Draft Final Technical Guidance Document on requirements for substances in articles[1]

Reach Implementation Project 3.8

[1] Disclaimer: The content of this report expresses the views of the contractor and may not reflect the position of the Commission.

Preface

Within the context of REACH, the European Commission has initiated REACH Implementation Projects (RIPs) with the intention of developing tools and guidance for the new legislation. REACH Implementation Project No. 3 covers a suite of individual projects all aimed at developing guidance for industry on various aspects of REACH. Under the RIP 3.8, a first draft guidance document on requirements for substances in articles was developed by May 2006.

That report was developed by a consortium co-ordinated by DHI Water & Environment (main contractor) and carried out by experts from DHI Water & Environment; Danish Toxicology Centre; Ökopol GmbH; Umweltbundesamt, Austria; Federal Environmental Agency, Germany; Swedish Chemicals Inspectorate; Danish Environmental Protection Agency and the Norwegian Pollution Control Authority within the time frame of May 2005 to May 2006.

That report has since been subject to written commenting from stakeholders and discussions by the Commission working group on practical preparations for REACH.

A draft update and revision of the first draft guidance document was done by Ökopol GmbH as part of a contract with the European Commission. The update was based on:

- The final REACH legal text.

- Input received from the Commission Working Group, incl. a sub-group on substances in articles

– Written comments received from stakeholders by AUG/SEP 2006 in response to a wide stakeholder consultation. Some of these comments have been further discussed with stakeholder resulting in additional comments since then.

That version (OCT 2007) was discussed during a Stakeholder Expert Group (SEG) meeting 14-15 November 2007 and made available for written comments in a wide stakeholder consultation. Comments received during the meeting and written consultation were taken into account for the current (DEC 2007) update of the draft RIP 3.8 guidance. This update was also done by Ökopol GmbH.

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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	Enter 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 Electronic 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

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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 addressed by this guidance?

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 figuring out 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 documents on registration and 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

[2] Explained further in Section 2.2.

6 of REACH, unless as indicated above his supplier outside the EU has appointed an only representative to fulfil the importer obligations.

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 also other final guidance documents can be found.

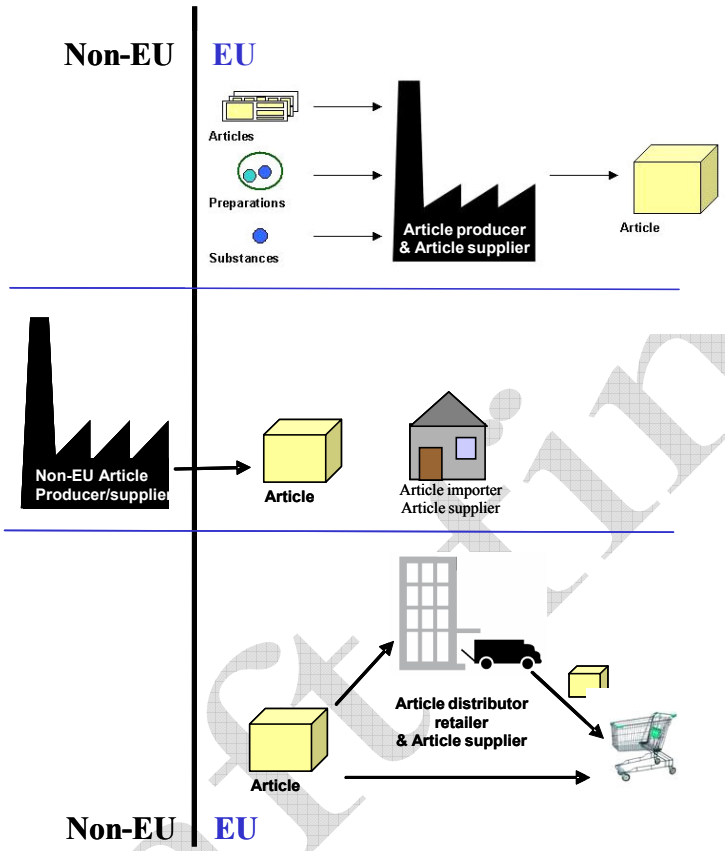

Figure 1 Article suppliers: producers, importers and distributors of articles

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 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 to be considered an article (Chapter 3)
- Communication about substances in the supply chain (Chapter 4).
- Chemical analysis as 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. Suppliers of articles, which don't also produce or import 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 which 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 can not 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 on 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 inclusion of substances into Annex XIV (substances subject to authorisation) and the Guidance on Application for Authorisation.

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 producer/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/) to get 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 intended released have 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 Registration for further information). As will be further explained in Section 2.5, 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 it is released from the article resulting in risks to humans 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)

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

- The substance is included in the candidate list[4] 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 Document on inclusion of substances in Annex XIV).

The obligation to notify substances in articles also applies for 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, if the articles containing them have been produced or imported before the substance has been included on the candidate list for authorisation.

2.3 Obligations according to Article 33

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[5] of the articles and as a mini-

[4] 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.

[5] 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 via Article 7(3) (exclusion of exposure) neither via Article 7(6) (already registered for that use).

Information available to the article supplier and 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 and 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 buttons for jackets are imported which 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 apply also for 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[6].

[6] 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

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[7] 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/import until he has made a registration as his substances would be considered a non-phase-in substance or until someone 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 have to register himself. 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.

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.

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

328 **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[8]
Communication about 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[9]	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

329 **2.6 Other relevant legislation**

330 The restrictions on the marketing and use of certain dangerous substances and preparations[10] in the
331 Annex I of Directive 76/769/EEC will be repealed on 1 June 2009 and included in Annex XVII of
332 the REACH: "Restrictions on the manufacture, placing on the market and use of certain dangerous
333 substances, preparations and articles". This means that existing restrictions, such as the ban of cer-
334 tain azo-colorants in textiles, will continue to apply.

335 Other legislation concerning restrictions, reducing the use of or the risks from hazardous substances
336 in articles still apply separately from REACH. Examples are the General Products Safety Directive
337 2001/95/EEC and product specific legislation such as Directive 2002/95/EC on the Restriction of
338 the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS), Directive
339 88/ 378 on toys or Directive 2000/53/EC on End of Life Vehicles (ELVs). A list of relevant legisla-
340 tion is provided in Appendix 7 of this guidance.

[8] 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.

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

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

2.7 Packaging and containers

Articles, but also substances or preparations 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 article or substance/preparation 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 packaged in carton boxes, the plastic and the carton box should be considered separate articles.)

Normally[11] there is no intended release from packaging materials. There may be exemptions, e.g. packaging releasing corrosion inhibitors. Here 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 besides 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 this 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, also if it is 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 of 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.

[11] 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. 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.

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 is its function: 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.

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.

412 **3.2 The shape, surface and design of an object**

413 The elements **shape**, **surface** and **design** represent the physical appearance of an article and can be
414 understood as other than chemical characteristics. Shape means the three-dimensional form of an
415 object, like depth, width and height. Surface means the outmost layer of an object. And design
416 means the arrangement of the 'elements of design' in such a way as to best accomplish a particular
417 purpose. The design of a textile may be determined by the twist of fibres in the yarn, the weave of
418 threads in a fabric and the treatment of the surface of the textile.

419 An object may be built up with a high level of sophistication of these characteristics. Nevertheless,
420 characteristics simply *improving* the function of an object but not as such *changing* the function
421 should not be overestimated for the reasons explained in section 3.1.

422 **3.3 Workflow for deciding if an object is an article or not**

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

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

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

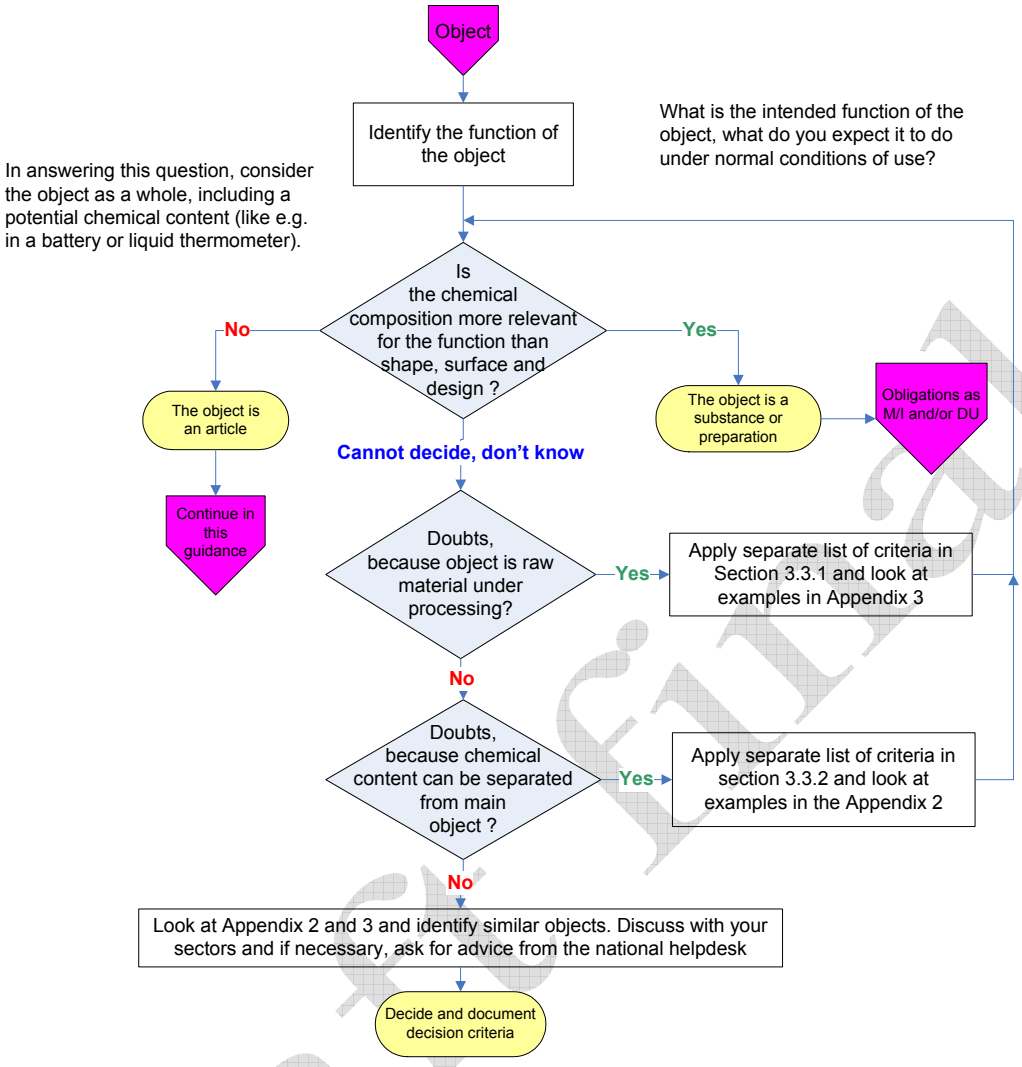

Figure 2 Decision taking on the article definition

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 on whether or not the raw material is an article or not should consider the various relevant indications and not rely on one question or consideration only.

- 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?
  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.

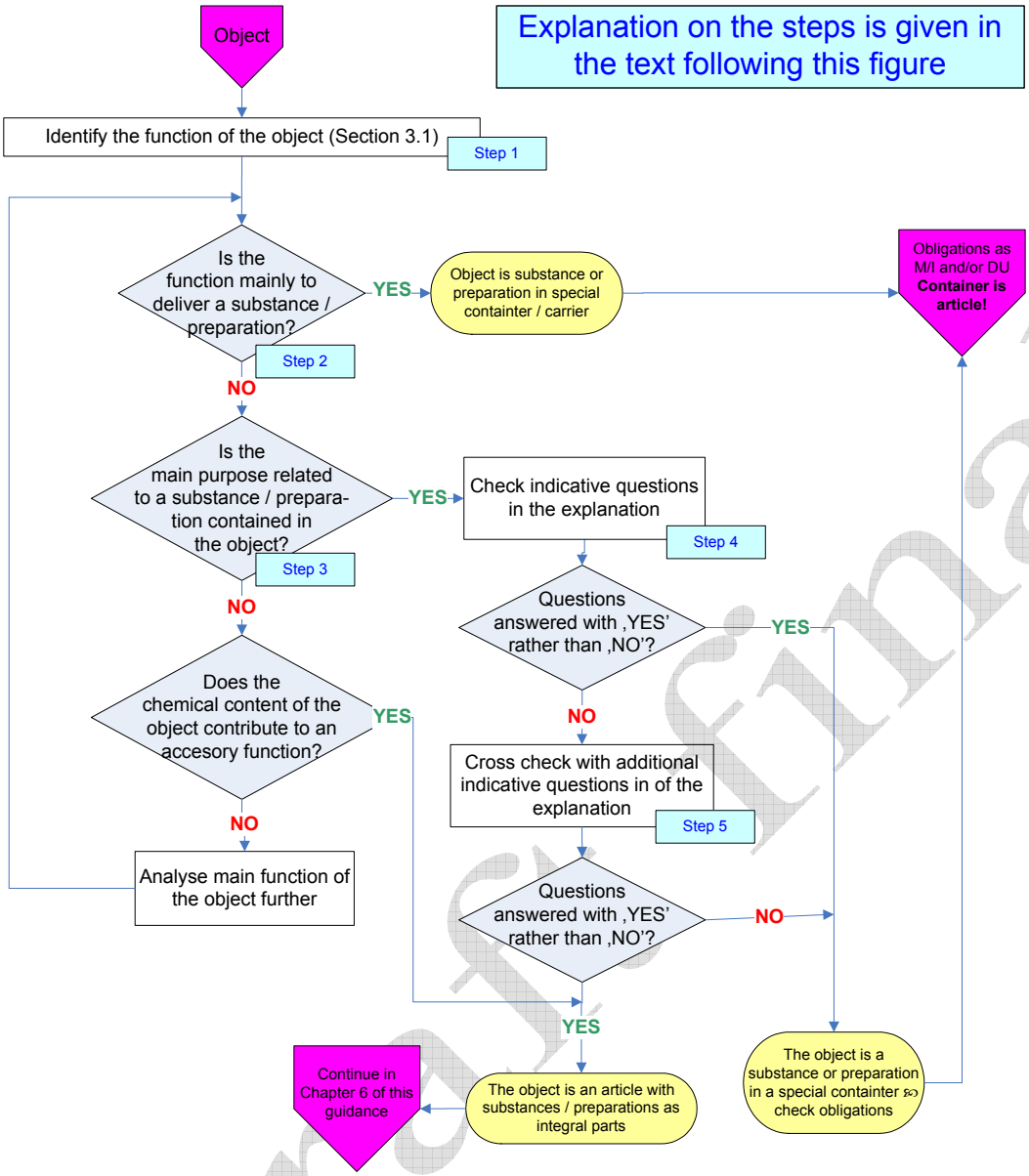

Figure 3 Deciding on borderline between substances / preparations in special containers / carrier materials or as integral part of articles

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 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 [12]?

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[13] under Article 6 of REACH and that the container / carrier material itself is an article and obligations under Article 7(2) and Article 33 need to be complied with.

[12] Function as described in section 3.1.

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

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 on 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 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 recommendable to think of other ways how the function can be achieved to decide if this is more depending 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 has to 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 not be useful anymore at all. 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 disclose 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 in 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 constituent 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. Which information is actually needed depends on a case-by-case assessment and is explained in the respective Sections in this guidance.

Only representatives taking care of 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 take over 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[14].

Some information needed to comply with Articles 7 and 33 can be derived from safety data sheets

[14] 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.

or Article 32-information[15] of substances or preparations[16] which have been used to manufacture an 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-inforamtion
- 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 preparing the Chemical Safety Report).

As previously noted, an article producer importing substances (on their own or preparations) has registration obligations for these. 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.

[15] 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.

[16] 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.

Article importers will not receive any comparable standardised information together with their 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 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 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 have to be made. It is acknowledged that supply chains are complex and that confidentiality or supply contracts may hinder communication to a large extent. Furthermore, enquiring substance identities and/or contents will need time and resources.

EU producers, importers and other EU-suppliers of articles would take similar steps to obtain information. Table 2 shows which actors in the supply chain have which 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 which information on substances as such, in preparations and in articles and which of that information they are required to forward to their customers and which could be provided voluntarily. The following table gives an overview.

688 **Table 2** Availability of information in the supply chain

Information REACH Actor	Relevant information that must be provided 'automatically' for non-classified substance / preparations	Relevant information that must be provided 'automatically' if substance / preparations 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

689 Producers, importers and only representatives of articles with intended release of substances may
690 have to register these substances; including non-classified substances. They need to know the iden-
691 tity and amount / concentration of all substances intended to be released from that article as well as
692 the total amount contained in that article and all other articles intentionally releasing that substance
693 (See also Section 2.1). In order to benefit from the deadlines for phase-in substances, pre-
694 registration is required (see further details in section 2.5).

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

697 • Article producers using substances and preparations as well as articles for their produc-
698 tion, will receive respective information in safety data sheets, as Article-32-information or
699 accordance with Article 33(1) from their EU suppliers. Information on the exact concen-
700 tration / amount may have to be requested.

701 • Importers of articles and only representatives will not automatically receive this informa-
702 tion but have to actively ask for it.

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

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

2) Information is 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 which information is needed and which 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 business secrets or to be involved in extensive communication.

However, there may be cases where supply chain communication will not be successful. In these cases other means to identify the substance e.g. a combination of publicly available information in data bases, branch knowledge and conclusions from chemical analysis have to be used.

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 related 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 don't 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 can not 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 looked for.
    iv. The quantification of substances requires additional measurements

Chemical analyses have to be planned carefully taking into account which 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

767 sector organisations, research institutions and/or accredited chemical analysis laboratories on the
768 article which is analysed[17].

769 **5.1 Chemical analysis in the context of substance registrations**

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

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

774 • Consult experts or sector information sources to narrow down which substances to look for
775 (both with regard to the tonnage threshold and groups of substances). Specific requirements to
776 substances in articles are often linked with standard methods for analytical control of compli-
777 ance (see Appendix 5).

778 • Develop a strategy for testing as a tiered process, i.e. broad screenings, narrow screenings and
779 identification by e.g. semi-quantitative methods

780 • Identify from which part of the article to sample: Separated liquids, gases or powders, extracts
781 from article matrix or other types of sample from the article

782 • Perform the chemical analysis for the identification of substances

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

790 It may be possible to combine the results of an analysis with other knowledge on the article to reach
791 conclusions on the identity of substances intended to be released. If it is not possible to determine
792 the identity of the substances intended to be released, also if they are multi-constituent substances or
793 substances of unknown or variable composition, they should be identified as such.

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

[17] 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 concentration ranges) 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

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 to 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 SVHCs:

- 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 know that the concentration is above 0.1%, some calculations could be made based on worst-case assumptions about the maximum possible concentration.

- 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

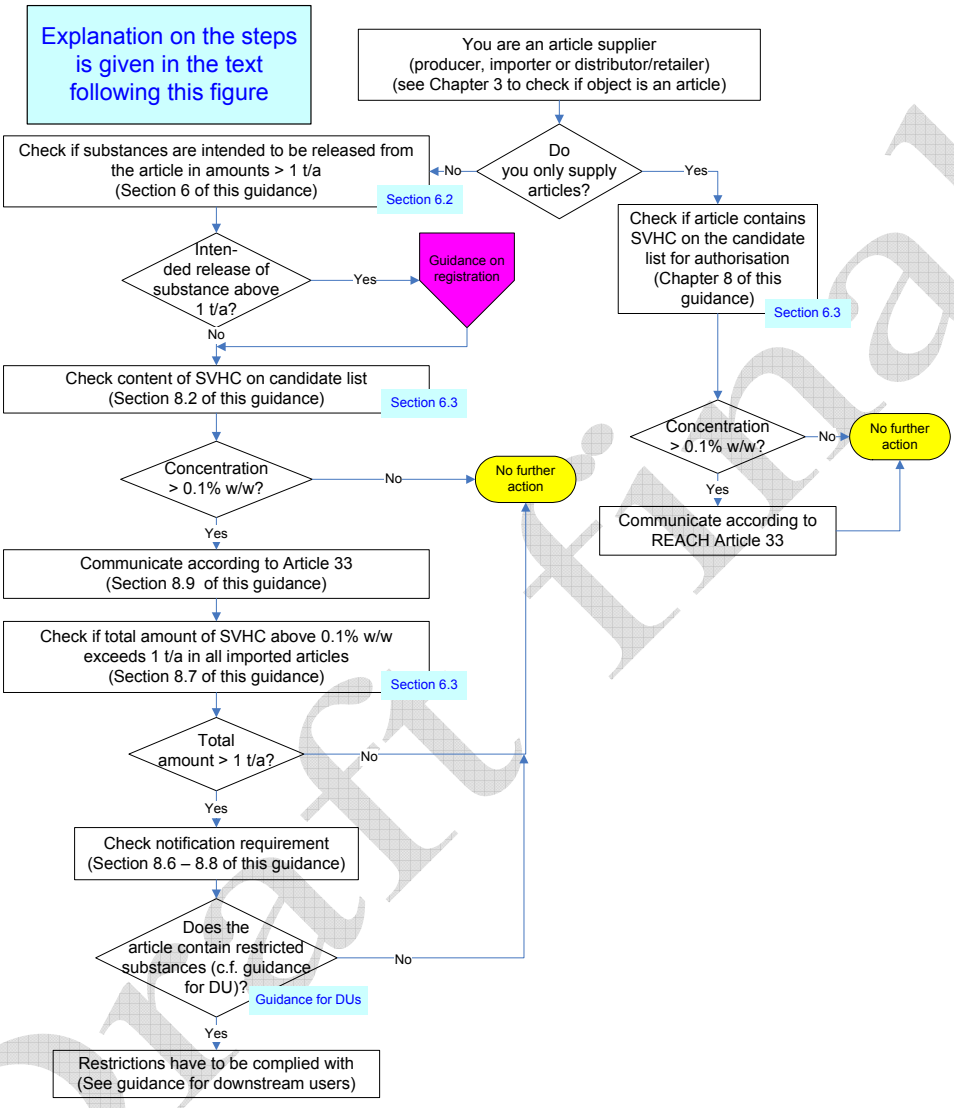

Figure 4 Identification of requirements for substances in articles

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

Note that if you import articles from outside EU, you should answer 'no' to the first question: "Do you only supply articles?".

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 got (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 register 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[18]; thus the release of the substance carries out a function of the article
- The total amount of the substance present in all articles[19] 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 releases' relates to a function of an article[20]. 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

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

[19] 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 intentionally release of that substance. See also section 2.1.

[20] 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.

930 • check whether the substances have already been registered for that use (Chapter 9)

931 • pre-register, join a Substance Information Exchange Forum (SIEF) and participate in joint regis-
932 trations

933 • determine the total amount of each identified substance in the articles with intended release.

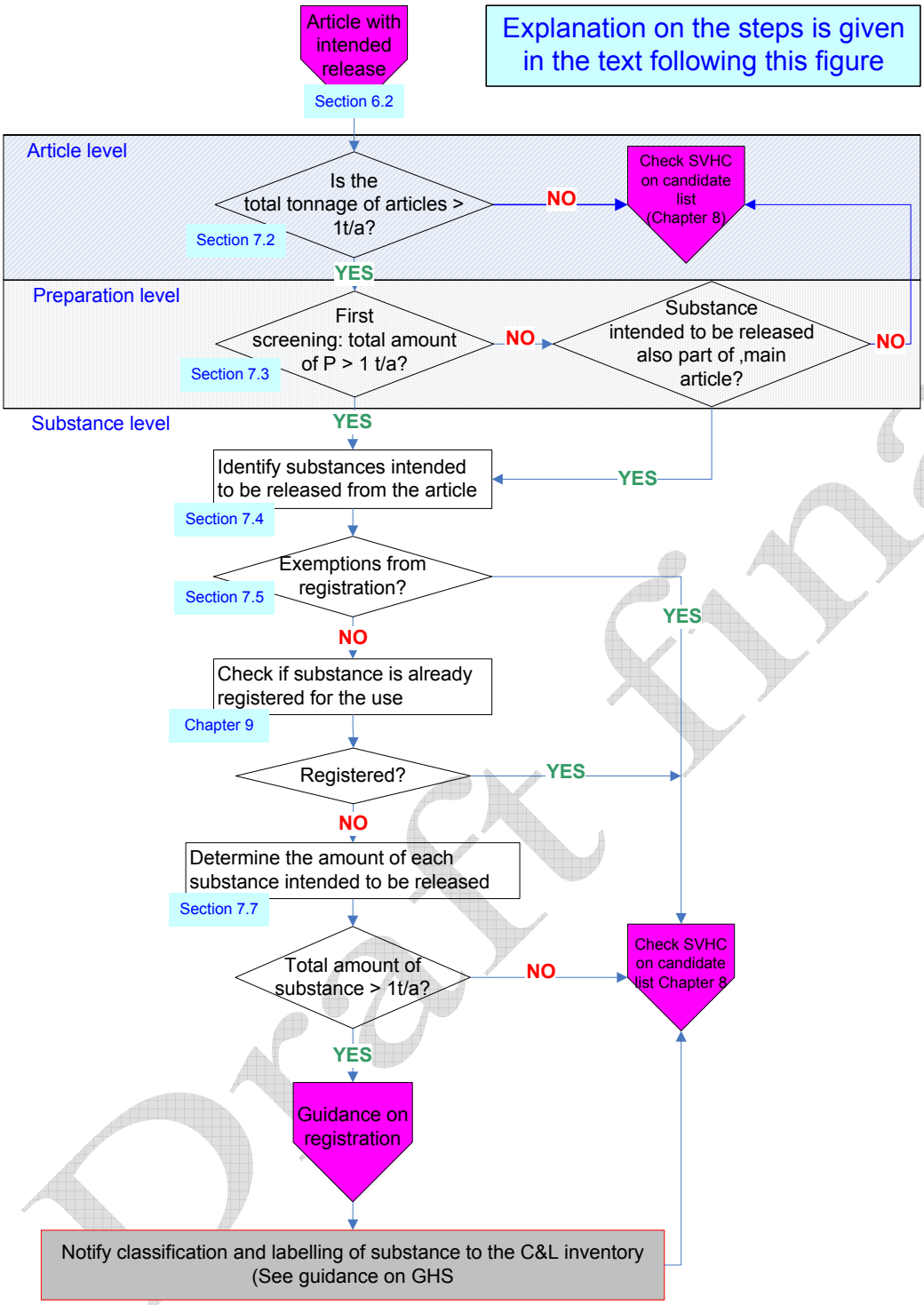

Figure 5 Workflow for checking if registration is required

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

7.2 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 / preparation 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 decision only if it can be excluded that further non-released substance / preparation is not 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:

$$Vol_{article}\ [t/a] < \frac{1[t/a]}{\max\ Conc_{preparation}\ \text{in article}[\%] \cdot 0.01} \qquad \text{or}$$

$$Number_{article}\ [number/a] < \frac{1[t/a]}{\max Conc_{preparation}\ \text{in article}[t/article]}$$

$Vol_{article}$ = tonnage of articles produced / imported
$Number_{article}$ = number of articles
$Conc_{preparation}$ 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 focussed 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 (or if known a specific) of the substances used in the fragrance.

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 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, it is as a first step 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 not 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 starting in 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 substances 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 have 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 have to 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 and preparations in the preparation	Substances below the concentrations communicated by the supplier. Requests for preparations 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	Substance identity and composition	Should receive only 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 has to 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. It depends on the registered amount (total quantity of the substance in all articles of one actor). 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 information requirements, Guidance on data sharing and Guidance on pre-registration.

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 SVHC 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 which 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). Safety data sheets of substances or preparations imported from non-EU Member States will often specify classified substances, also.

EU suppliers of articles containing SVHC in concentrations exceeding 0.1% (w/w) must deliver information available to them and sufficient 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) in addition the total amount in the produced/imported articles needs to be known, 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[21]

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 and also consider other legislation

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

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, as a first step, 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[22], 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 activities 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.

[22] 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 efforts than notifying itself. It is recommended to evaluate the costs before going into a more thorough assessment instead of just fulfilling a notification.

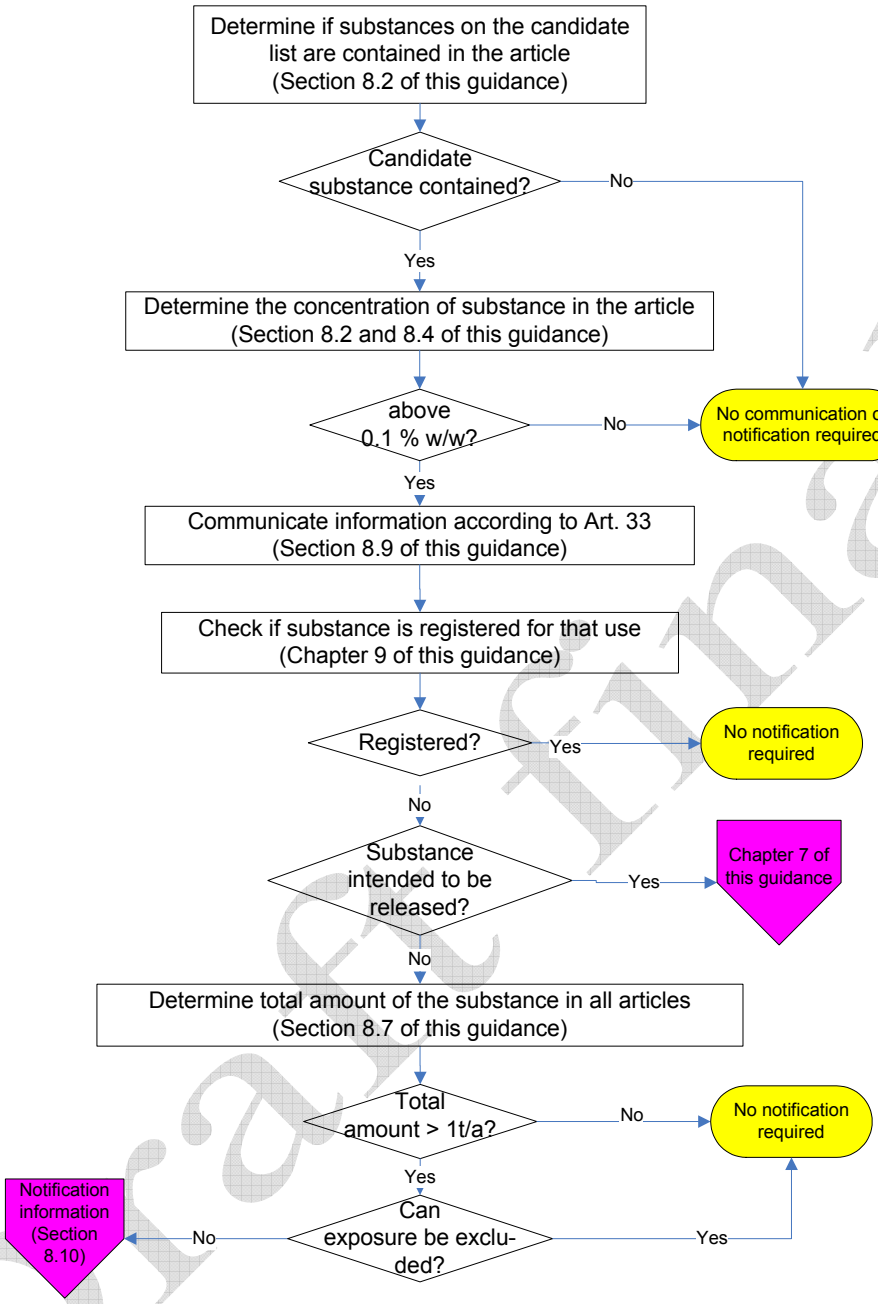

Figure 6 Checking the requirement to notify and to forward information on SVHC

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

For each article, it must be determined whether the concentration of the identified SVHC is > 0.1% (w/w) in order to know which 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 5.2and

Section 8.2). However, it should be noticed 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. 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 you (Article 33) and possibly notified by the supplier of the component. If no such information is supplied, it can be assumed that no candidate substance is contained in the components in relevant amounts.

As producer of the computer, he does not have to notify any substance in the article. The assembler of the computer will also supply it to professional users and/or private consumers. As no information of any SVHC in the components was provided, no SVHC information has to be communicated. If he himself adds SVHC, he will have to check whether the 0.1% threshold 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 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 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

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 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.

8.7 Determining the total amount of substances on the candidate list in all articles

It is possible that the concentration of a substance on the candidate list is greater than 0.1% (w/w) in several individual types of 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:

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

The total volume is:

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

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%:

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

Conclusion: The company has to notify 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).
- 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 on the substances properties, e.g. the substance is fully immobile in the article due to the way it is included and because of its inherent physicochemical properties
- quantification based on exposure models, demonstrating no exposures 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 the Chemical Safety Report (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[23] 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* of which the article is made of

  Structure and chemistry of the article matrix including physicochemical parameters and the way in which the substance is incorporated in it (chemical bonding 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.)
  - The question 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 emission potential 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. Another way, in which substances may be released, is through normal wear and tear of articles (abrasion). Here, 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).

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

8.8.3 Exposure of 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 of humans is obvious and cannot be excluded.

B: Environment

Exposure of 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. Thus, for determining which 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 to address the life-cycle of a substance from the stage of the respective actor. Thus, 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 communication should consider which 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 in 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[24].

Examples of information which could be provided to consumers

- An article is supplied with a risk for human exposure if sucked at 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 for small children. Handle waste as hazardous waste."
- A piece of clothes is supplied where there is risk for 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 which information could be provided to professional users

- Metal article e.g. a sheet that normally will 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 of the environment during outdoors use. For professional indoors use only."

The following checklist could be use to decide which information may be required to forward for professional users.

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

The information could be included in already existing information, like use instructions, packaging etc. The information may be transferred in various ways. Paper labels might in some cases be suitable but other techniques could be developed.

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

[24] 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.

1410 **Table 4** Inforamtion types for communicating on SVHC in articles

Item	Obligatory	Example
Substance name	Yes	Diarsenic trioxide in
CAS Number	No	1327-53-3
Registration number (if provided by supplier)	No	01-1234567-49-00
Classification	No	Carc. Cat. 1; R45; T+; R28; C; R34 ; N; R50/53 May cause cancer
Concentration in the article[25]	No	1% w/w
Information on safe handling including safe disposal if relevant	(Yes)[26]	Prevent from heating up above 60 °C Keep article out of reach of children This article should be disposed of as hazardous waste. Please do not put it in your normal household waste

1411 ## 8.10 Notification of a substance in articles

1412 The information to be notified according to Article 7(2) shall include the following items:

1413 • The identity and contact details of the producer or importer of the article

1414 • The registration number(s) for the substance, if available

1415 • The identity of the substance(s) (cf. Annex VI of REACH). This information will be available
1416 on the candidate list

1417 • The classification of the substance, which will be available from the Agency

1418 • A brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of
1419 Annex VI and of the uses of the article(s) (cf. Section 8.8.1)

1420 • The tonnage range of the substance contained in the articles, i.e. 1-10 tonnes, 10-100 tonnes etc.
1421 This information can be estimated as explained in Section 8.7.

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

[26] If the information is necessary to ensure safe handling and disposal by the user of the article, it is obligatory to forward to the recipients and consumers on request.

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 sameness of substances[27].

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.

A standardized system of descriptors has 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). The current version of the Article category pick-list is attached in Appendix 8 to this guidance. Please refer to the Guidance on preparing the Chemical Safety Report and the IUCLID 5 guidance for full information of the context in which the list is 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, including whether the substance is intentionally released or not. 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 being made 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 all 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.

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

9.1 Information in the supply chain

If you want to find out for which uses a substance has been registered, the most promising 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 of 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 have 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[28]

You may also rely on registration of your use in other supply chains.

Look 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 (at minimum an identification number, such as CAS, EINECS, ELINCS). 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).

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