concentration of a specific substance in the preparation (e.g. from a SDS delivered together with the preparation) are known, the maximum amount of the substance in the produced/imported article can be calculated. The maximum amount or volume of the substance in the article which is intended to be released is:

$$Vol_{substance}\ [t/a] = \cdot\ Weight_{article}\ [t] \cdot (max.conc._{preparation}\ [\%] \cdot 0.01) \cdot (max.conc_{substance}\ [\%] \cdot 0.01) \cdot (number\ of\ article/a)$$

If, however, the loss of preparation during production (e.g. loss through evaporation, wash out or surplus substances) can be quantified, the substance volume to be registered may be reduced by the respective percentage, if this is the only process where the substance is included in the article.

Example 8 Reduction of substance volume to be registered

***Example*:** If the producer can document that 10% of the solvent contained in a fragrance for scenting a textile evaporates before the textile is finished, he may reduce the volume of the solvent to be registered by 10%.

If the same substance is intended to be released from different articles of one producer or importer, the volumes of this substance in all those articles have to be summed up:

$$\text{Total Vol}_{\text{substance}}\ [\text{t/a}] = \sum \text{Vol}_{\text{substance}}\ [\text{t/a}] \text{ per article}$$

Example 9 Registration of same substance in several articles

Example: The same solvent is used in textiles and erasers

$$\text{Total Vol}_{\text{substance}}\ \text{t/a}] = \sum \text{Vol}_{\text{substance}}\ [\text{t/a}] \text{ per article}$$

$$= \text{Vol}_{\text{substance}}\ [\text{t/a}] \text{ textile} + \text{Vol}_{\text{substance}}\ [\text{t/a}] \text{ eraser}$$

The calculation of the total amount of a substance could be further improved by the use of specific concentration of a substance. The total amount of substance contained in the article can be calculated if the produced or imported amount of the article is known:

$$\text{Vol}_{\text{substance}}\ [\text{t/a}] = (\text{Conc.}_{\text{substance}}\ [\%] \cdot 0.01) \cdot \text{Vol}_{\text{article}}\ [\text{t/a}]$$

Example 10 Registration of substance intended to be released

Example: A T-shirt contains a fragrance substance intended to be released.

Assumption: The fragrance constitutes 5% by weight of the T-shirt produced within EU in an amount of 100 t/a and it is not contained in other articles of the same producer.

$$\text{Vol}_{\text{fragrance}}\ [\text{t/a}] = (\text{Conc}_{\text{fragrance}}\ [\%] \cdot 0.01) \cdot \text{Vol}_{\text{T-shirt}}\ [\text{t/a}] = (5\ [\%] \cdot 0.01) \cdot 100\ [\text{t/a}] = 5\text{t/a}$$

Conclusion: The threshold of 1 t/y is exceeded; the producer of the T-shirt must register the fragrant for that use.

7.8 Registration of substances intended to be released from articles

For substances intended to be released from an article that has to be registered, the producer or importer of the article shall submit a registration to the Agency. The requirements for the registration dossier are in general the same as for manufacturers and importers of substances. However, if a chemical safety report is required (volume > 10 t/a) and the substance is classified as dangerous or PBT/vPvB, the article producer must cover in his exposure assessment and risk characterisation only the use of the article (i.e. article service life) and the disposal of the article.

The information to be submitted needs to be in accordance with Article 10 of REACH and depends on the registered amount; i.e. the total quantity of the substance in all articles with intentional release (see Section 2.1). All available information as well as the standard information requirements described in Annexes VII to X of REACH (taking into account the general adaptation rules of Annex XI and the criteria of Annex III) shall be collected and submitted for the registration.

Guidance on how to prepare a registration dossier is provided in the Guidance on registration. Assistance for participation in the SIEF and information collection can be obtained from the Guidance

on pre-registration, Guidance on data sharing and Guidance on information requirements and chemical safety assessment.

8 CHECKING IF ARTICLE 33 AND ARTICLE 7(2) APPLY

The legal obligations of Article 33 and Article 7(2) are explained in Section 2.3 and 2.2 of this guidance.

8.1 Obtaining information about substances of very high concern on the candidate list

Communication with suppliers is the best way for any article supplier to find out whether or not substances of very high concern on the candidate list for authorisation are contained in the articles. Communication can be targeted, as the identity of substances is available from the candidate list. Furthermore, for many substances the article supplier can exclude their presence based on knowledge on the substance itself, as well as information on the article (see also Section 5.2). In communicating, the complexity of supply chains needs to be taken into account, as well as confidentiality related to concentrations of substances in preparations and articles. Principles of supply chain communication and what information can be obtained from which actors are explained in Chapter 4. Chemical analysis should only be applied as a last resort (see also Section 5.2).

In many cases substances of very high concern can be traced in the documentation of substances and preparations used to produce the article. Producers of articles receive information on SVHC from their EU suppliers of substances/preparations as the identity, the classification and the concentration ranges of SVHC in preparations have to be communicated either in safety data sheets or with information according to Article 32 (if contained in concentrations above the cut-off limits in REACH article 14). In addition, safety data sheets of substances or preparations imported from non-EU Member States will often specify classified substances.

EU suppliers of articles containing SVHC in concentrations exceeding 0.1% (w/w) must deliver information available to them, sufficiently to enable safe use of the articles, as a minimum the name of the substance according to Article 33(1) of REACH.

To identify communication obligations under Article 33 only the identity and concentration of an SVHC on the candidate list need to be known.

To notify substances in articles according to Article 7(2), the total amount in the produced/imported articles needs to be known in addition to the information required for article 33 communication, although exemptions apply if

- The SVHC has already been registered for that use(s)
- exposure of humans or the environment during normal and reasonable conditions of use including disposal can be excluded[24]

8.2 Determining whether the article contains substances of very high concern

Article 7.2 and 33 do not apply if the concentration of a substance of very high concern on the candidate list is either not present or does not exceed 0.1 % (w/w) in his articles. In investigating this he could use the strategies outlined in Section 5.2, including the likelihood of the presence or absence of certain substances in the articles or parts of the articles, as well as considering other legis-

[24] See Section 2.8 in relation to documentation of such a conclusion.

lation restricting or banning the use of certain substances in articles (see also a list of relevant legislation in Appendix 7).

Article suppliers should consider how to document their compliance checking (see Section 2.8) and could include for example statements of their suppliers that substances of very high concern on the candidate list for authorisation are not used, calculations proving that the concentrations in articles remain equal to or under 0.1 % (w/w), safety data sheets of input materials, supply contracts and documentation of their implementation and auditing etc.

If the content of SVHC cannot be excluded, initially, it is only necessary to know whether or not the article contains a SVHC on the candidate list. The information may be obtained via: safety data sheets, Article 32 information[25], supply chain requests etc. (see Chapter 4 and 5)

When no safety data sheet or other standardised information is available for the substances and/or preparations in the article or the presence of an SVHC cannot be excluded, the following actions could be performed:

Article producers

- Request the supplier of substances/preparations included in the article to provide the registration number, when available, the identity and concentration range of any SVHC on the candidate list and contained therein. For article components, ask the supplier to either confirm that no SVHCs on the candidate list are contained in concentrations > 0.1% (w/w) in the article or to specify the identity and concentration of the SVHC in the article.

Article importers and only representatives

- Request the supplier to confirm whether or not an article contains any SVHC on the candidate list in concentrations > 0.1% (w/w). If the supplier cannot confirm this, ask for the identity and the amount (or concentration) of these substances in the article. If he is not willing or able to provide these, ask him to forward your request to the next actor up his supply chain or to provide you with the contact details of his suppliers.

All article suppliers

- Collect information from studies and surveys, if available, on the specific article made by e.g. EU Member States (e.g., www.mst.dk "Survey and migration of chemical agents in toothbrushes", Survey No. 42, 2004) and branch knowledge to confirm information from supply chain communication or to find information on the likelihood of an SVHC being contained in the article.

- Check if the article conforms to any specific requirements such as standards, labels or other legislation that ensures that the content of some SVHCs is below a certain threshold level, e.g. the TOXPROOF label/certificate of cars (Appendix 6).

If no or insufficient information to comply with articles 33 and 7(2) is made available by through supply chain communication and branch knowledge for a specific article as a last resort, a chemical analysis may be conducted. For this, knowledge about which parts and materials of the article may contain a SVHC is an advantage. For more information see Section 5.2.

[25] Note that SDS and Art. 32 information can only confirm the presence of SVHC not exclude it.

8.3 Workflow for checking whether forwarding information and notification are required

If SVHC(s) have been identified in the article, you may use the following workflow to check, if you have to forward information in the supply chain and/or notify the Chemicals Agency. You may start in the workflow at any point, depending on which information is available or easiest to obtain. For example, it may be easier to calculate the total amount of an SVHC in the article than to check a registration for that specific use.

The workload for notification is relatively low compared to that of registration and the amounts of the substance in the article only need to be known in tonnage ranges (for example 1, 10, 100 or 1000). Avoiding a notification by excluding exposures (Article 7(3)) may require more effort than a notification itself. It is recommended to evaluate the costs before going into a more thorough assessment instead of just fulfilling a notification.

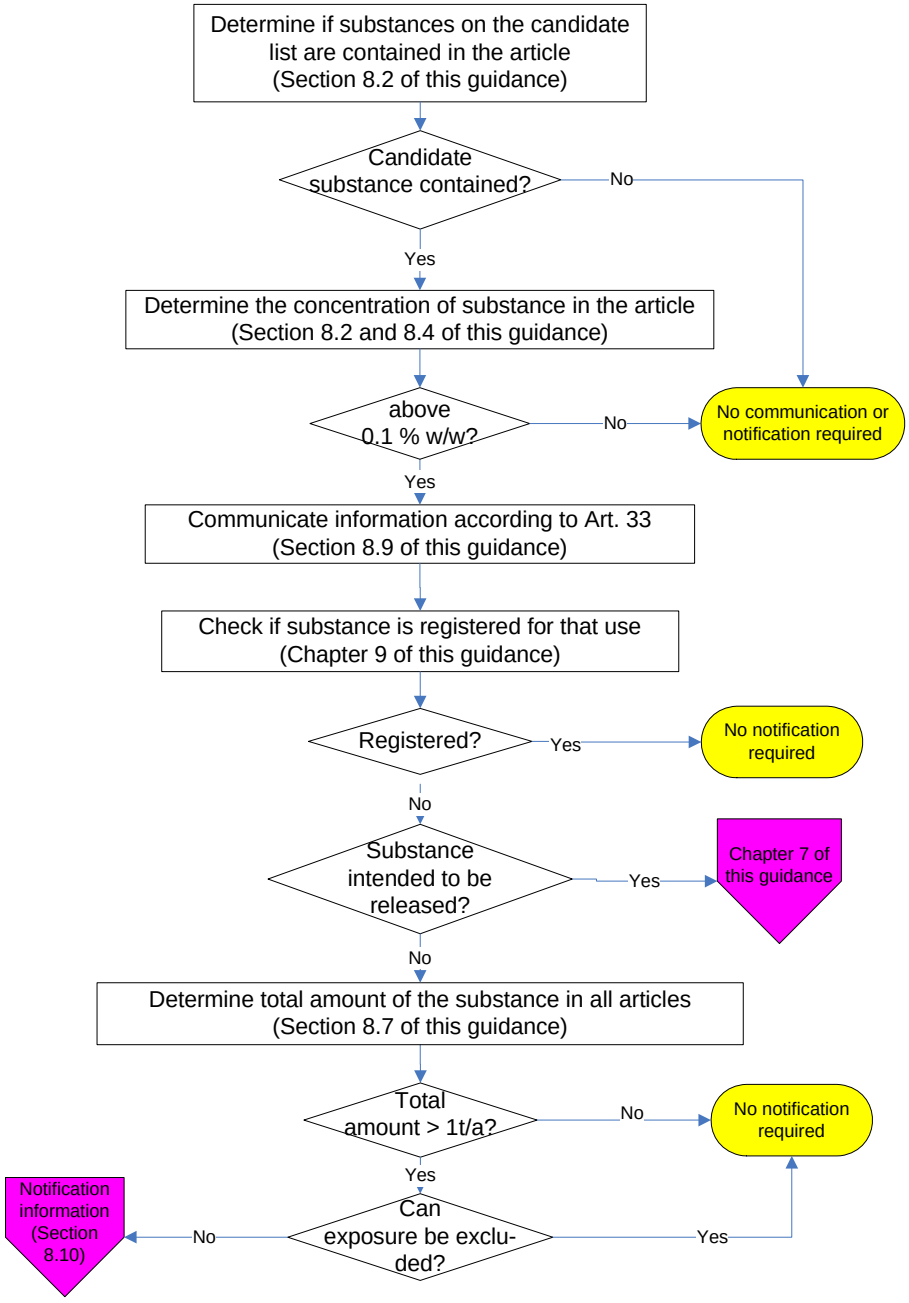

Figure 6 Checking the requirement to notify and to forward information on SVHC

w/w = weight per weight; Art = REACH Article, t/a = tonnes per year

8.4 Determination of the concentration of SVHC – focus on articles with different components[26]

For each article, it must be determined whether the concentration of the identified SVHC is > 0.1% (w/w) in order to know what information has to be communicated down the supply chain. A further assessment is needed to find out if a notification of these SVHC is required. Methods for obtaining information on the concentrations of SVHC in articles and the use of quantitative chemical analysis have been elaborated in previous chapters of this guidance (see Chapter 4, Section 5.2 and Section 8.2). However, it should be noted that an article producer should consider the possibility of using mass balance for determining the concentration of SVHC in his articles and also be aware of the possibility of accumulating a SVHC through a process. This chapter focuses on determining the concentration of a SVHC in articles with different components.

The SVHC may be contained in different concentrations in different components of the same article, e.g. one concentration in the chassis of a computer and another concentration in the transformer. The concentration threshold of 0.1% (w/w) refers to the average concentration of the entire article as produced or imported.

The principle to be applied when calculating the concentration of an SVHC in an article is illustrated by two cases:

1 Different components for a computer such as transformer, rectifier, mother board, memory, processor, hard drive, graphics card, network card, sound card and chassis are purchased by a producer of a computer. All these components are obtained from producers and importers within the EU and the content of SVHC above 0.1% (w/w) should be indicated to the producer (Article 33) and possibly notified where needed by the suppliers of the components. The producer of the computer would therefore not have to notify any of those substances again.

   Furthermore, if no components contain above 0.1% of a SVHC on the candidate list, also the entire computer would not contain above 0.1% and no further considerations are needed.

   If one or more of the components contain more than 0.1% of a SVHC on the candidate list, the producer of the computer would have to check whether the computer he places on the market would contain above 0.1% of that SVHC – averaged over the weight of the computer. If yes, he will have to supply information according to Article 33.

   If the producer himself adds a SVHC to one or more parts of the computer, he will have to check whether the 0.1% threshold is exceeded for the computer he finally places on the market. If yes, he will have to provide information according to Article 33. He may additionally have to notify if the 1 tonne tonnage trigger for that SVHC is exceeded.

2 A chair is imported from Taiwan. It consists of a wooden part and a plastic part. The producer of the chair informs that the two parts contain xyz% and abc%, respectively of a SVHC on the

[26] Dissenting views (http://reach.jrc.it/docs/guidance_document/dissenting_en.pdf), questioning the application of the 0.1 % threshold to the entire article have been notified by 6 Member States in writing (Austria, Belgium, Denmark, France, Germany and Sweden) and publication of this part of the guidance document was not endorsed by these Member States.

candidate list. Based on this information, it is obligatory to check if the threshold of 0.1 % is exceeded. This could be done by calculating the concentration of this SVHC in the whole chair as described below and illustrated in the below example box.

The average concentration of a SVHC in an article is calculated as follows:

$$\text{Conc. of SVHC}\,[\%] = \frac{\text{Amount of SVHC}\,[\text{g}]\cdot 100}{\text{Weight of the whole article}\,[\text{g}]}$$

Example 11 Calculation of a concentration

Example of calculating a concentration:

A chair consists of a wooden part and a plastic detail. The weight of the chair is 2.001 kg.

The wooden part of a chair contains 10 mg of a SVHC. The weight of the wooden part is 2 kg.

A plastic detail of the chair contains 1 mg of the same SVHC and the weight of the plastic detail is 1 g.

The SVHC concentration in the chair: $\frac{(10\cdot 10^{-3} + 1\cdot 10^{-3})\text{g}\cdot 100}{(2001)\text{g}}\% = 0.0005\%\,\text{(w/w)}$, which is < 0.1%.

Conclusion: The producer/importer has neither to communicate information down the supply chain according to Art. 33 nor to notify according to Article 7(2).

If the exact concentration in the article or the article parts is not known, a first screening may be performed on the basis of the maximum amount or concentration in the whole article or the different parts. If this shows a concentration > 0.1%, a more precise determination of the SVHC amount or concentration should be made.

8.5 Check for an intended release of the SVHC[27]

If the SVHC is intended to be released, registration may apply (See chapter 7). As previously described, notification is not needed if a registration according to Article 7(1) is required. The obligation to forward information to customers may however still be applicable if the concentration of the substance in the entire article is greater than 0.1 % (w/w).

8.6 Check for an existing registration for that specific use

According to Article 7(6) of REACH, substances in articles already registered for that use do not need to be notified. See further guidance in Chapter 9.

[27] Dissenting views (http://reach.jrc.it/docs/guidance_document/dissenting_en.pdf), questioning the application of the 0.1 % threshold to the entire article have been notified by 6 Member States in writing (Austria, Belgium, Denmark, France, Germany and Sweden) and publication of this part of the guidance document was not endorsed by these Member States.

8.7 Determine the total amount of substances on the candidate list in all articles[28]

It is possible that the concentration of a substance on the candidate list is greater than 0.1% (w/w) in several different articles, e.g. a bag and a belt. To find out if a notification is required, the total amount of the substance in all of these articles must be determined and summed up.

Calculate the total amount of the SVHC (g) in each article produced or imported per year with a concentration of the SVHC > 0.1% (w/w):

The amount in one article is:

$$\text{Vol}_{\text{SVHC}}[g/a] = (\text{max. conc. of SVHC in article}[\%] \cdot 0.01) \cdot (\text{weight of article}[g] \cdot 10^{-6}) \cdot (\text{number of article/a})$$

The total volume is:

$$\text{Total Vol}_{\text{SVHC}}\ [\text{t/a}] = \sum \text{Vol}_{\text{SVHC}}\ [\text{t/a}] \text{ of each type of article}$$

Example 12 Calculation of the total amount of a SVHC used in production or imported

Example of calculation of the amount of a SVHC:

A company imports 20000 pairs of shoes, 3000 belts, and 60000 bags per year to the EU market. A pair of shoes contains 0.05% (w/w) of a SVHC, a belt contains 0.15% (w/w), and a bag contains 2% (w/w) of the same SVHC. The weights of the articles are 0.7 kg per pair of shoes, 700 g per belt and 1 kg per bag.

Concentration in belt and bag > 0.1% (w/w) ⇒ calculate the total volume of the SVHC for each of the articles.

The total volume of the SVHC imported by the articles:

- Belts: Vol_{SVHC} [t/a] = (0.15% · 0.01) · (700 [g] · 10^{-6}) · 3000 = 0.0032 t/a
- Bags: Vol_{SVHC} [t/a] = (2% · 0.01) · (1000 [g] · 10^{-6}) · 60000 = 1.2 t/a

Sum up the total volume for all sorts of articles with a concentration of the SVHC > 0.1%:

$\sum \text{Vol}_{\text{SVHC}}$ = (0.0032 + 1.2) t/a = 1.2032 t/a, which is > 1 t/a

Conclusion: The company has to submit a notification for the SVHC in the bag and the belt. Furthermore, the company has to provide information for both the belt and the bag according to Article 33 of REACH.

8.8 Can exposure be excluded during normal or reasonably foreseeable conditions of use

Notification is not required if the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal (Article 7(3).

Exposure to human or the environment can be excluded in the following situations:

- There is no release of the substance of concern during normal and reasonably foreseeable conditions of use(s) or disposal (see explanation of these terms in Appendix 1).

[28] Dissenting views (http://reach.jrc.it/docs/guidance_document/dissenting_en.pdf), questioning the application of the 0.1 % threshold to the entire article have been notified by 6 Member States in writing (Austria, Belgium, Denmark, France, Germany and Sweden) and publication of this part of the guidance document was not endorsed by these Member States.

- There is a release but the article is embedded during use(s) and the substance will not escape to the environment or get into contact with humans during use or disposal. This could be the case e.g. for electronic parts inside of machinery.

This means that a producer/importer wanting to demonstrate 'exclusion of exposure' has to ensure that the substance of very high concern on the candidate list does not come in contact with the users of the article or with the environment, regardless of its dangerous properties. Note that all exposure routes at all life-cycle stages (service life of the article and disposal) have to be considered. Ways of showing that no exposure occurs include arguments based on

- knowledge of the article and its service life, e.g. the SVHC is fully contained in the article, and the article is collected and disposed of in a manner that prevents any release to the environment and exposure to humans under normal and reasonably foreseeable conditions
- knowledge of the substances properties, e.g. the substance is fully immobile in the article due to the way it is integrated and because of its inherent physicochemical properties
- quantification based on exposure models, demonstrating no exposure during service life and disposal
- measurements proving that no emissions from the article take place including during its disposal

Note, that it may be more difficult to demonstrate 'no exposure' than making a notification. Some basic principles are described below, for further guidance on how demonstrating that no exposure occurs see the Guidance on information requirements and chemical safety assessment (exposure based waiving).

8.8.1 Use and function of the substance and the article

The assessment of a possible exposure cannot be separated from the function (if any) or the use of the substance in the article[29] and the use conditions of the article. The article producer or importer needs to consider all normal and reasonably foreseeable conditions of use including disposal of the article and assess whether exposures can be excluded or not. It is recommended to document the considerations made on the normal and reasonably foreseeable conditions of use if the conclusion is that exposure can be excluded.

8.8.2 Potential for release

The potential for release of a substance from a material in an article will depend on:

- *The substance*

  Physicochemical parameters like vapour pressure and water solubility, stability in contact with air, water etc. and how the substance is combined into or onto the material.

- *The material* the article is made of

[29] A brief description of the use(s) of the substance in the article has to be included when notifying (Art. 7(4e)).

Structure and chemistry of the article matrix including physicochemical parameters and the way in which the substance is incorporated in it (chemically bonded or not)

- *The uses and disposal* of the article
  - Location of use (indoor or outdoor use, private homes, workplace etc.)
  - Physical conditions at place of use (temperature, ventilation etc.)
  - Whether or not articles are part of a comprehensive waste collection scheme
  - The disposal technology

Some chemical substances are very firmly bound in the material, e.g. chromium in stainless steel, and the potential emission of chromium is therefore very low. Other substances are loosely incorporated in a matrix, e.g. softening additives in PVC. Such substances, like phthalates, are continuously emitted from the surface of the article. An alternative way, in which substances may be released, is through normal wear and tear of articles (abrasion). In this case, the substances are released together with the article matrix, e.g. additives in car tyres or outside surface coatings of the car underbody.

A potential for emission may already have been identified if a material containing the specific SVHC has been used before REACH enters into force. Check in the supply chain, branch organisations and available data sources (see examples in Appendix 6).

8.8.3 Exposure to humans and the environment

The next step is to assess whether exposure to humans or the environment can be excluded. The whole life cycle of the article must be considered.

A: User groups

Consider the user group (industrial users, professional users, waste operators, consumers etc.). An industrial process may be performed in a closed system. Note that waste processing operations may give rise to considerable exposure of workers. For articles used close to the body, like clothes, shoes or jewels, the exposure to humans is obvious and cannot be excluded.

B: Environment

Exposure to the air, soil and water must be considered for the use phase as well as the disposal operations (cf. Guideline for exposure assessment in Guidance on preparing the Chemical Safety Report).

Can exposure be excluded?

- *If yes → supply appropriate instructions (cf. Section 8.9)*
- *If no → notification is necessary (cf. Section 8.10)*

8.9 Forwarding information according to Article 33

According to Article 33(1), any supplier of an article containing SVHC on the candidate list in concentrations exceeding 0.1 % w/w shall supply the recipients with sufficient information, available to

the supplier, to allow safe use of the article. As a minimum the name of the SVHC shall be provided. Article 33(2) requires the same type of information to be forwarded to consumers upon their request.

In any case, providing the name of the SVHC contained in the article is obligatory. In addition to the name, it is obligatory to provide any information necessary to ensure safe use. This means that obligatory additional information depends on what a user needs to know to ensure safe use. In order to determine what information shall be provided to the recipient or to the consumer on request, 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 consider the service life of the article and appropriate instructions for its disposal. Specific storage or transport conditions should also be considered, where relevant for safe use of the article.

The information necessary to ensure safe use of the article could be communicated in different ways and formats. The communicator should consider what type of information and level of detail is appropriate to the respective addressee, considering the conditions of their use and the level of knowledge. Information for the same article may thus be different regarding information type and detail (a professional user would e.g. normally not be informed that an article should be kept out of reach of children) and format (consumers may be informed with stickers, whereas professional user would rather be provided with use instructions).

Whatever technique being used, ready access to the information should be guaranteed to any user[30].

Examples of information which could be provided to consumers

- An article is supplied with a risk of human exposure if sucked by small children and/or for environmental exposure if discarded as household waste:
  "Contains substance X that is (very) dangerous to health and/or the environment. Keep out of reach of small children. Handle waste as hazardous waste."
- An item of clothing is supplied with a risk of dermal exposure if in contact with skin:
  "Contains substance Y which is (very) dangerous to health. Do not wear in direct contact with skin."

Examples of what information could be provided to professional users

- Metal article e.g. a sheet that would normally be grinded during use and dust containing the SVHC may be inhaled:
  "Avoid inhalation of dust from grinding by using effective point ventilation systems and where necessary also appropriate personal protection."
- Plastic sheets from which the SVHC may leak to the environment if exposed to rain:
  "To avoid leakage to the environment do not use the sheets outdoors."
- Brake lining from which a large fraction will wear during normal use and expose the environment to the SVHC:
  "Will lead to exposure to the environment during outdoor use. Indoors: Only professional

[30] As the candidate list is subject to change, a link to a website with up-to-date information could be provided in addition to a paper label. However, a link would not be sufficient since the information is then not readily available.

use."

The following checklist could be used to decide what information may be required to forward to professional users.

- Exposure controls/Personal protection
- Handling and storage
- Disposal consideration
- Fire-fighting measures
- Transport information

The information could be included in already existing documents, such as instructions for use and packaging. Labels might be used in some cases. In addition, other techniques could be developed.

REACH does not specify a format for providing information with articles. You must choose a format that will ensure that the recipient can readily become aware of the information. Potential information items for inclusion are shown in Table 4.

Table 4 Information types for communicating on SVHC in article - Example

Item	**Example**
Substance name	Diarsenic trioxide
CAS Number	1327-53-3
Registration number (if provided by supplier)	01-1234567-49-00
Classification and SVHC properties	Carc. Cat. 1; R45; May cause cancer T+; R28; Very toxic is swallowed C; R34; Causes burns N; R50/53; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Concentration in the article[31]	1% w/w
Information on safe handling including safe disposal if relevant	Prevent from heating above 60 °C Keep article out of reach of children This article should be disposed of as hazardous waste. Do not dispose of via normal household waste

8.10 Notification of a substance in articles

The information to be notified according to Article 7(2) shall include the following items:

- The identity and contact details of the producer or importer of the article
- The registration number(s) for the substance(s), if available
- The identity of the substance(s) (cf. Annex VI of REACH). This information will be available on the candidate list

[31] Concentration ranges could be considered in order to preserve confidential business information

- The classification of the substance(s), which will be available from the Agency
- A brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s) (cf. Section 8.8.1)
- The tonnage range of the substance contained in the articles, i.e. 1-10 tonnes, 10-100 tonnes etc. This information can be estimated as explained in Section 8.7.

9 CHECKING WHETHER A SUBSTANCE IN AN ARTICLE HAS BEEN REGISTERED FOR THAT USE

A registration or notification of a substance in an article is not required, if the substance has already been registered for that use (REACH Article 7(6)).

This refers to any registration of that use of the substance up the same supply chain or any other supply chain. It needs to be ensured that it is the same substance that has been registered. Comparing names, and EINECS or CAS numbers may not always be sufficient to establish whether substances are to be considered 'the same'.[32]

Registrants have to provide a brief general description of the identified use(s) in the registration dossier according to Annex VI Section 3.5. This part of the REACH requirements have been implemented in IUCLID 5 registration software to also cover whether a substance has been registered for that use in relation to the article requirements via a standardised use descriptor system.

This standardised system has also been developed to facilitate the communication and description of uses (see Guidance on the Chemical Safety Report). The system consists of four elements, specifying the industry sector, the preparation types, the processes and the article categories a substance could be used in. It also specifies whether the substance is foreseen to be intentionally released or not from an article. If the elements of the use description in a registration fit to the article containing the substance, then this use can be regarded as a registered use. The use descriptors have been implemented in the IUCLID 5 software as standardised pick-lists (with options for the registrant to make more specific or further entries if needed). Please refer to the Guidance on preparing the Chemical Safety Report and the IUCLID 5 guidance for further information about the pick-lists and the context in which the lists are to be applied.

Consequently, a potential registrant or notifier of a substance in articles checking whether a substance has been registered 'for that use' has to check by which process the substance has been included in the article, and into which type of article the substance has been incorporated in line with the use descriptor system. Otherwise the substance is not considered registered for that use.

Information on non-dangerous substances and their registered use(s) will not normally be communicated along the supply chain, whereas for dangerous substances this should be communicated with the (extended) safety data sheet. However, the complete set of registered uses may not be identified in safety data sheets of preparations, as they are more specific, than those of the single substances.

Substances will be registered throughout the phase-in scheme until 2018. Thus, a substance may not yet have been registered at the time a producer or importer of an article checks if his use has already been registered. More information on how to handle this is provided in Section 2.5 and Section 7.6 of this guidance.

[32] Rules for the identification and naming of substances as well as criteria for substances being considered 'the same' or not are provided in the Guidance on Substance Identification.

9.1 Information in the supply chain

If you need to find out which uses a substance has been registered for, the most likely option would be to ask the suppliers in your supply chain, or to identify and ask a manufacturer or importer of that substance. They may either be aware of the registered uses from safety data sheets or other information or may have carried out a registration already and could tell you if they have registered your use. They may also know other registrants who have registered that use. Registrants or future registrants could also make a respective request in the Substance Information Exchange Forum (SIEF) (see also Section 2.5). Confidentiality of information may however be a problem for either side and exclude such communication.

You may start a request up the supply chain for registered uses of substances for which you have identified a possible registration or notification requirement. If you ask for a specific substance, this request may be forwarded straight up to the manufacture of the substance. Usually, however, substances are used in preparations and the request may therefore need to be differentiated for the different substances contained therein. If you ask for 'all substances in a preparation that you use', at each supply chain level, the request upstream may be forwarded to more actors as the different substances of a preparation may be supplied by various actors.

9.2 Information requests to the Agency[33]

You may also be exempted if a Registration of your use of the substance has been made by an actor in another supply chain.

Search for information on the Agency databases or make a request to the Agency to find out if a specific use of a substance has been registered. For this step, it is a prerequisite that the identity of the substance is known (as a minimum, an identification number, such as CAS, EINECS, ELINCS is required). On request, the Agency should be able to give a simple 'yes'/'no' answer to the question: "Do I have to register my substance in articles according to Article 7(1)?" based on the use identifier given by the potential registrant.

In case the article producer/importer is still in doubt about whether his use has been registered, he should consider further dialogue in this supply chain or within the Substance Information Exchange Forum (SIEF).

[33] This section may have to be revised, once the Agency working procedures on this issue have been established.

LIST OF APPENDICES

APPENDIX 1: DEFINITIONS AND EXPLANATIONS

Definition: Article according to Article 3(3)

"*Article* means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition".

Explanation

The main guidance contains comprehensive explanation about how the article definition is to be interpreted (see Chapter 3). In the following, the main principles are summarised:

1. In determining whether or not an object is an article or not, it is decisive that the shape, surface or design are more important for an article's function than its chemical composition.
2. It is important to determine the main function of an object (what its main purpose is) and to identify the relevance of physical and chemical characteristics for achieving that function.
3. The function of an object should be determined consistently for a whole category of similar objects. It should be determined by the manufacturer's/supplier's intention (as evidenced e.g. on the label texts, advertisements etc.), and/or by the expectations of the person acquiring it.
4. If an object merely acts as a container/carrier material to deliver a substance/preparation (such as a spray can with a preparation in it, a printer cartridge, a pen, a cleaning tissue containing chemicals, ink in a printed ribbon or on carbon paper etc.) then it is a substance/preparation in a container and not an article.
5. The article definition applies to an article 'as produced or imported'. An article may be directly used but may also be assembled into a complex article consisting of several articles (e.g. a computer or a car)[34].
6. The transition point of raw materials from substances/preparations to articles during processing is to be determined also by comparing the importance of physical and chemical characteristics for achieving the object's function. Indicative questions are part of the guidance and examples are provided in Appendix 3
7. Substances may be intended to be released from articles in order to provide an accessory function to the main function (e.g. fragrances in clothes).

Where the borderline should be set between substance/preparation and article may vary depending of either the function of the 'article' or the type of material. Examples of different families of 'articles' and how to treat borderline cases between 'article' and 'substance/preparation in a container' are presented in Appendix 2, while examples of the transition from 'substance/preparation' to 'article' are shown in Appendix 3.

[34] Dissenting views (http://reach.jrc.it/docs/guidance_document/dissenting_en.pdf), questioning the application of the 0.1 % threshold to the entire article have been notified by 6 Member States in writing (Austria, Belgium, Denmark, France, Germany and Sweden) and publication of this part of the guidance document was not endorsed by these Member States.

Definition: Use (Article 3(12))

"*Use*: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation".

Definition: Identified use according to Article 3(25)

"*Identified use* means a use of a substance on its own or in a preparation, or a use of a preparation that is intended by an actor in the supply chain, including his own use, or that is made know to him in writing by an immediate downstream user."

Explanation

'Identified uses' are uses which are intended by an actor in the supply chain. This may include his own uses, and uses made known to him in writing with the aim of making the use an identified use.

Registered for that use

Explanation

See Chapter 9 and details of the use descriptor system in Guidance on information requirements and chemical safety assessment, part D.

Intended release

Explanation

The requirements in Article 7(1) relate to substances (as such or in preparations) that are intended to be released under normal or reasonably foreseeable conditions during the service life of the articles. Both conditions, intended release and normal or reasonably foreseeable conditions of use, must be met before registration requirements under Article 7(1) can be triggered.

As a general rule, the intention of the article producer in relation to the release of the substance is relevant. The question "Is it wanted that a substance/preparation is released from the article during its normal and reasonably foreseeable use because this is necessary for it to fulfil a certain function of the article?" should be answered with yes. Intended releases are deliberately planned and have a specific function for the article, which is frequently not the main but an accessory function of the object[35].

A release of substances from articles is intended[36] when:

[35] In cases where an intended release of substances is the main function of an object, it is to be regarded as a container with substances / preparations inside but not an article. See also Chapter 3 of the guidance and Appendix 2 for further information on the borderline between substances / preparations in special containers / carrier materials and as integral parts of articles.

[36] The list is not comprehensive, further situations where releases are intended / not intended are possible

- The release contributes to a (accessory) function of the article, or, in other words the, release contributes to the 'added value' of the article, which is not directly connected to the end use function. If the release would not happen, that function could not be fulfilled.

  Example: Intended release in this sense is: Release of perfume from a perfumed eraser (function = to erase, added value / function for convenience = quality to smell good).

A release is not considered to be an intended[36] release in the following cases:

- A release occurs during removal of 'impurities' from a semi-finished or finished article during its production process (before marketing as a finished article).

  Example: A size is added to a fabric to improve its process ability. Sizes are released during further wet processing of the textile

- A release occurs during use or maintenance of the article and is meant to improve the product quality in a wide sense or the safety as a side effect but the released substances do not contribute to the function of the article.

  Example: Washing of clothes by the consumer where remnants of different chemicals (dye, softener, starch etc.) from processing are removed over some washing cycles

- A release of substances is an unavoidable side-effect of the functioning of the article. Without the release, the article would not work, but the release is not directly intended.

  Examples: wear and tear of materials under conditions with high friction, e.g. break linings, tyres

- A release of substances formed during chemical reactions of any kind

  Examples: Releases that are unavoidable for achieving the function, like ozone released from copy machines; release of substances from chemicals reactions caused by accidents or product malfunction, such as combustion products from articles catching fire

- A release is incidental, could be forced by undue use or in an accident[37]

  Examples: release of substances from a thermometer which drops and breaks. This also includes any form of misuse and inappropriate use which is not in accordance with the use instructions or functionality, even if it could have been anticipated: A release caused by a long-term, extremely intensive use of e.g. a tool by a consumer, who uses it in disregard of the recommendations in respect of operating time provided in the instructions of use)

Definition: <u>Manufacturer</u> (Article 3(7)), <u>Producer of an article (Article 3(4)) or Importer (Article 3 (11)</u>

"*Manufacturer* means any natural or legal person established within the Community who manufactures a substance within the European Community."

"*Producer of an article:* means any natural or legal person who makes or assembles an article within the Community"

[37] Although incidents could be foreseen under the conditions of use of the articles, releases caused by these are not intended. See also the explanation of intended release above.

"*Importer* means any natural or legal person established within the Community who is responsible for import."

Explanation

Note that the term "manufacturer" is used in REACH and the guidance documents in relation to the manufacture of a substance (as such or in a preparation). The main obligation of a manufacturer relate to the registration of substances. Importer may relate to importer of a substance (on its own or in a preparation) or an importer of an article.

The article producer/importer is responsible for fulfilling the requirements of Article 7 and 33 and can be any company established within the Community who is legally responsible for placing the article on the market in the EU. Article producers are actors who manufacture articles in the EU and article importers are actors importing articles manufactured outside the EU into the European market (EU). The article producer can be an importer of articles at the same time and also have other roles under REACH.

NB! Chapter 1 of the guidance explains that non-EU actors can appoint an Only Representative to fulfil the obligations of the importers.

Definition: Supplier of an article (Article 3(33))

"*Supplier of an article*: means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market"

Explanation

Actors supplying articles on the market may need to forward information on the content of SVHCs on the candidate list. Any actor who places an article on the EU market, including retailers and owners of small shops are thus included in the information chain of articles. Only representatives can also be suppliers of articles.

Normal conditions of use

Explanation

Normal conditions of use means the conditions associated with the intended function of an article. They are frequently documented in form of user manuals or instructions for use. Normal conditions of use for articles used by industrial or professional users may differ significantly from conditions that are "normal" for consumers. This may particularly be true for the frequency and duration of normal use as well as temperature, air exchange rates or conditions related to water contact.

Article producers or importers can give recommendations to avoid or exclude specific conditions during normal use. It is explicitly not a "normal condition of use" if the user of an article applies an article in a situation or manner that the supplier of the article has clearly recommended to avoid in writing, e.g. in the instructions or on the label of the article.

Examples of the exclusion of specific conditions of use are care labels in textiles "do not wash above 30°C" and warning statements such as "keep out of children's reach" or "do not expose to high temperatures".

Reasonably foreseeable conditions of use

Explanation

Reasonably foreseeable conditions of use mean conditions of use that are not as originally intended by the article producer or importer (normal use) but which can be anticipated as likely to occur because of the form, shape or function of that article[38]. The term is relevant in several contexts of REACH, e.g. registration and safety assessment under Article 6, for assessing whether a release is intended (Article 7(1)) or whether exposure of humans or the environment to an SVHC can be excluded under Article 7(3). Thus, the following list gives examples of which condition are reasonably foreseeable conditions of use but don't preclude whether a release under these circumstances are intended or not.

The following conditions are considered reasonably foreseeable:

- "Accidents" of high likelihood, e.g. breakage of fragile containers releasing the chemical content which is an integral part of the article. These are to be considered as worst-case situations.
- Uses not in accordance with the function but which can be anticipated because function and appearance of the article also suggests other uses than the intended ones
- Extremely intensive use (e.g. 'a consumer' working with a tool 12 hours a day for three months when building his own house)

Excluded from reasonably foreseeable conditions in situations of professional and industrial uses are:

- Uses, which are clearly and noticeably excluded by the article producer or importer. These uses are to be regarded as use deliberately against the intention
- Uses, which have been clearly advised to be avoided by means of product design or warning labels[39]
- Clear misuse

Children are a good example to illustrate how reasonably foreseeable conditions of use can be identified: It is commonly known that children do not always know the function of an article but use it for any purpose they associate with it. Especially small children put anything into their mouth or, if the object is too big, bite it or lick it. Therefore, when defining conditions of reasonable foreseeable uses of an article, children's access to the article should be assessed.

The assessment of reasonably foreseeable conditions of use for articles solely used by industrial or professional users can mainly focus on evaluating the likelihood of breakage/accidents (see comment in Annex VII of REACH) as uses not foreseen by the article function can normally (but not always) be excluded.

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38 The term is occurring in the General Product Safety Directive and in the guidance to the General Product Safety Directive, it is stated: "What are "reasonably foreseeable conditions" must be judged in the individual case and will change with market developments where consumers increasingly use complex products, for example medical devices and machinery"

39 An assessment of appropriateness of the design of a product to exclude such misunderstandings should be part of the considerations

The assessment of reasonably foreseeable conditions of 'use' should be targeted only to those situations where an increased exposure or an exposure via different pathways (inhalation, dermal contact or ingestion) as compared to the normal conditions of use occurs.

Definition: Recipient of an article (Article 3(35)

"Recipient of an article: means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers."

Definition: Substance (Article 3(1)) and Preparation (Article 32())

"*Substance* means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition".

"*Preparation* means a mixture or solution composed of two or more substances"

Explanation

Substances or preparations are used in the manufacture of articles. Under REACH, substances and preparations may be accompanied by a safety data sheet according to Article 31 (if dangerous) or by information according to Article 32 (non-dangerous, if (a preparation contains a) substance which is restricted, to be authorised or requires specific risk management measures although it is not classified as dangerous). These are important information sources to identify substances present in articles as well as registered uses of the substances.

How to define the identity of a substance and name it under REACH is described in the Guidance on Substance Identification.

Definition substances of very high concern (SVHC)

The following substances are considered substances of very high concern:

- Substances meeting the criteria for classification in accordance with Directive 67/548/EEC:
  - Carcinogenic category 1 or 2
  - Mutagenic category 1 or 2
  - Toxic for reproduction category 1 or 2
- Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII of REACH
- Substances having endocrine disrupting properties or substances having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties or any other property giving rise to an equivalent level of concern to those substances listed above.

Explanation

Substances of very high concern (SVHC) are substances, which may cause serious damage to human health or the environment (see above). They may be selected for inclusion in Annex XIV of REACH or the candidate list for inclusion on Annex XIV.

APPENDIX 2: BORDERLINE CASES OF SUBSTANCES/PREPARATIONS IN SPECIAL CONTAINERS/ON SPECIAL CARRIER MATERIALS OR AS INTEGRAL PARTS OF ARTICLES

In order to find out under which REACH article substances are to be registered, the status of the object and the relation to its content need to be clarified. The main text of the guidance provides a workflow and explanation on how to distinguish between a) articles with substances/preparations forming an integral part of the article and b) special containers or carrier materials which contain substances/preparations.

It is to be decided by the article producer or importer whether or not the article definition applies. The following examples, the conclusions of which are summarised in Table 5, illustrate how to apply the workflow and indicative questions in the main guidance and how to draw respective conclusions.

Table 5 **Summary of borderline cases described**

Item/object	REACH requirements		
	Registration according to Article 6[40]	Registration according to article 7.1[41]	Notification according to article 7(2) and communication according to article 33[42]
Printer cartridge	**x (ink)**		**(Cartridge)**
Spray can with paint	**x (paint)**		**(Can)**
Adhesive tape that delivers substances/preparations (e.g. "ski-tapes")	**x (the substance/ preparation delivered)**		**(Backing material)**
Adhesive tapes for fixing carpets			**x**
Car tyres			**x**
Scented eraser		**x**	
Battery			**x**
thermometer			**x**
Firecracker with gunpowder	**x (gunpowder)**		**(Container)**
Wet cleaning wipes	**x (cleaning liquid)**		**(Wipe carrier material)**
Panty hose with lotion		**x**	

[40] Special container/carrier material containing substances preparations

[41] Article with intended release

[42] Article with substances/preparations as an integral part (no intended release)

Table 6 **Indicative questions for borderline cases (articles with chemicals as integral parts or substances/preparations in containers)**

	Spray can with paint	**Printer cartridge**	**Firecracker**	**Thermometer with a liquid**
Function	Bring paint onto a surface	Provide ink for printing	Explode and make fireworks	Measure and indicate the temperature
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?	One could still make a painting even if the paint would be separated from the spray can. → YES	If the toner was removed and filled into any other type of printing or writing device, it could still execute its function. → YES	If the chemicals were removed, they could still explode and make light effects. →YES	If the liquid was removed it could still expand and contract with changing temperatures. To use this property for temperature measurement, the shape of object constraining the volume, e.g. within a capillary is necessary. The chemical loses its function without a container but could be used in other objects. → ambiguous
Question 4b: Does the object act as a container or carrier for release or controlled delivery of the substance / preparation or its reaction products?	The spray can is mainly intended to deliver the preparation in a controlled way (it controls speed and type of its release) → YES	The cartridge is mainly intended to deliver the toner in a controlled way (it provides the fit to the printer and controls the release). → YES	The function is to bring the substances or their reaction products into the air, thus to deliver them. → YES	It is not the function of the object to deliver a substance or preparation → NO
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?	The spray can is normally disposed of separately from the paint → YES	The toner is normally consumed during use and the cartridge is disposed of separately. → YES	The explosive substances react and are separated from the container during use. Any containers or container parts remaining are disposed of separately. → YES	The liquid and the container are disposed of together. → NO

Predominantly answering with YES indicates that the object is a substance/preparation in a container.

In the case of the spray can, the printer cartridge and the fire cracker, the criteria all unambiguously apply. Thus, these objects are containers with substances/preparations that need to be registered according to Article 6 of REACH. As noted in the main guidance these examples should be applied to guide decisions on similar borderline cases. As an example, writing materials would (in analogy with the printer cartridge) be considered substances/preparations in a (more or less sophisticated) container.

For the thermometer, it could be assumed that it is an article with chemicals as integral parts, but the additional criteria should be applied to further clarify its status.

Table 7 **Additional indicative questions for borderline cases (articles with chemicals as integral parts or substances/preparations in containers)**

	Thermometer with a liquid
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 fulfil its intended purpose?	The container loses its purpose without the liquid. → YES
Question 5b: Is the main purpose of the object other than to deliver the substance/preparation or its reaction products?	Delivering a substance / preparation is not the main function of the object. The thermometer contains the liquid and provides a shape to regulate its expansion, necessary to measure and to show the right temperature. It is not the purpose to deliver the liquid → YES
Question 5c: Is the object normally discarded with the substance/preparation at the end of useful life, i.e. at disposal?	The liquid and the container are disposed of together. → YES

Predominantly answering with YES indicates that the object is an article with substance/preparation as integral parts.

These questions can all be answered with yes, thus the thermometer is an article with the liquid inside being an integral part of it.

Table 8 Indicative questions for borderline cases (articles with chemicals as integral parts or substances/preparations on special carrier material)

	Printer ribbon	**Wet cleaning wipes**
Function	Transfer ink to paper	Cleaning (surfaces)
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?	If the ink was removed and filled into other materials / containers it could still fulfill its function → YES	If the cleaner was removed it could still carry out its function of cleaning. → YES
Question 4b: Does the object act as a container or carrier for release or controlled delivery of the substance / preparation or its reaction products?	The main function is to deliver the ink to the paper. → YES	The main function of the object is to deliver the cleaning agent[43]. → ambiguous
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?	When the ribbon is disposed, most of the ink has been consumed. → YES	The cleaning agents are predominantly consumed[44] and the wipe is disposed of separately. → YES

Predominantly answering with YES indicates that the object is a substance/preparation in a special carrier material.

For the printer ribbon, the answer to all questions is yes, thus it is a special carrier material with substances/preparations. For the wet cleaning wipes, the answers may be ambiguous and then the second set of indicative questions should be applied.

[43] It also has a second function in wiping the 'dirt' off.

[44] This is regarded as true, although in reality a large part of the cleaning agent may not actually be consumed, as its *function* is to be released as far as practical.

Table 9 Additional indicative questions for borderline cases (articles with chemicals as integral parts or substances/preparations in special carrier materials)

	Wet cleaning wipes
Additional criteria	There is one ambiguous answer, → additional criteria are used to cross-check
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 fulfil its intended purpose?	The dry wipe could also be used to clean however, the cleaning result would be less good and not achievable for 'specific dirt', for which the wipes are normally designed. It is the preparation added to the tissue that really makes the difference between one wet tissue (e.g. a glass/window cleaner) and another (e.g. a tissue to clean babies) → NO
Question 5b: Is the main purpose of the object other than to deliver the substance/preparation or its reaction products?	The main function of the object is to clean and in this to deliver a cleaning agent to the item to be cleaned. → ambiguous
Question 5c: Is the object normally discarded with the substance/preparation at the end of useful life, i.e. at disposal?	It is the intention that the cleaning lotion is consumed, although the disposed wipes still contain remnants of the substance. → YES

Predominantly answering with YES indicates that the object is an article with substance/preparation as integral part.

The cleaning wipe is regarded as a special carrier material with the cleaning agent being a preparation which is to be registered under Article 6.

ADHESIVE TAPES

Adhesive tapes can have different functions. In principle the adhesive layer provides the function to adhere. The carrier material (backing or the internal reinforcement) gives the tape a specific surface and design and provides the function of 'keeping the adhering items together' and/or to retain its specific surface shape and design. Without the carrier material (backing or the internal reinforcement), there would be no 'direction' in the adhering material and the tape would not retain its shape and design. Depending on the exact function and the way tapes work, three cases can be distinguished, which are assessed in the following table.

Table 10 Applying indicative questions to pressure sensitive adhesive tapes

	Adhesive tape that delivers substances / preparations onto a surface	Adhesive tapes that do not deliver substances / preparations onto a surface	Adhesive tape that do not deliver substances / preparations onto a surface but release substances
Example	Thermally activated tape and bonding films, adhesive mastics in tape form (mechanically activated), wax tapes for skis and transfer tape without an internal reinforcement.	Tapes with adhesive layers on one or both sides of a backing material (e.g. for fixing carpets) and transfer tapes with internal reinforcement.	Children's tape with fruit odour, decorative tape with insecticides.
Type of object	Special carrier material containing substances / preparations. The carrier material serves only as release liner and aid to easy application. The adhesive layer may change its shape upon application.	Article with adhesive layer and with a backing or internal reinforcement as an integral part	Adhesive tape with adhesive layer as integral part and release of substances / preparations as secondary function
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?	The adhesive layer is capable of carrying out its intended purpose (which is not necessarily mainly to adhere!), though with less convenience.	The function of the tape is determined by the interaction between the backing or reinforcement and the adhesive. The adhesive layer without the backing material or the reinforcement is not capable of carrying out the intended purpose of the tape.	
Question 4b: Does the object act as a container or carrier for release or controlled delivery of the substance / preparation or its reaction products?	The tape's function is the controlled delivery of a substance or preparation	The tape's function is not to simply control the release or delivery of the adhesive layer but to adhere to the substrate and to provide additional qualities through the backing or internal reinforcement.	
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?	The adhering layer and the carrier material are disposed of separately at the end of their respective useful lives	The adhesive remains on the tape at the end of its useful life	
Consequences regarding Article 7(1)	Substances in the adhesive layer may need to be registered under Article 6.	No registration requirement	The fragrances may need to be registered under Article 7(1)

Terms used in the table are defined according to EN 12481:
Backing: Flexible material like for example fabric, foil or paper which can be coated with a pressure sensitive adhesive.
Double coated or double sided tape: Backing which is coated on both sides with pressure sensitive adhesive.
Reinforcement: a material which strengthens the backing and/or the adhesive.
Release liner: a removable material which protects the adhesive face or faces.
Substrate: a surface or material to which the tape is applied.
Transfer tape: an adhesive tape having two pressure sensitive surfaces without the need of a carrier and with a release liner separating the adhesive surfaces. The adhesive layer can contain reinforcing materials.

BATTERIES

The main function of batteries is to provide electric current.

The voltage is produced through a chemical reaction (of) between two unlike materials, occurring simultaneously at two different electrodes (such as the positive and negative plates), which are immersed in an electrolyte (liquid or solid). Without the chemical reaction, no voltage would be produced. Hence the chemical composition is very important for the function.

The external and internal shapes and designs of the battery ensure that the reaction takes place in a controlled way and that the energy is provided continuously, at the time needed and in a useable form. Thus, also the shape and design of the battery are important for the function.

1) The electrolyte and the electrode active materials as such cannot provide any electric current outside the battery. Filled into other containers without the specific design of a battery, they would also fail to provide energy. The 'container part' of the battery, emptied of the electrolyte, is also not able to fulfill its function. However, there are different types of electrolytes which could be used in one battery casing.
2) The electrolyte and the electrode active materials are not released from the battery, thus the container does not have a function of 'delivering' it and does not control its release
3) The electrolyte, the electrode materials and the battery casing are normally discarded together.

As a consequence, the battery should be regarded as an article containing a preparation as an integral part. There are different types of batteries and some of them may not fulfill all criteria in the same way. For example in car batteries the electrolyte may in certain cases be exchanged and both elements are discarded separately. Also the shape and design can vary to a very large extent. However, the principle of functioning is the same and thus, all batteries should be treated in the same way.

PANTY HOSE WITH A LOTION

In the case of the panty hose, the main function is to provide clothing. Therefore, the pantyhose as such is clearly an article whose main function is unrelated to the lotion. The function of the lotion (skincare) is only accessory.

However, the lotion has an intended release, as the skincare function would not be achieved if the substance were not released.

As a consequence, the panty hose with a lotion should be regarded as an article with an intended release.

APPENDIX 3: EXAMPLES ON DECIDING THE BORDERLINE IN THE SEQUENCE OF PROCESSING NATURAL OR SYNTHETIC MATERIALS INTO FINAL ARTICLES, IN PARTICULAR DECIDING ON 'SEMI-FINISHED PRODUCTS'

The main guidance text (Chapter 3 and in particular Section 3.3.1) contains explanations and indicative questions to determine the transition point from a substance/preparation to an article for a raw material during its processing. This appendix should be used in conjunction with that text. The appendix illustrates the application of the article definition to different types of raw materials. It exemplifies how the indicative questions could be answered and how they could assist in deciding whether the material is to be considered an article.

It should be noted that the borderline between substance/preparation and article may be different for very similar types of materials (e.g. there might not be the one solution for all types of fibres). Thus, it should be avoided to draw conclusions on the status of the same type of a raw material in different sectors, as it may fulfil different functions.

Thus, whether or not a raw material is an article must be decided case-by-case. However, industry sectors may develop further guidance based on Section 3.3.1 in the guidance and this Appendix.

In the following, guidance on where and how to set the borderline during the refinement of raw materials and production of various final articles is given for four sectors: metals, textile (in cooperation with non-woven industry), paper and plastic. The examples are intended to illustrate the decision making process and it should be stressed that if in doubt a careful examination in line with the outlined criteria should always be conducted. In line with this, the following examples should be applied with care as also indicated in the accompanying text.

1 METAL PROCESSING - SHOWN FOR ALUMINIUM PRODUCTS AS EXAMPLE

The example of aluminium processing is included to show the transition point in the processing of bauxite to final aluminium products. It should be noted that the processing of other metals (for example iron/steel) may show different transition points. The following figure shows the different processing stages and the respective status of the raw material.

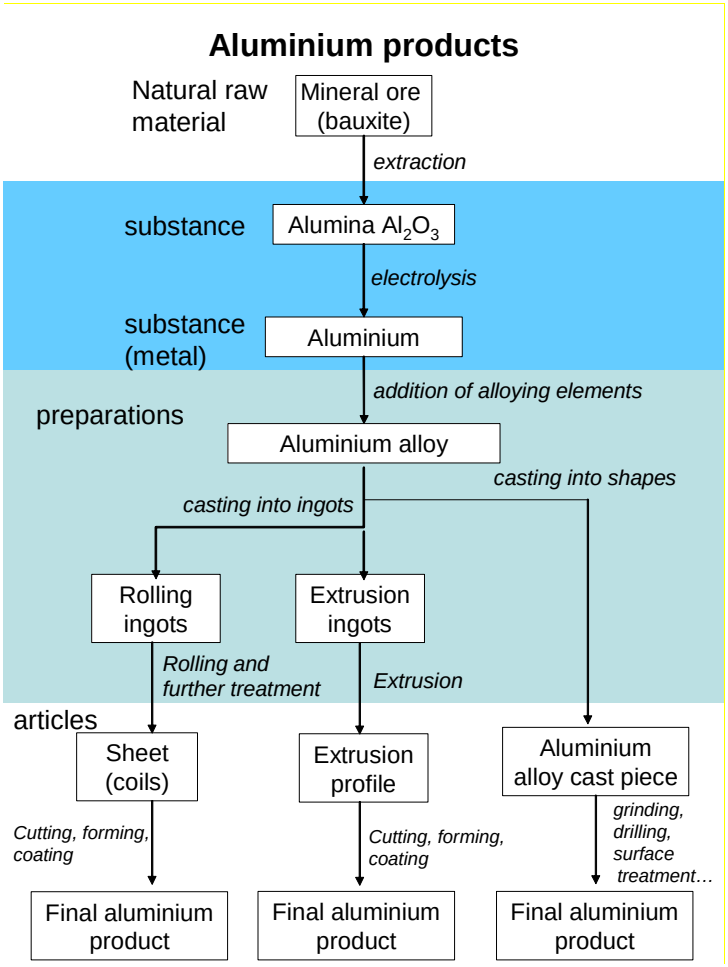

Figure 7 Example of the general transition point from mineral to final aluminium article[45]

The transition point from preparation to article is set between rolling ingots and sheets, extrusion ingots and extrusion profiles and aluminium alloy and alloy cast pieces. The decision process as supported by the indicative questions in the main guidance (See Section 3.3.1) could be as follows.

[45] **Note the exceptions as indicated in the text!**

Table 11 Inidcative criteria in aluminium raw material processing (coils, profiles)

Material **Question**	**Rolling and Extrusion Ingots**	**Coil/extrusion profile**	**Final product, e.g. coated sheet/final product**
Does the material in question have a function other than being further processed?	No	Aluminium extrusion profiles can often be directly used in construction works indicating that they should be considered articles. Extrusion profiles not having an end-use function should be considered preparations. NB! Other metal alloy coils may need considerable further processing, which may indicate that they should be considered preparations rather than articles.	Yes The coated sheet could be used for construction of vehicles. Modified extrusion profiles could be used in several applications such as tubes or, when anodised, as door and window frames.
Does the seller put the material on the market and/or is the customer mainly interested in acquiring a material because of its chemical composition or its shape/surface/design?	Seller/buyer of rolling ingot offers/acquires a certain chemical composition. The shape of the ingot determines the nature of next processing step (rolling), but is not considered more important than the chemical composition.	If the buyer of a sheet is most interested in buying a material with a specific shape and surface (flat sheet) for the purpose of its end use, then the material may be considered as an article. However, if the shape and surface (flat sheet) is mainly purchased for the convenience of transforming the shape, surface or design, then it is an indication that the material should be considered as a preparation.	The shape, surface and design of the material is normally of more importance for the buyer than the chemical composition. .
After which processing step is the function determined to a larger degree by the shape/surface/design?	Before rolling / extruding, the ingots have no specific form. After the rolling / extrusion they are significantly enlarged and have a totally different shape, which is created deliberately during the process.	The processing of coils to sheets and of extruded profiles to doors and window frames consists of e.g. cutting, forming, coating. The materials have more or less the same shape before and after the process (‘light processing').	
Does the chemical composition of the material as such remain similar in the next processing steps as a change may indicate the material being a preparation?	The chemical composition of the rolling ingot is not changed during the further processing	The chemical composition of the sheet could be changed during further processing (e.g. application of surface coating)	The overall chemical composition of the object may change in that substances may be added to the sheet/ extrusion profile, wire.

Similar raw material type in the form of metal and alloy semi-finished products as coil and profile are: bars, blanks (e.g. cut, machined, pressed, etc), coil (coated and uncoated), extrusion profiles, films and filaments, foil and ribbons, forgings, plate, pipe and tube (cast, seamless and welded), pipe and tube fittings, sintered semi-finished and final products, sheet and strip (coated and uncoated), stampings, wire rod and wire (coated and uncoated).

Conclusions on aluminium alloy rolling ingots/coils

Rolling ingots do not normally have an end-use function indicating that these would normally be preparations. It is ambiguous and case-dependent whether a coil has an end-function in itself. In any case a cutting or stamping process is required for achieving a definite function. As this would generally be considered as light processing, this question indicates towards the coil being an article.

The interest of the buyer/seller in chemical composition versus shape/surface and design generally changes between the ingot and the coil/profile. Although the composition plays a role with regard to the quality of the material, the buyer would primarily look for the form of the objects. In the case of the rolling ingots, the shape is considered important (determines the next processing step), but normally not more important than the chemical composition. This is an indication that the ingot is a preparation, whereas the coil is normally an article.

Whereas the rolling ingots only determine into which type of processing the raw material is introduced next, the form of the coil already determines that only sheets can be produced from it. The rolling process significantly changes the form of the ingots in many ways. The cutting / stamping and further processing of the coil only results in modifications of that basic shape and can be regarded as light processing. 'Limited processing' in the sector covers for example cutting, drilling, bending, piercing, surface treatment, coating, etc, but excludes processes such as melting, extrusion, sintering, etc, where the formed shape is destroyed or significantly changed. This is an indication that the process, after which the status of the raw material is changed, is the rolling into sheets/coils.

The basic chemical composition of the material (aluminium alloy) is not changed during the entire processing, although through coating or surface treatment (e.g. anodising) or lubrication (e.g. greasing, oiling, etc) substances / preparations may be added. This question is not a helpful indicator in this example, as it does not give clear indications on the raw material's status.

Conclusions on aluminium alloy extrusion ingots/profiles

Already the first question gives an unambiguous indication for the extrusion ingots having no end-use function and therefore indication for being preparations, whereas the extrusion profiles, which can be used directly to fulfil a distinct function, have a clear indication for being articles.

The interest of the buyer/seller in chemical composition versus shape/surface and design generally changes between the ingot and the profile. The shape of the extrusion ingots is irrelevant with regard to the extrusion profile, thus the buyer of the ingots would only be interested in the chemical composition of the material. This is a clear indication that the ingots are preparations.

The extrusion process significantly changes the form of the ingots in many ways, whereas the processing steps carried out with the extrusion profiles only result in modifications of that basic shape. This shows that the transition point of the material should be after the extrusion process.

The basic chemical composition of the material (aluminium alloy) is not changed during the entire processing, although through coating or surface treatment (e.g. anodising) or lubrication (e.g. greasing, oiling, etc) substances / preparations may be added. Also in this case, the question is not helpful in determining the transition point.

Table 12 Inidcative criteria in aluminium raw material processing (cast piece)

Material **Question**	**Alloy ingots for remelting**	**Alloy cast piece**	**Final aluminium product**
Does the material in question have a function other than being further processed?	No	Yes Castings (alloy cast pieces) are produced close to the required finished design and shape and only require further light processing.	Yes Aluminium final products are used in the construction of vehicles, domestic appliances and, when anodized, for architectural and building applications.
Does the seller put the material on the market and/or is the customer mainly interested in acquiring a material because of its chemical composition or its shape/surface/design?	Seller/buyer of alloy remelting ingots offers / acquires a certain chemical composition rather than a certain shape. The shape of the ingot does not determine the nature of next processing steps (melting and casting).	The buyer of an alloy cast piece (casting) is interested in it having already the basic shape and design. The chemical composition is (normally) of less importance as compared with the shape/surface/design.	The shape, surface and design of the material is normally of more importance for the buyer than the chemical composition.
After which processing step is the function determined to a larger degree by the shape/surface/design?	As the shape of alloy remelting ingots is entirely lost during the melting process, they have no specific form. After casting, a totally different shape is developed, which is created deliberately during the process.	The processing of alloy cast pieces (castings) to finished products consists of e.g. grinding, drilling, surface treatment. The materials have more or less the same shape before and after the process (‘light processing').	
Does the chemical composition of the material as such remain similar in the next processing steps as a change may indicate the material being a preparation?	The chemical composition of the alloy remelting ingot is not changed during the further processing	The chemical composition of the alloy cast piece (casting) could be changed during further processing (e.g. anodizing)	The overall chemical composition of the object may change in that substances may be added to the alloy cast piece (casting).

Similar raw material types as the aluminium alloy cast piece: castings (e.g. centrifugal, die, investment, sand, etc), continuous cast shapes (e.g., bars, billets, blooms, rounds, slabs),

A case-by-case consideration should normally be done to make the final decision on a material’s status.

The examples of the metal industry show that it is not always a straight forward decision whether or not a raw material has a function that is determined by its shape, surface or design. This is particularly true, when an object could be used either for an end use or for further processing and where the further processing is only modifying the shape.

2 TEXTILE AND NON-WOVEN PROCESSING

NB! This example cannot be directly applied for all types of (man-made) fibres.

The figure shows the various processing steps and methods applied in the textile and non-woven industry. Independent of the type of raw material (synthetic or natural material), the processing stage 'man-made textile and non-woven fibres' is regarded as an article. Thus, any further processing is seen as processing of articles.

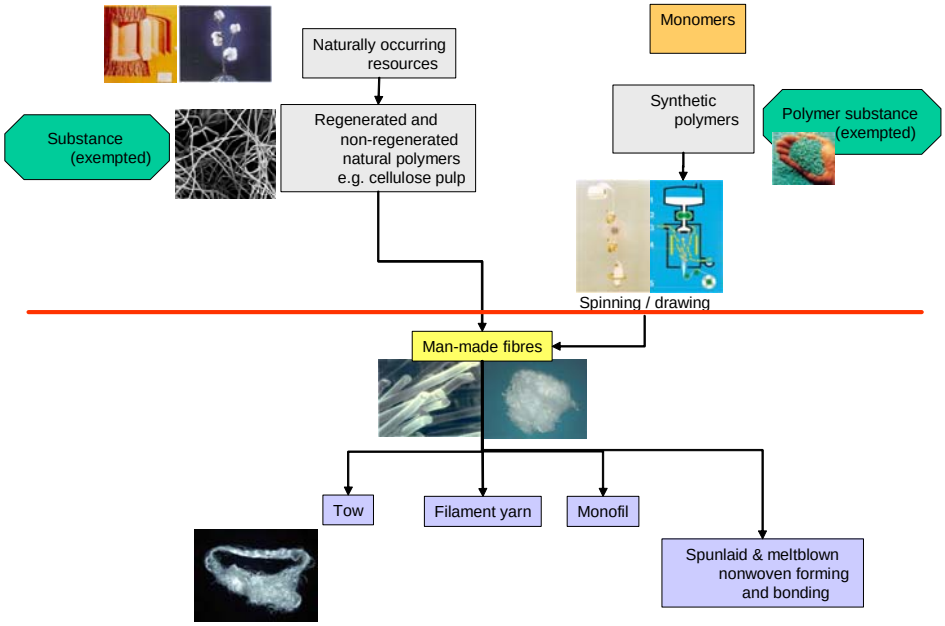

Figure 8 Illustrative example of the general transition point from raw materials final textile / non-woven articles[46]

[46] **Note the exceptions as indicated in the text!**

Table 13 Inidcative criteria in textile/non-woven raw material processing (man-made fibres)

Material **Question**	**Synthetic polymer**	**Man-made fibre**	**Tow rope**
Does the material in question have a function other than being further processed?	No	Man-made fibres could for example be used as filling material for pillows or dental floss	Tow ropes have various functions
Does the seller put the material on the market and/or is the customer mainly interested in acquiring a material because of its chemical composition or its shape/surface/design?	The interest in polymers is clearly in its chemical nature and not in its shape	The shape, surface and design of the material is normally more important for the person acquiring a man-made fibre. Shape and design determine the end-use function. In many applications synthetic fibres can be substitutes for each other.	The shape of the tow rope is more important for the buyer than the chemical composition.
After which processing step is the function determined to a larger degree by the shape/surface/design?	The polymer does not yet have a specific form. By spinning / drawing fibres are produced which have a shape and design ('diameter') which are deliberately formed during processing.		Before the processing the fibres already have a specific form which is further developed in the next processing steps, such as cutting, twisting, finishing. The fibre itself exists in the same state as before but has been 'bundled'.
Does the chemical composition of the material as such remain similar in the next processing steps as a change may indicate the material being a preparation?	The composition is changed before extrusion (additives, cross-sectionalization)	The chemical composition of the man-made fibre may be changed in order to enhance its processability, or through dyeing. The basic composition of the fibre is however the same	The tow rope is not further processed.

For the man-made fibre, for some applications the first question can be answered unambiguously, as the man-made fibres already have a function other than being further processed whilst for other applications the main function is the further processing. Thus the fibre in principle can be an article already. The same applies to the tow rope.

The buyer of a man-made fibre is normally most interested in acquiring a material with a specific shape, rather than a certain composition. The fact that fibres with different composition can substitute each other is another indication for the higher relevance of physical properties.

The buyer of a tow rope is undoubtedly most interested in the shape of the tow rope than in its chemical composition.

The type of extrusion / drawing determines the diameter of the fibre and therefore it is the processing step that deliberately forms the shape of the fibre. Further properties like strength, elongation and shrink are given to the fibres in this step as well. The man-made fibres are 'assembled' in different processes to form the final products, like the tow rope. These processes are mainly mechanical and do not change the base structure of the fibre, but simply 'aggregate' it to larger units.

The basic chemical composition of the polymer may be changed after the extrusion / drawing through various types of processing (depending on the type of further processing).

The example shows that the stage at which the function is determined by shape, surface and design may be very early in the raw materials processing. Furthermore, the design is the relevant physical property of the fibre, as its overall shape does not change significantly in the further processing.

3 POLYMER PROCESSING

In the polymer processing industry, the transition point from preparation to article is defined after the conversion of polymer pellets. The conversion process is what transforms the preparation into an article. The figure shows one example product / process which can be regarded as typical for the polymer processing industry and therefore represents also other processes like calendaring, injection moulding, etc.

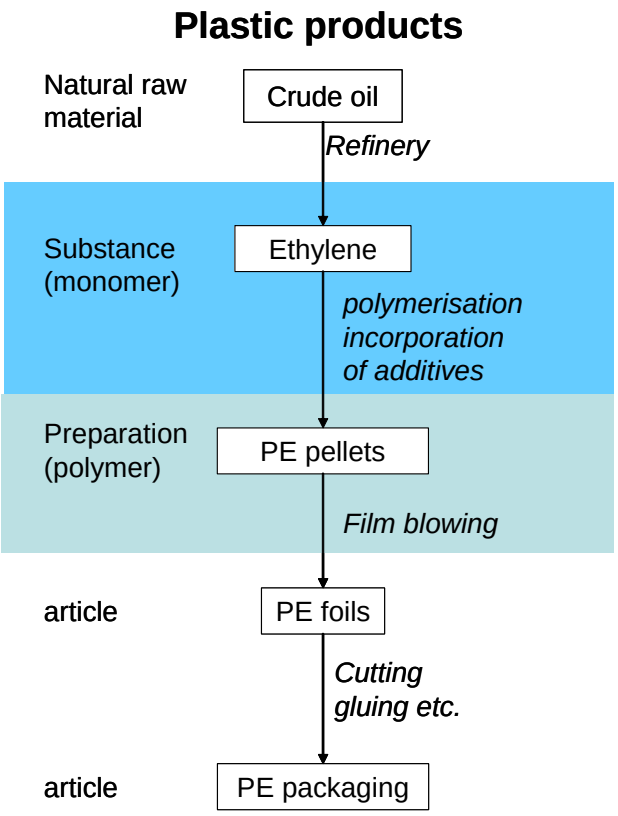

Figure 9 Illustrative example of the general transition point from raw materials to plastic articles (PE foils)

Table 14 Inidcative criteria in processing of polymers

Material **Question**	**Polymer pellet**	**PE-foils**	**PE packaging**
Does the material in question have a function other than being further processed?	No	Direct application as packaging possible, also without further processing.	Packaging
Does the seller put the material on the market and/or is the customer mainly interested in acquiring a material because of its chemical composition or its shape/surface/design?	The converter selects polymer pellets according to their chemical composition. The shape is not relevant.	The buyer of foils is most interested in its shape. For many functions foils of different chemical composition can be used.	
After which processing step is the function determined to a larger degree by the shape/surface/design?	The conversion unit causes the deliberate formation of a shape of the polymer material, which determines its function.	Further processing doesn't change the design (except if the material is reused) but only modifies it.	
Does the chemical composition of the material as such remain similar in the next processing steps as a change may indicate the material being a preparation?	Before extrusion, additives are mixed into the raw material to obtain certain functionalities.	The chemical composition of the foil itself does not change in the further processing steps, but it could be printed onto.	

Whereas the polymer pellets do not have an end use function yet, the converted materials are likely to have one. In the example, the PE foil can directly be used for packaging and can also be used and modified in further processing.

In the conversion unit, the structure and design of the polymer compounds is changed. In the resulting material the design and structure is kept in any further process (except if the material is reused).

Thus, for the polymer processing example, the criterion of an existence of an end use function coincides with the existence of a fixed design (micro and macro structure) of the material.

For the polymer sector, this means that processes including for example, but not limited to, pipe extrusion, film blowing, blow moulding, sheet forming, rotomoulding, foaming, compression moulding, fibre spinning or tape slitting calendaring, coating or injection moulding mark the 'red line' between preparation and article.

4 PAPER PROCESSING

The transition point from preparation to article is between the stock and the dried paper.

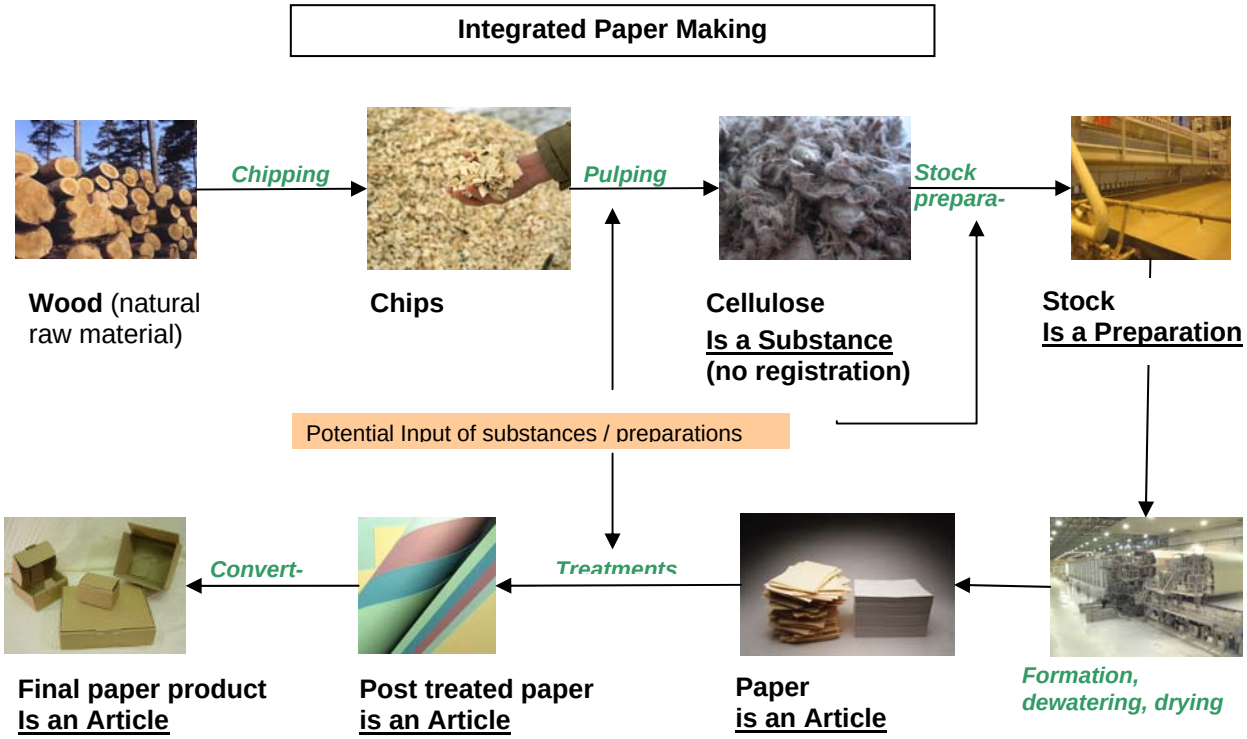

Figure 10 Illustrative example of the general transition point from wood to paper articles

Table 15 Indicative criteria in raw materials processing in paper manufacture

Material **Question**	**Stock**	**Paper**	**Postcard**
Does the material in question have a function other than being further processed?	No	Yes, could be used as such e.g. for packaging	Yes, no further processing
Does the seller put the material on the market and/or is the customer mainly interested in acquiring a material because of its chemical composition or its shape/surface/design?	Stock is mostly liquid and thus does not have a shape, surface or design, yet	For the buyer the shape of the paper is most relevant.	
After which processing step is the function determined to a larger degree by the shape/surface/design?	After dewatering / drying the stock is given a specific shape, surface and design for the first time.	The further processing (here: cutting, printing) does not change the basic design. Although shape & surface are modified, the properties of the 'paper' already determine the function	
Does the chemical composition of the material as such remain similar in the next processing steps as a change may indicate the material being a preparation?	Chemicals may be added	Yes, surface treatment, gluing etc. may add substances / preparations.	No further processing

The paper as obtained from the paper machine could already have an end-use function, e.g. packaging of filling material. Although it is further processed to better fulfil a specific purpose, the paper already has a function apart from being raw material for further processing.

The dewatered paper is the first stage of the raw material, which does have a specific shape, surface and design. Any previous production stages of the raw material can therefore not represent an article status.

The further treatment of paper may change the overall shape of paper significantly however; the design is not changed.

APPENDIX 4: ILLUSTRATIVE CASES FOR CHECKING IF REQUIREMENTS UNDER ARTICLE 7 AND ARTICLE 33 MAY APPLY[47]

Case study on intended release from articles - work processes under REACH Article 7(1)

Scented children's toys

Description of case

Scented children's toys are chosen as an example of articles with intended release.

As no specific toy study was identified, a study on scented felt tip pen/markers was used to establish some basic information (Danish EPA-unpublished[48]). It is *assumed* that the results from that study are representative for this toys case and the same process of data collection is assumed to have been taken for children's toys.

NB! It should be noted that in case a felt tip pen would have been considered, the release of ink (in analogy with other writing/printing materials – see Appendix 2) would be considered a preparation in a container, whereas the scent in such a pen would provide an accessory function and therefore be a case for registration under Article 7(1).

The case is chosen to illustrate the difficulties that an importer of articles may face if he cannot get any information on the substances contained in the imported article from his suppliers.

The following is assumed:

- Import per year: 1 million scented toys
- Weight of toy part containing the fragrance: 2 g
- No information on content of substances to be released
- No information on registration
- Results on the analysis from the survey report are assumed to be performed on the toys by the importer

Substance identity

In order to identify the substances intended to be released, the importer of the scented toys could take the approach as done in the Danish study on felt tip pens, the process of which is quoted here:

In the Danish study, in order to obtain information on the substances to be released from the pens the following analyses were done:

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[47] Dissenting views (http://reach.jrc.it/docs/guidance_document/dissenting_en.pdf), questioning the application of the 0.1 % threshold to the entire article have been notified by 6 Member States in writing (Austria, Belgium, Denmark, France, Germany and Sweden) and publication of this part of the guidance document was not endorsed by these Member States.

[48] The survey report concerns the release of fragrance substances from children's play toys including scented markers. In the report fragrance substances and volatile substances were analysed. The study included a screening of substances contained in the inner part of the pen as well as the emissions of substances from the pen.

1 Analysis on fragrances (24 in total) classified as sensitising by EU's Scientific Committee on Cosmetics (SCCNFP 1999). Pens with different smells, Lemon and Strawberry, were examined. The analysis was done on the inner part containing the fragrance.

2 The pen with lemon scent was examined in an emission test to analyse the release.

3 Screening for extractable organic compounds by GC/MS.

A total of 11 sensitising fragrance substances were found in the analysis on fragrances and substance names and CAS numbers could be identified. During the emission test various compounds were detected and identified by substance name. Only one substance was identified by name in the screening for extractable compounds. The CAS numbers were searched in an online database for toxicological data (Thomson Microdex). Classification was searched for in lists from the Danish EPA. It was not possible to find the CAS number for all the identified substances using the available substance name.

Transferring these results to the importer making a chemical analysis for the children's toys, although able to identify a few substances by chemical name, from which he could also derive a CAS number, he may not be able to derive further information on their identity, in terms of their composition. To illustrate the further work process it is assumed that the substance D-limonene, which is a fragrance exceeds the tonnage threshold in the children's toys of the importer and is thus chosen for registration.

Check for existing registration

Having the substance name and CAS number available the importer has the possibility to request the Agency if the substances has been registered. Assuming that it has not been registered, yet the importer would proceed.

Information on concentration of the substance

In the Danish survey, the concentration of D-limonene was determined for the inner part of the pen. The classification was obtained from data bases.

Table 16 *Further information gathering on D-limonene in the pens (Danish Survey)*

Substance	***CAS no***	***Classification***	***Concentration (mg/kg (inner part))***
D-limonene	*5989-27-5*	*R10 Xi;R38 R43 N;R50/53*	*800*

Information on amount of substance used

Based on the assumptions for the case of the importer, the quantity of D-limonene in the scented toys can be calculated as the amount in each toy multiplied by the amount of toys imported annually. The annual amount of D-limonene in the toys is 1.6 kg/a, which is below 1 t/a.

(800 mg/kg × 0.002 kg/toy × 1,000,000 toys/a)

It can also be calculated how many toys the importer can import before reaching the threshold of 1 t/a on D-limonene:

$$\text{Number}_{\text{article}}\ [\text{number of toys/a}] < \frac{1\,[t/a]}{1.6\ mg/toy} = 625 \text{ mill. toys/a}$$

Illustration of the decision process on registration

Example: Toy with lemon scent (D-limonene)

Consult Chapter 1:

Are you the first EU producer or importer of the object?

YES

Is your object an article?

YES, the company imports toys which are articles, because the shape determines its purpose.

Consult Chapter 4 "Checking if requirements under Article 7 or 33 apply":

All types of requirements could apply, as substances are released during the use of the article. The release is an additional quality of the toy and the release is therefore intended, otherwise the article would not smell. Furthermore, SVHC could be contained in the toy as well.

Go to Chapter 5 and 6 on registration of substances intended to be released and on SVHC in articles

As the importer has no information except the results from the chemical analysis he could do the following:

1) Collect information on sector knowledge and typically content of substances in this type of article, standards like the toys directive etc. He would compare that information with the candidate list for authorization and may have doubts whether he can exclude SVHC. He does not find information on the fragrances intended to be released.

2) Check the supply chain requesting if any of the substances on the candidate list is included in the article / in the substances / preparations used to produce the article or receive confirmation that they are not present in the article. Check the supply chain and ask, if the supplier of the fragrance substances can be identified. If yes, he may try to obtain a safety data sheet.

3) Plan and perform screening for substances on the candidate list by analytical methods if no information is obtained from the suppliers and content of SVHC is likely (→ results above)

4) Check if identified substances are listed on the candidate list. (The emission test revealed the presence of compounds classified with R50/53 and R51/53. After establishment of the candidate list the list should be consulted for these compounds, as they may potentially fulfil the criteria as PBT/vPvB).

5) Calculate amount of substances identified in the screening analysis and assess whether the tonnage threshold could be exceeded for registration

Work process for calculating the amount (Step 5)

1. Is the total volume of articles > 1 t/a (all articles should be considered and summed up)?

YES. 1 million toys containing 2 g of parts containing fragrance makes the total volume of articles at least 2 t/a.

2. Total amount of the preparation > 1 t/a (all such articles in a company should be considered)?

YES. The fragrance is included in light felt with very small weight, thus the total volume of fragrance is approx. 2 t/a.

3. Identify each substance intended to be released from the article.
A total of 11 fragrance compounds were identified to be contained in the toy. During the emission test various compounds were detected and some of the detected compounds were identified with CAS number and classification.
The output from the analysis was the substance name only. The C&L inventory to be established should be consulted in order to obtain CAS number and classification.

Further steps in this case are focused on D-limonene, which was identified in the chemical analysis.

4. Substances exempted from registration?
The guidance should be consulted after establishment to find out if the substance is exempted from registration.

5. Check for existing registration for that use.
Having the substance name and CAS number available the importer have the possibility to request the Agency if the substance has been registered.

6. Determine the amount of each substance intended to be released (all such articles in a company should be considered and summed up).
Based on the chemical analysis the content of D-limonene intended to be released is determined to be 800 mg/kg in the inner part of the toy. The content of D-limonene in the toy is 1.6 mg as the weight of the inner part was 2g.

7. Total amount > 1 t/a?
Is the total amount of this substance in all such articles in the company above the threshold volume of 1 t/a. It is assumed that this toy is the only article containing D-limonene and imported by the company. The annual amount of D-limonene is calculated to be 1.6 kg.

Registration of D-limonene is not required for the use in the felt tipped pen

Comments on the case

In the Danish survey, only pens with two different fragrances were analysed, strawberry and lemon. In the example, the importer may import toys with several other fragrances, which also have to be examined. Each individual substance to be released has to be identified.

Only 24 selected fragrances were analysed for content in the article. There are more substances present in the felt tip pen therefore also an emission test was done. In the emission test a range of volatile substances released into the air was identified. Here, only the release was analysed and not the content. The emission test did not include the fragrances.

The analysis for fragrances and the emission test, where specific known compounds were searched for in the entire article (extraction of content of the pen) and in the substances released (emissions were captured and analysed) was supplemented by a GC-MS screening for extractable organic compounds, where any compound is detected and characterised by a spectrum. However, the compounds found in the emission test were not found in the GC-MS analysis, hence the content of the volatile substances could not be determined using this method.

This case illustrates how difficult it is to provide full documentation on substances to be released from the article based on chemical analysis. If possible the documentation of the identity and quantity of substances to be released from the article should be based on composition of the formulation used for the article. In case of imported articles the documentation might include supporting documents as letters from the suppliers or by certificates stating the content of e.g. fragrances in the article.

Case studies on notification of substances in articles according to Article 7(2) under REACH

CASE 1: Clothes

Description

Clothing was selected to exemplify a situation where exposure could be expected. Furthermore, the example represents a case from a sector subject to high attention and comprehensive knowledge about chemical substances in their articles. The company NN, which participated in this case, has already established a program, which sets demand to the content of dangerous substances in products from their suppliers. This has resulted in a phase-out of SVHC in their textiles.

Criteria for selecting clothes

- Users and application: A large group of users and a wide application; The users include vulnerable groups such as children
- Type of material: Represents a material used in many other articles than clothing, which could make the case applicable for other producers/importers of articles.
- Exposure scenarios: An example of possible direct exposure to skin and migration of substances.
- Supply chain pattern: Represents a supply chain with high degree of imported articles and minor production within the EU.
- Documentation: A Swedish company, NN provided information on their import of belt buckles.

Producer/Importer of articles

The selected company imports belt buckles and jewels from a non-EU Member State. Therefore, the role of the company in the supply chain is as EU-importer of articles in relation to the belt buckles.

Substance identity

The company must consult the candidate list for authorisation. This should be done as soon as the list is made available by the Agency. Metallic lead, which was focused on in this case study, is not classified in the Annex I of Directive 67/548/EEC. However, an ongoing voluntary risk assessment is being conducted by the lead industry. It is assumed in the example that metallic lead is a possible candidate to Annex XIV[49].

The company explained that it is often difficult to obtain complete lists of chemicals from the suppliers. However, this is not necessary when a company has to check whether he has obligations according to the Articles 7(2) and 33. The suppliers could be asked directly about the content of the specific substances on the candidate list.

[49] Note that substances fulfilling the criteria of article 57 can be included on the candidate list only according to the procedure described in article 59. For more information see the Guidance on Preparing an Annex XV dossier for identifying SVHC and Guidance on Inclusion of Substances to Annex XIV of REACH.

Check for existing registration

To be done when REACH enters into force.

Information on concentration of the substance

There is no obligation to deliver SDS for articles or other information from non-EU Member States. The different ways to obtain information suggested in Chapter 4, 5 and 8 of this guidance could be applied, based on considerations about the simplest way to obtain the information required.

In this case the company has an upper limit for the content of lead in the belt buckles at 0.3% (w/w) and in their jewellery at 0.01% (w/w). The use of these maximum concentrations in the assessment will give a worst case scenario.

The alloy used in the buckle was not made known in this case. However, it should be noticed that the chemical compositions of most alloys are published as national, European or international standards. If an alloy is not standardized, its chemical composition can usual be obtained by routine chemical analysis.

Information on amount of substance used

The total yearly amount of lead in the articles of the company was estimated on the basis of the amount of belt buckles imported the year before. The calculations were based on the total amount of belt buckles imported and the maximum concentration of lead in a buckle at 0.3%.

Illustration of the decision process on registration

Example: Company A - Metallic lead in belt buckles

Consult Chapter 1:

Are you the first EU producer or importer of the object?

YES

Is your object an article?

YES, belt buckles and jewels are articles

Use Chapter 4 "Checking if requirements under Article 7 or 33 apply":

1. Is there an intended release from the article

NO

Conclusion for registration: No need for registration.

2. Does the article contain SVHC - included in the candidate list?

The list has to be checked when it is available. Metallic lead (7439-92-1) is not classified in the Annex I of Directive 67/548EEC but it is a substance with properties of very high concern, which might be included in the candidate list. In this example it is assumed that it will be on this list.

YES

Go to Chapter 6 "Checking if Article 33 applies and if notification is required":

1. Determine the concentration of the SVHC, which in this example is lead

The company limit for lead in jewels is 0.01% (w/w), which is below the threshold limit at 0.1% (w/w). For lead in a functional item as a buckle the company limit is 0.3% (w/w). Thus the maximum concentration of lead in the buckles exceeds the threshold limit. It is not possible for the company to analyze large parties of buckles and they assume that the concentration in all buckles is 0.3% (w/w). The company imports approx. 13 000 000 buckles per year (in total approx. 650 different orders/styles).

Based on experience from tests it is known that most of the buckles contain much less than 0.1% of lead, however, it is not documented by chemical analysis or certificates from the supplier.

Concentration above 0.1% (w/w)?

YES. **Conclusion after this step: communicate information according to Art. 33 and continue to the next step in the assessment.**

2. Is the SVHC (lead) intended released?

NO. Continue

3. Has the substance already been registered for that use?

To be checked after REACH has entered into force. It is assumed that lead isn't registered for that use: → NO.

4. Determine the amount of the SVHC (lead) present in all articles?

The buckles are the only articles brought into the EU by the company with a lead concentration above the threshold limit at 0.1%. The total amount of lead brought into the EU per year in all the buckles is:

The import of buckles in 2005: 13,000,000 items

The weight of one buckle: 100 g

The maximum lead concentration in a buckle: 0.3% (w/w)

Calculation of the total lead amount in the buckles in 2005:

- The total amount of lead: $(0.3 \cdot 0.01) \cdot (100 \cdot 10^{-6}) \cdot 13{,}000{,}000 = 3.9$ t per year

5. Is the total amount of the lead > 1 t/a?

YES. The total amount of lead brought into the EU-market is 3.9 t/a. This amount exceeds the threshold limit at 1 t/a.

6. Can exposure be excluded during normal or reasonable foreseeable conditions of use?

The function of the substance in the articles:

A small amount of lead lowers the melting point of the alloy. Lead would almost certainly be present as discrete particles in the matrix of the alloy and as such it would retain its own intrinsic properties.

The use(s) of the article:

Normal use(s): The importer sells the belt buckles to companies, which are producing belts of e.g. leather for both children and adults.

Reasonable foreseeable use(s): If the producer of the belts treats the buckle in such a way that particles are emitted from the buckle e.g. at grinding or sand papering, appropriate protection has to be used. If soldering or welding is used, lead will be emitted in the form of gas and appropriate protection has to be used. Furthermore, children may suck on the buckle in the end-use situation.

Potential for emission during use(s) and disposal – Look at the routes of exposure:

The routes of exposure in the case of metallic lead are by inhalation and by ingestion. Inhalation can be discounted in this case. However, it is within the realms of possibility that lead may be transferred from the buckle to the hands of the consumer and subsequently ingested.

Furthermore, it can not be excluded that there will be a release of lead from the metal buckle after disposal.

Lead has been used in articles for many years. Therefore, it would be obviously to look for further information for 'that use' of lead in sector organisations, the open literature and databases. Look for emission of lead from buckles and similar materials and exposure of humans and the environment.

Can exposure to humans or environment be excluded?

NO

Conclusion: Notification is required

Go to Section 6.11

Communicate information to the recipients according to Art. 33

Comment on the case

The case illustrates the possibility of using the maximum concentration or company upper limit of a specific SVHC in articles as a worst case scenario for assessing whether an importer has an obligation under Articles 7(2) and 33. The use of the maximum concentration leads to the conclusion that both notification and communication of information is required. A next step could include a more precise determination of the lead concentration in the buckle by chemical analysis if applicable. The information to be delivered within the supply chain, according to Article 33 could e.g. include recommendations of protective equipment to be used during production of the finished belt and instructions on waste handling.

The results obtained completing the workflows 1 and 2 in this guidance could be documented in a table e.g. as in the example above either on paper or electronically. Certificates from suppliers of the articles stating the limits of the SVHC, results of possible chemical analyses and data of the imported articles volumes could be annexed. Documentation procedures to be followed during the assessment of obligation under Article 7 and 33 could be implemented e.g. as a part of a possible existing quality management system.

CASE 2: Automotive tyres

Description of the case

Tyres were selected as a case due to the existing knowledge about the polycyclic aromatic hydrocarbons (PAHs) contained in high aromatic (HA) extender oils, which are used in the production of tyres. The present case study should, however, not be considered as a complete study covering all aspect of the use and risks of PAHs in tyres. Furthermore, the case is not based on the knowledge of a single producer or importer but the sector knowledge within EU.

Automotive tyres are a complex and high-tech safety product that consists of a mixture of synthetic and natural rubbers, textile and metal reinforcing materials and a wide range of additives (e.g. high aromatic extender oils, zinc oxide, etc) to ensure the finished tyres' performance, durability and safety. As tyres are the vehicles' only contact point with the road surface, they are of great importance to road safety. The tyre is here considered to cover both winter and summer tyres for cars, trucks, buses and trailers.

Users are in contact with new tyres via two routes. One is through the "original equipment market" where tyres are mounted on the wheels of a new car. The other, is the "replacement market" where old tyres are replaced with new ones. The retreating market belongs to the replacement market, but it is a special case as it is only the tread, which is new.

The so-called "End of life tyres" (ELT) are covered by producer responsibility in the majority of EU member states. These ELT are used for various applications, such as: alternative fuels, retreating, and material recycling. In Sweden the predominant use of collected tyres is the use as alternative fuel. A smaller part is recycled and retreated. Granulates and shredded tyres could also be used in civil engineering projects as materials beneath the road surface and beneath buildings.

Criteria for selecting tyres

- User groups and application: Wide spread use.
- Supply chain pattern: Represent a supply chain with a considerable part (70%) of the production located within the EU.
- Exposure scenarios: Exemplifies exposure to environment and a case where substances are contained in wear off from the article.
- Documentation: Existing knowledge from a former project performed by KemI, Sweden (1994)[50] and information delivered by BLIC (The European Association of the Rubber Industry).

Producer/Importer of articles

The case has not been developed for a specific company but illustrates a general scenario where the tyre is produced within the EU. The scenario is also applicable for imported tyres.

Substance identity

The company must consult the list of the SVHC on the candidate list for authorisation. It should be done as soon as the list is made available by the Agency (Chapter 6).

[50] KemI (1994). Nya hjulspår – en produktstudie av gummidäck (New Wheel Tracks - a product study of rubber tyres). Report 6/94

It was decided to focus on the high aromatic (HA) extender oils, which are classified as category 2 carcinogens on the basis of their content of PAHs that are present as impurities in the oil. It is assumed that some of the PAHs will be on the candidate list of SVHC mentioned above.

PAHs are complex 'group' of substances and many of them are harmful to health and the environment. They are in fact the largest group in number of carcinogenic substances known today. Many of their effects are linked to the flat structure of the molecules and their ability to affect the DNA in the cell nucleus. Most living organisms can convert PAHs, but the products formed during the degradation are often more harmful than the original substance.

Several of the individual PAHs contained in HA oils are classified as category 2 carcinogens in the Community wide classification list (KIFS 2001:3). The PAHs' classified according to this system are listed in Table 13. Several of them are also included in the Water Framework Directive and international conventions due to their inherent hazardous properties.

It has to be noticed that marketing and use of these HA-oils in tyres will be banned as of the 1st of January 2010. The tyre industry is currently working on the substitution of the HA-oils, by alternative non-carcinogenic oils.

Table 17 Some important properties of some of the PAHs in HA oil

Substance	Persistent	Bioaccumulative	Carcinogenic[51] (Cat. 2)
Antanthrene			(+)
Benzo(a)anthracene	+	+	+
Benzo(a)pyrene	+	+	+
Benzo(b)fluoranthene	+	+	+
Benzo(e)pyrene		+	+
Benzo(g,h,I)perylene	+	+	-
Chrysene	+	+	+
Dibenzo(a,h)antracene	+	+	+
Fluoranthene	+	+	-
Indeno (1,2,3-c,d)pyrene	+	+	-
Pyrene Benzo(j)fluoranthene Benzo(k)fluoranthene	+	+	- + +

The criteria for persistence and bioaccumulation originate from the TGD[52]
The criteria for persistence and bio-accumulability originate from the TGD[53].
+ = persistent, bioaccumulative or classified as category 2 carcinogenic in the Community-wide classification list (KIFS 2001:3).
(+) = has caused cancer in experimental animals but is not classified as carcinogenic.
? = too few studies are available to assess whether the substance is carcinogenic.
- = negative result.
Blank box = studies lacking.

[51] Source IPCS, 1998.

[52] Technical guidance document in the program for existing chemicals

[53] Technical Guidance Document/Technical guidance document in the programme for existing substances in the EU.

Check for existing registration

To be done when REACH enters into force.

Information on concentration of the substance

The content of HA-oils in a tyre depends on which kind of tyres you are looking at. An average passenger car tyre for the EU market contains approximately 600 g of HA-oil. The oil is dissolving in the rubber mixture but is not reacting chemically. The PAHs content in these HA-oils is less than 400 ppm and the typical average values vary between 100 - 200 ppm.

The concentration of PAHs in tyres was calculated for the worst case scenario and the average situation on the bases of the total weight of a tyre and the PAH content of the extender oils (Table 9). The calculation was based on Life Cycle Assessment (LCA) of an average European passenger car tyre made by BLIC.

Table 18 Calculation of amounts of PAHs in average passenger car tires on the EU market

Weight of an average European passenger car tyre	oil content in the tyre	PAHs content (ppm = µg/g) in the oil					
		400		200		100	
		mg in tyre	% in tyre	mg in tyre	%	mg in tyre	%
8700 g	600 g	240	0,003	120	0,001	60	0,0007
		= 27,6 ppm		= 13,8 ppm		= 6,9 ppm	

The figures in Table 9 show that the total concentration of PAHs in tyre is much below the threshold limit for notification (Art. 7(2)) and communication of information down streams (Art. 33) at 0.1 % (w/w). Therefore, it is obvious that the concentration of individual PAHs is << 0.1%.

Information on amount of the substance produced per company and year

This is not relevant in this case as the concentration limits are not exceeded. This case does not provide any company specific data on production volumes.

Illustration on the decision process for one company checking his obligation according to Articles 7 and 33)

Example: Tyres containing high aromatic extender oils

Consult Chapter 1:

1. Are you the first EU producer or importer of the object?

YES

2. Is the object an article?

YES, tyres are articles

Use Chapter 4 "Checking if requirements under Article 7 or 33 apply"

3. Is there an intended release from the article?

NO

Conclusion on registration: No need for registration

4. Does the article contain SVHC – included in the candidate list?

YES. HA oils classified as Category 2 Carcinogen due to their content of PAHs, which are an impurity generated in the production process of the HA oil. For the purposes of this example, it is assumed that DEHP has been included on the candidate list.

It shall be noticed, that following the 27th Adaptation to Technical Progress (ATP) of Directive 76/769/EC, the marketing and use of high aromatic oils for the product of tyres will be banned as of 1 January 2010 and a substitution process is ongoing.

Go to chapter 6: "Check if Article 33 applies and if notification is required"

5. Determine the concentration of the SVHC?

The concentration of the PAHs (group of substances) in the oil is 400 ppm in a worst case scenario and between 100 and 200 ppm (mg/kg) in average. It shall be noticed that this is the value for the PAHs as a group of substances. The concentration of PAHs per tyre from the oil varies between 27 (worst case) and 7 ppm, as illustrated in Table 12. This demonstrates that the PAHs content in the tyre is below threshold at 0.1%.

6. Concentration above 0.1% (w/w)?

NO → STOP: It is not necessary to continue the assessment process.

Conclusion: Notification is not needed. Communication of information to recipients is not required

Comment on the case

The case illustrates how sector knowledge may be used in the assessment whether a producer/importer has obligation under Articles 7 or 33.

Based on the knowledge of the PAHs content in the aromatic oil applied in the production of tyres, it can be concluded that the concentration of the possible SVHC in the tyre are well below the threshold limit of 0.1%. Therefore, neither notification according to the Article 7(2) nor communication of information to the recipients according to Article 33 is required.

The results obtained completing the workflows in this guidance could be documented in a table e.g. as in the example above and the results of chemical analyses and the data for the yearly produced/imported articles volumes could be annexed. The documentation procedures to be applied during the assessment could be implemented e.g. as a part of a possible existing quality management system.

CASE 3: Bath mattress

Description

The case on bath mattresses presented below illustrated the different steps in the notification process and could be used as a guidance to understand the different steps in the flow chart. Di-(ethylhexyl)-phthalate (DEHP) in bath mattresses has been used as an example due to the following reasons.

Criteria for selecting Bath mattresses

- Users and application: Large user groups. The users include vulnerable groups such as children.
- Type of material: Represent a material used in many other articles, which could make the case applicable for a range of different article producers/importers.
- Exposure scenarios: An example of possible direct exposure to skin and migration of substances.
- Supply chain pattern: Represent a supply chain with high degree of imported articles.
- Documentation: The case is built on a real example but has been adjusted to illustrate the different steps in the notification process.
- Likeliness for the substance to be included in the candidate list and/or Annex XIV. DEHP is a CMR substance and may be on the candidate list for eventual inclusion in Annex XIV.

Producer/Importer of articles

The bath mattresses are imported from a non-EU Member State and then distributed to retailers within the EU.

Substance identity

The physical and chemical properties of the phthalates have made them suitable as plasticizers in polymers such as plastic and rubber

Plasticizers are not permanently bound to the PVC polymer, and phthalates are therefore released from plastic products throughout their lifetimes. DEHP are classified as toxic and toxic to reproduction, i.e. they cause reduced ability to reproduce and damage to the unborn child.

The company must consult the candidate list for authorisation. It should be done as soon as the list is made available by the Agency (Chapter 6). In this example it is assumed that DEHP is a possible candidate for inclusion in Annex XIV.

Check for existing registration

To be done when REACH enters into force.

Information on concentration of the substance

In accordance with the legislation the company has substituted DEHP in toys but it is still used as softener in other articles. The importer of the mattress has been informed that the concentration of DEHP is 30% (w/w).

Information on amount of substance used

The total yearly amount of DEHP in the articles of the company was estimated on the basis of the amount of mattresses imported the year before. The calculations were based on the total amount of bath mattresses imported and the concentration of DEHP in a mattress at 30.0%. (See calculations below)

Illustration of the decision process on registration

Example: Company B – DEHP in bath mattresses

Consult Chapter 1

1. Are you the first EU producer or importer of the object in the supply chain?

YES, we import bath mattresses

2. Is your object an article?

YES, the bath mattress is an article

Use Chapter 4 "Checking if requirements under Article 7 or 33 apply":

3. Is there an intended release from the article

NO

Conclusion for registration: No need for registration

4. Does the article contain SVHC - included in the candidate list?

The list has to be checked when available. DEHP is classified as toxic and toxic to reproduction and which are criteria for inclusion on the candidate list. For the purposes of this example, it is assumed that DEHP has been included on the candidate list. → YES

Go to Chapter 6: "Check if Article 33 applies and if notification is required"

5. Determine the concentration of the SVHC, which in this example is DEHP

To determine the concentration limit the company asked their supplier for information. The supplier informed that the concentration of DEHP was 30% (w/w) in the mattresses. No test protocols were available from the supplier to confirm concentration levels and the company did not find any reason to question the information given by the supplier.

6. Concentration above 0.1% (w/w)?

YES. The concentration of DEHP in the bath mattresses exceed the threshold limit at 0.1%

Conclusion for this step: "Communicate information according to Art. 33" and continue to the next step in the assessment.

7. Communicate information according to article 33

As the bath mattress contains more than 0.1% DEHP and is distributed to retailers within the EU. The company has to give information to allow safe use of the article. Information to be considered as important is the following:

- *Substance name: di(ethylhexyl)phthalate*
- *CAS. No: 117-81-7*
- *Registration No: not available for the time being*
- *Classification: R 60-R61 is classified as toxic and toxic to reproduction, i.e. the substance causes reduced ability to reproduce and damage to the unborn child.*
- *Exposure control: Avoid long term dermal contact by children or pregnant women*

8. Is the SVHC intended to be released?

NO. Continue

9. WF3: Has the substance already been registered for that use?

To be checked after REACH has entered into force. It is assumed that DEHP isn't registered for that use: → NO.

10. Determine the amount of the SVHC (DEHP) present in all articles?

The DEHP concentration in the mattresses is > 0.1% and therefore, the total amount of DEHP brought into the EU-market in the mattresses has to be considered. The total amount of DEHP per year in all imported mattresses is:

- The import of mattresses in 2005: 150,000 items
- The weight of one mattress: 900 g
- The maximum DEHP concentration in a mattress: 30% (w/w)

Calculation of the total DEHP amount in 2005:

The total amount of DEHP: $(30 \cdot 0.1) \cdot (900 \cdot 10^{-6}) \cdot 150{,}000 = 40.5$ t per year

11. Is the total amount of the DEHP > 1 t/a?

YES. The total imported amount of DEHP is 40.5 t/a. This amount exceeds the threshold limit of 1 t/a.

12. Can exposure be excluded during normal or reasonable foreseeable conditions of use?

The function of the substance in the articles: Plasticizers are not permanently bound to the PVC polymer, and phthalates are therefore released from plastic products throughout their lifetimes.

The use(s) of the article:

→ Normal use(s): In bath mattresses for adults

→ Reasonable foreseeable use(s): It is very likely that the mattresses also will be used by children or fertile women.

Potential for emission during use(s) and disposal – Look at the routes of exposure:

Dermal exposure could be considered to be the most likely way of exposure. It could be assumed that naked skin often would be in direct contact with the article during use. Exposure through inhalation may occur if the article is used in-doors. Exposure through ingestion is also possible as it could be considered to be reasonable foreseeable that children might suck on the mattress, although due to the size and shape of the product exposure through ingestion is regarded as limited.

Further more as the product is mainly used in direct sunshine in temperatures above 20 degrees the temperature can be up to 50 degrees on the material which could contribute to a considerable emission of DEHP.

Can exposure to humans or environment be excluded?

NO

Conclusion: Notification is required

Go to Section 6.11

Communicate information according to Art. 33

Comment on the case

The case shows how information from the suppliers may be used in the assessment. Notification of the use of the substances in the article as well as communication of information is required. The case gives examples on the information to be communicated to the recipients of the article.

The results obtained completing the workflows in this guidance could be documented in a table e.g. as in the example above. Certificates from suppliers of the bath mattress stating the identity and concentration limits of the SVHC, potential results of chemical analyses, and the data of the yearly imported volumes of bath mattress could be annexed. The documentation procedures to be applied during the assessment of the obligation under REACH could be implemented e.g. as a part of a possible existing quality management system.

APPENDIX 5: INFORMATION SOURCES ON SUBSTANCES IN ARTICLES

The list contains examples of available information sources on substances in articles. They provide various information, e.g. which substances to expect in certain types of articles, which substances can be ruled out from presence in certain articles, which type of substances can be expected to be released from articles etc. It is not a complete list of information sources.

Name	Address	Content
Information sources on substances in miscellaneous articles		
Marketing and use restrictions	COUNCIL DIRECTIVE of 27 July 1976 76/769/EEC	Restrictions on use and marketing of substances in various preparations and articles, e.g. textiles and treated wood
Substances in consumer products	http://www.mst.dk/chemi/01080000.htm	Survey reports made by national authorities e.g. the Danish EPA
Eco-Label: EU flower German Blue Angel Nordic Svan Umweltzeichen Thai greenlabel	http://www.eco-label.com/default.htm http://europa.eu.int/comm/environment/ecolabel/index_en.htm http://www.svanen.nu/ http://www.blauer-engel.de/ http://www.umweltzeichen.at/ http://www.tei.or.th/greenlabel/	Eco label requirements
Toxproof certificate	http://www.tuvdotcom.com/pi/web/index.xml	Labelling of cars, textiles, furniture, construction materials, paints; and the mattress & floor covering to a complete ready-built house List of substances that can damage health or cause allergenic reactions Banned azo-dyes
EIS-ChemRisk-Project	http://web.jrc.ec.europa.eu/eis-chemrisks/	Substance in products for consumer use. Focus: human health
Emission Scenario Documents	http://appli1.oecd.org/ehs/urchem.nsf http://www.oecd.org/document/46/0,2340,en_2649_34373_2412462_1_1_1_1,00.html http://ecb.jrc.it/biocides/	OECD's Database on Use and Release of Industrial Chemicals ESD on biocides
Information sources on substances in child care products		
Standards for child-care products	Standard EN 14350-2 Mandate to CEN and CENELC in the field of consumer safety related to the safety of child-care articles (16. December 1997). ISO/IES Guide 50 Safety aspects – Guidelines for child safety (2001)	Limits of the release of certain elements from drinking equipments (EN 14350-2). The guideline provides migration limits for certain chemicals regulated in other products. Chemical substances in toothbrushes (DIN 53160-1)
Information sources on substances in construction material		
Construction products, AgBB-Approach	http://www.aivc.org/frameset/frameset.html?../publications/publications.html~mainFrame http://www.umweltbundesamt.de/bauprodukte/dokumente/AgBB-Bewertungsschema2005.pdf http://www.umweltbundesamt.de/building-products/archive/AgBB-Evaluation-Scheme2005.pdf	Substances in construction products and indoor air quality CMR substances may not be introduced in to the material AgBB-Scheme in German and English
Information sources on substances in electrical and electronic equipment		
Electrical and electronic equipment (EEE), RoHS Directive	Directive 2002/95/EC on the restrictions of the use of certain hazardous substances in electrical and electronic equipment	Six substances are banned in EEE: Pb, Hg, Cd, Cr VI, PBB and PBDE
GreenPack	www.greenpack.org	Software-tool for electronic articles
Material Declaration Wizard	www.goodbyechain.com	Software-tool for electronic articles
Information sources on substances in plastic articles – food contact material		
Food contact material – practical guide	http://cpf.jrc.it/webpack/ http://europa.eu.int/comm/food/food/chemicalsafety/foo	Rules for substance in food contact material according to European Directives

Name	Address	Content
	dcontact/practical_guide_en.pdf	
Food contact material	http://bfr.zadi.de/kse/	Germany: Recommendations for substances in polymers
Directives on food contact material	Directive 2002/72/EC	Lists specify the use of substances and possible restrictions for usage 78/142/EEC: limits for the content of vinyl chloride in a finished material or released by this material
Information sources on substances in textiles		
OekoTex 100	www.oeko-tex.com	Requirements for substances in textiles
Information sources on substances in vehicles		
ELV and IDIS	Directive 2000/53/EC of 18 September 2000 on end-of life vehicles (ELV) and International Dismantling Information System (IDIS)	Database/software on car components containing restricted substances

APPENDIX 6: INFORMATION SOURCES ON RESTRICTIONS AND METHODS FOR DETERMINATION OF SUBSTANCES RELEASED FROM ARTICLES

The list contains examples of available sources on information on restricted substances in articles, declaration duties, chemical analysis of substances banned in articles, standardise release testing methods and experiences from testing and analyses related to articles. It is not a complete list of information sources.

Product	Identification of substances	Determination of substance content	Determination of substance release
Miscellaneous articles:			
Marketing and use restriction for textile articles	A list of substances banned for the use in articles in general is provided: Tris(2,3 dibromopropyl) phosphate, Tris-aziridinyl)-phosphinoxide, penta- and octabromo diphenylethers, Polybromo biphenyls(PBB), pentachlorphenol, mercury compounds, cadmium and its compounds, nonylphenol- and ethoxylates (processing). A list of azodyes, which could by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines, is provided. Methods for the determination of certain aromatic amines derived from azo colorants Part 1: Detection of the use of certain azo colorants accessible without extraction (EN 14362-1:2003) Part 2: Detection of the use of certain azo colorants accessible by extracting the fibres (EN 14362-2:2003)		
Construction products			Requirement for documentation of release during use according to hygiene, health and the environment. The construction work must be designed and built in such a way that it will not be a threat to the hygiene or health of the occupants or neighbours. There are ongoing activities in CEN to develop standard on selected substances such as formaldehyde and brominated flame retardants. The Commission's Expert Group on Dangerous Substances (EGDS) are working on test methods in product standards.
AgBB-Approach	CMR substances may not be introduced in to the material		Chamber test with single product sample (DIN V ENV 13419-1 to 3) thresholds for Σcarcinogens, TVOC, ΣSVOC, individual substances (list of LCIs included) , Σnonassessable substances Test is similar to emissions tests for eco-labels
Eco-Label Type III ISO TR 14025, R-Symbol ARGE kdR	Declaration duties	Declaration duties	Chemical analysis of potential emission according to standardised tests
Substances in vehicles:			
ELV and IDIS	Database on car components containing restricted substances		

Product	Identification of substances	Determination of substance content	Determination of substance release
Toxproof certificate	Based on a list of substances that can damage health or cause allergic reactions The procedure of research follows in consideration of experiences from manufacturers and from other fields (indoor air, work place requirements): Identification of each material/component using a received material list. basic analysis for each material like textiles, leather, plastics analysis of each material with skin contact analysis of indoor air toxicological expert appraisal	Content testing like: banned azo-dyes (DIN EN 14326-1/2)	Standardised release testing methods used: Static headspace (VDA-norm 277) with flame ionisation detector (FID) or mass spectrometry (MS) condensable substances (DIN 75201) gravimetrical method or gas chromatography odour of emitted components (VDA 270) olfactory test subskin test (patchtest)
Electrical and electronic equipment (EEE):			
RoHS and WEEE	Six substances are banned in EEE: Pb, Hg, Cd, Cr VI, PBB and PBDE	Chemical analysis by existing analytical methods for all applications Further methods have to be developed.	
Material data bases for electronic equipment:	Wizard and GreenPack: IT-Communication tool Suppliers have to enlist substances in components		
Child care products and toys:			
Standards for child-care products	Analytical methods are given in the guideline "Child use and care articles – General and common safety guidelines" and Standard EN 14350-2.		Standard EN 14350-2 has limits of the release of certain elements from drinking equipments. The guideline provides also migration limits for certain chemicals regulated in other products. Chemical substances in toothbrushes (DIN 53160-1)
Toy safety	Substance lists: Dangerous substances/ preparations must not be used	Chemical analysis Screening methods	The migration of heavy metals, inorganic and organic substances can be measured according to the EN 71-3 standard where the simulant 0.07 M hydrochloric acid (HCl) simulates artificial saliva or gastric acid. Analytical method is given in Survey no. 46 (Chemical substances from tents and tunnels for children, Wooden toys: Will be published within August 2005) Survey no. 14: Mapping of Chemical Substances Discharge when heating Clay
Plastic articles – food contact material:			
practical guidance on food contact material	Requirements to be considered positive lists purity standards for substances special conditions of use for substances and/or the materials/articles in which they are used and SMLs	Numerous Standards for identification and quantification of substances in materials and articles and detailed rules concerning sample taking and analytical methods	Software tool Migratest Lite 2001: migration model for the simulation in migration tests. Certain conditions are defined depending on the material, the food simulant (e. g. fatty, aqueous), time and temperature

Product	Identification of substances	Determination of substance content	Determination of substance release
Directives on food contact material		In Germany: recommendations for substances in polymers: http://bfr.zadi.de/kse/	Release in the context of the directives means a migration of substances from material to the foodstuff. Overall migration limit (in mg/dm² as a measure for inertness of the material or mg/kg): Specific migration limits (SML, in mg/kg or mg/l)
Directive 2002/72/EC	Lists specifying the use of substances: monomers and starting substances additives (Annex III) and products obtained by means of bacterial fermentation (Annex IV) possible restrictions (Annex V, VI) for usage.	Another possible method to exclude a relevant migration is to measure the quantity (Q) of a substance in the finished material or article and to compare it with the value of its specific migration (SM) known from experimentation or valid diffusion models 78/142/EEC: limits for the content of vinyl chloride in a finished material or released by this material	General analysis of overall migration For detailed information on analytical methods the directive refers to other documents like: 82/711/EEC: basic rules necessary for testing migration of the constituents of plastic materials and articles 82/572/EEC: simulates to be used in migration tests 97/48/EEC (temperature and time) Standards EN 1186 (globalmigration) Standards EN 13130 (specific migration)
ESD on additives used in Plastic Industry			Estimation: Potential release as emission or loss factors over service life: 10 additive types (e.g. antioxidants, anti-static agent, colourants) according to their function identified. The loss is estimated as a percentage of the amount of additives used (dependent on particle size (threshold value 40 µm) and volatility (related to the vapour pressure). It depends on the application of the additives and the values of service life.
EURO-CAD	Report formats were used to communicate Alert and EURASCP system: a report format to inform colleagues inspectors within the EU and Norway when products with an exceed limit value of cadmium are found and it seems possible that it is planned to transport them to other EU countries. Report form EuroCad company inspections.	Quantification methods for cadmium content in articles: INAA (instrumental neutron activation analysis) DIN V ENV 1122 AAS (atom adsorption spectroscopy), XRF (x-ray fluorescence spectroscopy) and others	
Labelling requirements:			
Nordic swan for writing instruments	Lists of substances excluded from use in these products are used. supplier has to provide a declaration of classification, content of named substances and product composition.	Only general (GLP) requirements for content analysis on substance identification and quantification are given	

Product	Identification of substances	Determination of substance content	Determination of substance release
Thai Green Label for writing instruments	lists of substances that are excluded from use in certain applications	To ensure product quality the following general standards and requirements must be passed: Thai Industrial Standards or Industrial Standard product quality test as TISI 346, ball-point pens TISI 650, black lead pencils TISI 822, oil based marking pens TISI 1147, colour lead pencils pens TISI 1149, wax crayons or an acceptable international /national standard or the International/national standardised test of product quality and manufactured, transported, disposed as required by legislation e.g. Factory Act 1992.	
Furnishing Blue Angel for furniture based on wood	substance lists exclusion from use in the product (with declaration from producer) Documentation of compliance:	Thresholds for Formaldehyde in the raw state of the wood product, i.e. prior to machining or coating: a steady state, concentration of 0.1 ppm in the test chamber Content of Formaldehyde and TVOC in the finished product Test Methods for Wood-Based Materials, Federal Health Bulletin 10/91 p. 487-483	Limit values of emissions from finished furniture Chamber test with a sample of the finished product or parts of the product Formaldehyde and VOC (substances are listed) after 24 h +/- 2 h Formaldehyde and VOC after 28 days (it is recommended to take samples on at least 3 days in between) Identification and quantification with GC-MS Official Journal of BAM (Federal Institute for Materials Research and Testing), vol. 29, 1999, p. 234-250
Blue Angle for wood panels	No use of: wood preservatives (fungicides, insecticides, fire protection agents) halogenated organic compounds Documentation of compliance: Recipe for the production of the wood-based material and of the coating.		Limit values for the emission of substances. Chamber test with product sample Formaldehyde, VOC and individual substances Phenol ("Phenol Measurement - p-nitroanilin process", VDI Directive 3485) MDI phenol-containing binding agents Identification and quantification with GC-MS

Product	Identification of substances	Determination of substance content	Determination of substance release
Label for upholstery and mattresses	The used materials (leather, textiles, upholstery and coating material, adhesives) must not contain substances that are toxic, CRM[54], known as a strong contact allergen (leather)[55] No use of certain dyes or pigments (substance list) The following documents are requested for compliance: recipe for the production of the wood-based material and, if the occasion arises, of the coating. test certificates statement or declaration of the suppliers product information for the used materials		Chamber test with product sample (according to RAL-UZ 76 wood products, DIN ENV 13419-1, VDA 276) LANXESS criticises that the scenario chamber test is very expensive and time-consuming. They prefer other smaller scaled methods from the automotive industry: Headspace-method: RAL-GZ 479/VDA 277 (PV 3341), PB VWL 709/VDA 278 overall-emission, for leather used in cars, RAL-GZ 479/DIN EN 717-3/VDA 275 free formaldehyde in for leather used in cars, Fogging DIN 75201/ISO 6452 condensable emission for leather used in cars
Nordic Swan for Furniture and Fitments	Not allowed are: biocides classified by WHO as Type 1A or 1B (mandatory) for wood CMR, toxic, allergenic substances halogenated organic substances heavy metals individual substances (substance list) For documentation of compliances: The producer of wood material shall submit information on total amount (in g/kg panel) of chemical substances classified as environmentally harmful. The supplier has to classify the constituents.	Methods for detection and measuring of formaldehyde depending on material are: ENV 717 (perforator method) Finnish classification system: "Emission Classification of building material" [56]and Climate Chamber, method, ENV-717-1 Chamber method used for correlation of emission potential (EN 120) as mg/100 , emission level expressed in ppm or mg/m³ EN ISO 14184 (emission from padding materials and textiles) CEN standard 131 (for adhesives) Nitrosamines: chamber test (ENV 13419-1 after 24 h and 30 h) or ZH ISO 1/120.23[57] for air sampling; Thresholds for emission and content: formaldehyde substances harmful to the environment aromatic solvents organic solvents and substances classified environmentally harmful (e.g. quantity per m² surface	
The IKEA way of purchasing	IKEA provides a negative list of substances, which must not be used by its suppliers. IKEA demands a minimum chemicals management system of its suppliers, including listing all chemicals used.	Content and release analysis is carried out to control whether products comply with IKEA specification on chemical compounds (see below).	Release analysis (e.g. chamber tests) are also carried out to identify potential risks related to long term exposure of substances

[54] According to Directive 67/548/EEC annex I, GefStV, TRGS, MAK- und BAT-Werte-Liste

[55] List of the German BfR (https://gripsdb.dimdi.de/websearch/servlet/Gate?accessid=bfrKABasic&language=de#__DEFANCHOR__)

[56] http:www.rts.fi/emission_classification_of_building_materials.htm

[57] Hauptverband der gewerblichen Berufsgenossenschaften

Product	**Identification of substances**	**Determination of substance content**	**Determination of substance release**
ESD on textiles			A total release is estimated for volatile substances to the atmosphere for biocides from indoor articles to wastewater through cleaning for biocides from outdoor articles to wastewater and soil.
Oeko-Tex 100	Testing methods for detection of banned substances (substance lists)	Testing methods to control compliance with thresholds for: content of pesticides and chlorinated phenols formaldehyde or containing trace amounts (significantly lower than the required legal limits)	Testing methods to control compliance with thresholds for: release of heavy metals under artificial perspiration conditions For pigment, vat or sulphurous colorants a minimum grade of colour fastness to rubbing of 3 (dry) is acceptable
EU-Flower for textiles	Documentation includes a manufacturing system diagram with flow diagram and list of all suppliers list of used chemicals, dyes and pigments in the product	Analysis of chemicals and emissions by laboratories which are accredited according ISO 17025. Test methods/standards are indicated in the criteria documents (content and release) Named substances are prohibited (substance list) Thresholds for individual substances	
ChemRisk		As a reference system ChemTest is part of the toolbox and provides available analytical methods suitable to close data gaps remaining in the knowledge based analysis. Development and validation of biomarkers are key issues of EIS-ChemRisks (low dose biomarkers). Tool working with ExpoScenarios as standard scenarios. The focus of EIS-CHEMRISKS will be to evaluate the feasibility of using data derived from modelling activities in the EU and in the world.	

APPENDIX 7: LEGISLATION RESTRICTING THE USE OF SUBSTANCES IN ARTICLES

Instrument	Coverage	Conditions	Notes
Directive 76/769/EEC Marketing and use restrictions Directive	Placing on the market and use of hazardous substances in Annex I	Restrictions on marketing and use of substance, may contain exemptions	Restrictions will be taken up in Annex XVII of REACH ((also see Art 137 on transitional measures regarding restrictions)
Directive 98/8/EC Biocides Directive	Biocidal products	• Substances included in Annex I may be used as active substances in biocidal products, Annex I may contain substance specific conditions; and • Authorisation of biocidal products at national level.	• The use of certain biocides is restricted by Directive76/769/EEC; and • restrictions of non-active substances should be under Directive 76/769/EEC.
Directive 94/62	Packaging and packaging waste	Concentration limits for heavy metal content in packaging materials	
Directive 76/768	Cosmetics	List of banned and permitted substances for use in cosmetic products	
Directive 842/2006	Greenhouse gases	Restrictions on fluorinated greenhouse gases	
Directive 89/106 on construction products Directive 89/686 on personal protective equipment Directive 93/42 on medical devices Directive 98/79 on in vitro diagnostic medical devices Directive 90/385 on active implantable medical devices	"New approach" Directives	Contains general provisions on the materials from which the products covered can be made, especially specifying that they should not affect health of users and/or not release toxic gases This also has a provision on bioavailability of substances in the devices	

Instrument	Coverage	Conditions	Notes
Environment-Other			
Directive 2002/95/EC Restriction of Hazardous Substances (RoHS) Directive	Electrical and electronic equipment falling under categories set in Annex IA to Directive 2002/96/EC (Waste Electrical and Electronic Equipment)	• New equipment may not contain Pb, Hg, Cd, Cr(VI), PBB, PBDE; and • exemptions listed in an Annex.	Stakeholder consultation on proposals for additional exemptions ongoing
Amendment 2006/690/EC	The use of Pb in crystal glass in specific materials and components used in electrical and electronic equipment	• Exemptions for applications of Pb in crystal glass	
Amendment 2006/691/EC	Exemptions for applications of Pb and Cd in electrical and electronic equipment	• Exemptions granted based on a review process	Stakeholder consultation on proposals for additional exemptions ongoing
Amendment 2006/692/EC	Exemptions for applications of Cr(VI) in electrical and electronic equipment	• Exempted until 1/07/2007	
Directive 91/157/EEC, Directive 98/101/EC	Batteries and accumulators	Marketing of batteries and accumulators containing more than 0,00005 % of Hg prohibited (exemption: more than 2 % of Hg in button cells)	The revision of the directives is under preparation. Directive 2006/66 will replace Directive 91/157 as of 26/9/2008
Directive 2000/53/EC End-of-life vehicles (ELVs) and International Dismantling Information System (IDIS)		The use of Pb, Hg, Cg and Cr(VI) is prohibited in vehicles and their components.	The directive aims to reduce the amount of and risks from (hazardous) waste from disposal of ELVs. The IDIS software is designed from car manufacturers for providing information to dismantling companies about the content of the four banned heavy metals in car components
Consumers			
General Product Safety Directive (GPSD) 2001/95/EEC	All consumer products or aspects of those products that are not covered by specific European safety legislation	A number of measures, including published standards and codes of good practice may be taken into account in assessing safety.	Products must provide the safety which consumers can reasonably expect.
Directive 88/378/EEC Toys Directive	Toys as defined in Article 1	Limit values for bioavailability of metals resulting from the use of toys	Use of certain substances in toys restricted by Directive 76/769/EEC
Directive 93/11	Elastomer or rubber teats and soothers	List of permitted, authorised and banned nitrosamines and N-nitrosatable substances in elastomers or rubber teats and soothers	

Instrument	Coverage	Conditions	Notes
Directive 89/107/EEC Food additives	Additives to be used in foodstuffs	Positive list of substances (only these to be used in foodstuffs and only certain conditions specified therein)	
Directive 1935/2004/EEC Food Contact Materials	Materials and articles intended to come into contact with foodstuffs	In Annex I groups of materials and articles are listed which shall be subject to specific directives.	Aims to ensure that all materials and articles in their finished state that come in contact to foodstuffs do not transfer substances in quantities that endanger human health or bring an unacceptable change in the composition of the foodstuffs (Art. 2).
Directive 2002/72/EC Plastic Food Contact Materials	Plastic materials and articles intended to come into contact with foodstuffs	Positive lists with authorised substances which excludes all others from use in a certain application. Annex II 'monomers and other starting substances' Information on impurities in substances and constituents of mixtures Overall and specific migration limits	The aim of a positive list of substances is to protect consumer against health risks due to exposure to substances migrating into food
Directive 84/500 Ceramic food contact materials	Symbol that may accompany materials and articles intended to come into contact with foodstuffs	determining the symbol that may accompany materials and articles intended to come into contact with foodstuffs	
Directive 78/142 Food Contact Materials	Materials and articles intended to come into contact with foodstuffs	Migration limits for vinylchloride monomer in food contact materials	
Directive 93/10 Food Contact Materials	Materials and articles intended to come into contact with foodstuffs	Migration limits for cellulose in food contact materials	
Directive 1895/2095 Food Contact Materials	Materials and articles intended to come into contact with foodstuffs	Contains list of permitted substances Food contact materials containing epoxy derivatives	