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APPENDIX 1: DEFINITIONS AND EXPLANATIONS

Definition: *Article according to Article 3(3)*

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

Explanation

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

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

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

Definition: *Use (Article 3(12))*

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

56 **Definition: Identified use according to Article 3(25)**

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

60 **Explanation**

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

63

64 ***Registered for that use***

65 **Explanation**

66 See Chapter 9 and details of the use descriptor system in Guidance on preparing the Chemical
67 Safety Report, part D.

68

69 ***Intended release***

70 **Explanation**

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

75 As a general rule, the intention of the article producer in relation to the release of the substance is
76 relevant. The question “Is it wanted that a substance/preparation is released from the article during
77 its normal and reasonably foreseeable use because this is necessary for it to fulfil a certain function
78 of the article?” should be answered with yes. Intended releases are deliberately planned and have a
79 specific function for the article, which is frequently not the main but an accessory function of the
80 object¹.

81 A release of substances from articles is intended² when:

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

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

¹ In cases where an intended release of substances is the main function of an object, it is to be regarded as a container with substances / preparations inside but not an article. See also Chapter 3 of the guidance and Appendix 2 for further information on the borderline between substances / preparations in special containers / carrier materials and as integral parts of articles.

² The list is not comprehensive, further situations where releases are intended / not intended are possible

A release is not considered to be an intended² release in the following cases:

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

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

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

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

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

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

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

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

- A release is incidental, could be forced by undue use or in an accident³

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

Definition: *Manufacturer* (Article 3(7)), *Producer of an article* (Article 3(4)) or *Importer* (Article 3(11))

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

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

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

³ Although incidents could be foreseen under the conditions of use of the articles, releases caused by these are not intended. See also the explanation of intended release above.

Explanation

Note that when the term “manufacturer” is used in REACH or the guidance documents, the manufacturers of substances as such or in preparations are meant. Their main obligations relate to the registration of substances. Importer may relate to importer of a substance on its own or in a preparation or an importer of an article.

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

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

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

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

Explanation

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

Normal condition of use**Explanation**

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

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

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

158 ***Reasonably foreseeable conditions of use***

159 **Explanation**

160 Reasonably foreseeable conditions of use mean conditions of use that are not as originally intended
161 by the article producer or importer (normal use) but which can be anticipated as likely to occur be-
162 cause of the form, shape or function of that article⁴. The term is relevant in several contexts of
163 REACH, e.g. registration and safety assessment under Article 6, for assessing whether a release is
164 intended (Article 7(1)) or whether exposure of humans or the environment to an SVHC can be ex-
165 cluded under Article 7(3). Thus, the following list gives examples of which condition are reasona-
166 bly foreseeable conditions of use but don't preclude whether a release under these circumstances are
167 intended or not.

168 The following conditions are considered reasonably foreseeable:

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

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

- 177 • Uses, which are clearly and noticeably excluded by the article producer or importer. These uses
178 are to be regarded as use deliberately against the intention
- 179 • Uses, which have been clearly advised to be avoided by means of product design or warning
180 labels⁵
- 181 • Clear misuse

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

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

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

⁴ The term is occurring in the General Product Safety Directive and in the guidance to the General Product Safety Directive, it is stated: "What are "reasonably foreseeable conditions" must be judged in the individual case and will change with market developments where consumers increasingly use complex products, for example medical devices and machinery"

⁵ An assessment of appropriateness of the design of a product to exclude such misunderstandings should be part of the considerations

194

195 **Definition: Recipient of an article (Article 3(35))**196 “Recipient of an article: means an industrial or professional user, or a distributor, being supplied
197 with an article but does not include consumers.”

198

199 **Definition: Substance (Article 3(1)) and Preparation (Article 32())**200 “*Substance* means a chemical element and its compounds in the natural state or obtained by any
201 manufacturing process, including any additive necessary to preserve its stability and any impurity
202 deriving from the process used, but excluding any solvent which may be separated without affecting
203 the stability of the substance or changing its composition”.204 “*Preparation* means a mixture or solution composed of two or more substances”205 **Explanation**206 Substances or preparations are used in the manufacture of articles. Under REACH, substances and
207 preparations may be accompanied by a safety data sheet according to Article 31 (if dangerous) or by
208 information according to Article 32 (non-dangerous, if (a preparation contains a) substance which is
209 restricted, to be authorised or requires specific risk management measures although it is not classi-
210 fied as dangerous). These are important information sources to identify substances present in arti-
211 cles as well as registered uses of the substances.212 How to define the identity of a substance and name it under REACH is described in the Guidance
213 on Substance Identification.

214

215 **Definition substances of very high concern (SVHC)**

216 The following substances are considered substances of very high concern:

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

226 **Explanation**

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

230

Draft final

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

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

It is to be decided by the article producer or importer whether or not the article definition applies. The following examples, the conclusions of which are summarised in Table 1, illustrate how to apply the workflow and indicative questions in the main guidance and how to draw respective conclusions.

Table 1 **Summary of borderline cases described**

Item/object	REACH requirements		
	Registration according to Article 6 ⁶	Registration according to article 7.1 ⁷	Notification according to article 7(2) and communication according to article 33 ⁸
Printer cartridge	x (ink)		(Cartridge)
Spray can with paint	x (paint)		(Can)
Adhesive tape that delivers substances/preparations (e.g. "ski-tapes")	x (the substance/ preparation delivered)		(Backing material)
Adhesive tapes for fixing carpets			x
Car tyres			x
Scented eraser		x	
Battery			x
thermometer			x
Firecracker with gunpowder	x (gunpowder)		(Container)
Wet cleaning wipes	x (cleaning liquid)		(Wipe carrier material)
Pantyhose with lotion		x	

⁶ Special container/carrier material containing substances preparations

⁷ Article with intended release

⁸ Article with substances/preparations as an integral part (no intended release)

Table 2 **Indicative questions for borderline cases (articles with chemicals as integral parts or substance / preparations in containers)**

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

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

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

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

Table 3 Additional indicative questions for borderline cases (articles with chemicals as integral parts or substance / preparations in containers)

	Thermometer with a liquid
If the substance / preparation were to be removed or separated for a similar type of substance / preparations, would the object be un able to fulfill its intended purpose?	The container loses its purpose without the liquid. → YES
Is the main purpose of the object other than to deliver a substance / preparation?	Delivering a substance / preparation is not the main function of the object. The thermometer contains the liquid and provides a shape to regulate its expansion, necessary to measure and to show the right temperature. It is not the purpose to deliver the liquid → YES
Is the object normally discarded together with the substance / preparation?	The liquid and the container are disposed of together. → YES

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

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

Table 4 Indicative questions for borderline cases (articles with chemicals as integral parts or substance / preparations on special carrier material)

	Printer ribbon	Wet cleaning wipes
Function	Transfer ink to paper	Cleaning (surfaces)
If the chemical content were removed from the object, could it still carry out its function?	If the ink was removed and filled into other materials / containers it could still fulfill its function → YES	If the cleaner was removed it could still carry out its function of cleaning. → YES
Does the object act as a container or carrier for release?	The main function is to deliver the ink to the paper. → YES	The main function of the object is to deliver the cleaning agent ⁹ . → ambiguous
Is the chemical content predominantly consumed during use and separated from the object before disposal?	When the ribbon is disposed, most of the ink has been consumed. → YES	The cleaning agents are predominantly consumed ¹⁰ and the wipe is disposed of separately. → YES

⁹ It also has a second function in wiping the 'dirt' off.

¹⁰ This is regarded as true, although in reality a large part of the cleaning agent may not actually be consumed, as its *function* is to be released as far as practical.

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

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

Table 5 Additional indicative questions for borderline cases (articles with chemicals as integral parts or substance / preparations in special carrier materials)

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

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

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

ADHESIVE TAPES

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

Table 6 Applying indicative questions to pressure sensitive adhesive tapes

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

Terms used in the table below are defined according to EN 12481:

Backing: Flexible material like for example fabric, foil or paper which can be coated with a pressure sensitive adhesive.

Double coated or double sided tape: Backing which is coated on both sides with pressure sensitive adhesive.

Reinforcement: a material which strengthens the backing and/or the adhesive.

Release liner: a removable material which protects the adhesive face or faces.

Substrate: a surface or material to which the tape is applied.

Transfer tape: an adhesive tape having two pressure sensitive surfaces without the need of a carrier and with a release liner separating the adhesive surfaces. The adhesive layer can contain reinforcing materials.

297

298 BATTERIES

299 The main function of batteries is to provide electric current.

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

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

307

308 1) The electrolyte and the electrode active materials as such cannot provide any electric current out-
309 side the battery. Filled into other containers without the specific design of a battery, they would
310 also fail to provide energy. The 'container part' of the battery, emptied of the electrolyte, is also not
311 able to fulfill its function. However, there are different types of electrolytes which could be used in
312 one battery casing.

313 2) The electrolyte and the electrode active materials are not released from the battery, thus the con-
314 tainer does not have a function of 'delivering' it and does not control its release

315 3) The electrolyte, the electrode materials and the battery casing are normally discarded together.

316

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

323

324 PANTYHOSE WITH A LOTION

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

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

330 As a consequence, the pantyhose with a lotion should be regarded as an article with an intended re-
331 lease.

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

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

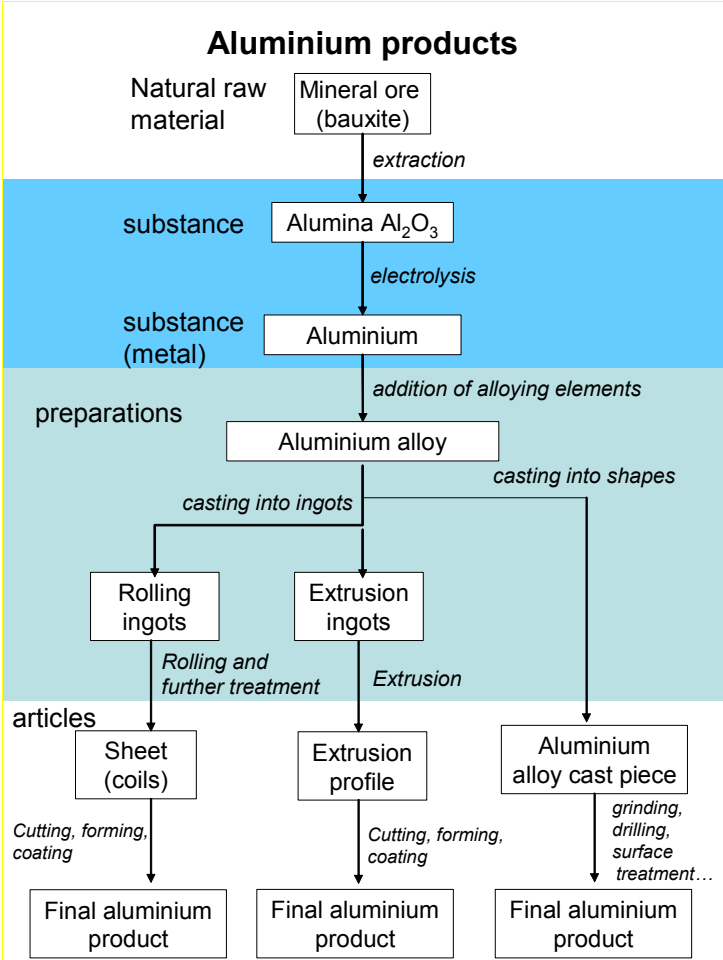
It should be noted that the borderline between substance/preparation and article may be different for very similar types of materials (e.g. there might not be the one solution for all types of fibres). Thus, it should be avoided to draw conclusions on the status of the same type of a raw material in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

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

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

353 **1 METAL PROCESSING - SHOWN FOR ALUMINIUM PRODUCTS AS EXAMPLE**

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



358

359 **Figure 1** Illustrative example of the general transition point from mineral to final
360 aluminium article¹¹

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

¹¹ Note the exceptions as indicated in the text!

364

Table 7 Indicative criteria in aluminium raw material processing (coils, profiles)

Material Question	Rolling and Extrusion Ingots	Coil/extrusion profile	Final product, e.g. coated sheet/final product
Does the material in question have a function other than being further processed?	No	Partly (may not be applicable to all metals or alloys) Copper-beryllium coils could be stamped into various electrical components, while stainless steel coils could be stamped /pressed to form finished forks and spoons. Cut lengths of stainless steel coil could be welded to conveyor belts for continuous furnaces and ovens. The coils as such don't have a function without being cut or stamped. However; these steps do not significantly change the raw material, which is an indication of the coil fulfilling the definition of an article. Extrusion profiles could be directly used in construction works	Yes The coated sheet could be used for construction of vehicles Modified extrusion profiles could be used in several applications as tubes or, when anodized, as door and window frames.
Does the seller put the material on the market and/or is the customer mainly interested in acquiring a material because of its chemical composition or its shape/surface/design?	Seller/buyer of rolling ingot offers/acquires a certain chemical composition. The shape of the ingot determines the nature of next processing step (rolling), but is not considered more important than the chemical composition.	The buyer of a sheet is most interested in buying a material with a specific shape and surface (flat sheet). The buyer of an extrusion profile is interested in it having already the basic shape. The chemical composition is of less importance as compared with the shape/surface/design.	The shape, surface and design of the material is normally of more importance for the buyer than the chemical composition. .
After which processing step is the function determined to a larger degree by the shape/surface/design	Before rolling / extruding, the ingots have no specific form. After the rolling / extrusion they are significantly enlarged and have a totally different shape, which is created deliberately during the process.	The processing of coils to sheets and of extruded profiles to doors and window frames consists of e.g. cutting, forming, coating. The materials have more or less the same shape before and after the process ('light processing').	
Does the chemical composition of the material as such remain similar in the next processing steps?	The chemical composition of the rolling ingot is not changed during the further processing	The chemical composition of the sheet could be changed during further processing (e.g. application of surface coating)	The overall chemical composition of the object may change in that substances may be added to the sheet/extrusion profile, wire.

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

370 Conclusions on rolling ingots / coils

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

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

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

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

393

394 Conclusions on extrusion ingots / profiles

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

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

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

405 The basic chemical composition of the material (aluminium alloy) is not changed during the entire
406 processing, although through coating or surface treatment (e.g. anodizing) or lubrication (e.g. greas-
407 ing, oiling, etc) substances / preparations may be added. Also in this case, the question is not help-
408 ful in determining the transition point.

409

Table 8 Indicative criteria in aluminium raw material processing (cast piece)

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

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

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

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

426

Table 9 Indicative criteria in textile / non-woven raw material processing (man-made fibres)

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

427 For the man-made fibre, the first question can be answered unambiguously, as the man-made fibres
 428 already have a function other than being further processed. Thus the fibre in principle can be an
 429 article already. The same applies to the tow.

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

433 The buyer of a tow is undoubtedly most interested in the shape of the tow than in its chemical com-
 434 position.

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

440 The basic chemical composition of the polymer may be changed after the extrusion / drawing
 441 through various types of processing.

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

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

446 **3 POLYMER PROCESSING**

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

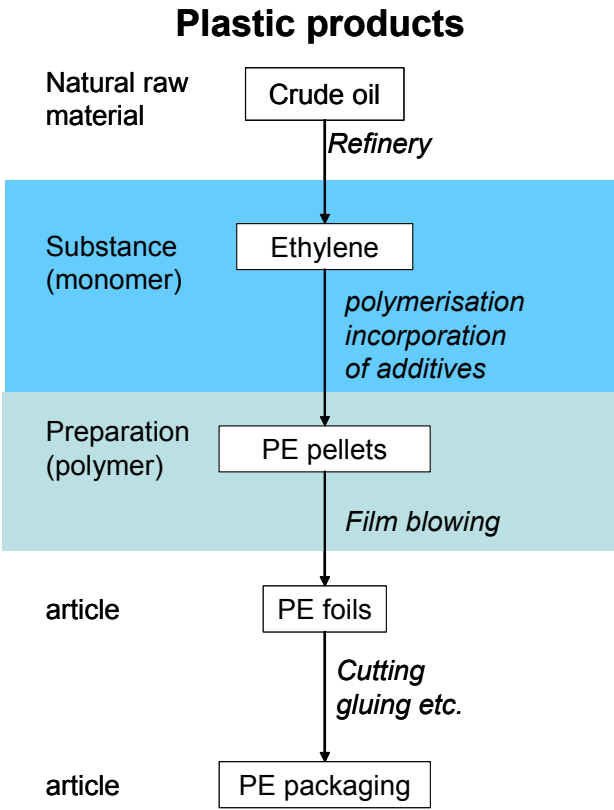


Figure 3 Illustrative example of the general transition point from raw materials to plastic articles (PE foils)

456 **Table 10** Indicative criteria in processing of polymers

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

457

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

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

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

465 For the polymer sector, this means that processes including for example, but not limited to, pipe ex-
 466 trusion, film blowing, blow moulding, sheet forming, rotomoulding, foaming, compression mould-
 467 ing, fibre spinning or tape slitting calendaring, coating or injection moulding mark the 'red line' be-
 468 tween preparation and article.

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475 **Table 11** Indicative criteria in raw materials processing in paper manufacture

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

476

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

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

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

485

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

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

Scented children's toys

Description of case

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

As no specific toy study was identified, a study on scented felt tip pen/markers was used to establish some basic information (Danish EPA-unpublished¹³). It is *assumed* that the results from that study are representative for this toys case and the same process of data collection is assumed to have been taken for children's toys.

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

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

The following is assumed:

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

Substance identity

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

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

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

¹³ The survey report concerns the release of fragrance substances from children's play toys including scented markers. In the report fragrance substances and volatile substances were analysed. The study included a screening of substances contained in the inner part of the pen as well as the emissions of substances from the pen.

518 2 *The pen with lemon scent was examined in an emission test to analyse the release.*

519 3 *Screening for extractable organic compounds by GC/MS.*

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

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

532 **Check for existing registration**

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

536 **Information on concentration of the substance**

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

539 **Table 12** *Further information gathering on D-limonene in the pens (Danish Survey)*

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

540 **Information on amount of substance used**

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

544 $(800 \text{ mg/kg} \times 0.002 \text{ kg/toy} \times 1,000,000 \text{ toys/a})$

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

547 $\text{Number}_{\text{article}} [\text{number of toys/a}] < \frac{1 [t/a]}{1.6 \text{ mg / toy}} = 625 \text{ mill. toys/a}$

Illustration of the decision process on registration

Example: Toy with lemon scent (D-limonene)

Consult Chapter 1:

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

YES

Is your object an article?

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

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

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

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

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

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

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

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

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

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

Work process for calculating the amount (Step 5)

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

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

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

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

3. Identify each substance intended to be released from the article.

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

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

4. Substances exempted from registration?

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

5. Check for existing registration for that use.

Having the substance name and CAS number available the importer have the possibility to request the Agency if the substances has been registered.

6. Determine the amount of each substance intended to be released (all such articles in a company should be considered and summed up).

Based on the chemical analysis the content of D-limonene intended to be release is determined to be 800 mg/kg in the inner part of the toy. The content of D-limonene in the toy is 1.6 mg as the weight of the inner part was 2g.

7. Total amount > 1 t/a?

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

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

Comments on the case

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

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

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

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

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

CASE 1: Clothes

Description

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

Criteria for selecting clothes

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

Producer/Importer of articles

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

Substance identity

The company must consult the candidate list for authorization. It should be done as soon as the list is made available by the Agency. Metallic lead, which was in focus in this case study, is not classified in the Annex I of Directive 67/548/EEC. However, an ongoing voluntary risk assessment is being conducted by the lead industry. It is assumed in the example that metallic lead is a possible candidate to Annex XIV¹⁴.

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

¹⁴ Note that substances fulfilling the criteria of article 57 can be included on the candidate list only according to the procedure described in article 59. For more information see the Guidance on Preparing an Annex XV dossier for identifying SVHC and Guidance on Inclusion of Substances to Annex XIV of REACH.

655 **Check for existing registration**

656 To be done when REACH enters into force.

657 **Information on concentration of the substance**

658 There is no obligation to deliver SDS for articles or other information from non-EU Member States.
659 The different ways to obtain information suggested in Chapter 3 and Section 6.3 of this TGD could
660 be applied. The starting point should be the simplest way.

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

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

668 **Information on amount of substance used**

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

672 **Illustration of the decision process on registration**

673 **Example: Company A - Metallic lead in belt buckles**

674 *Consult Chapter 1:*

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

676 YES

677 **Is your object an article?**

678 YES, belt buckles and jewels are articles

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

680 **1. Is there an intended release from the article**

681 NO

682 **Conclusion for registration: No need for registration.**

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

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

687 YES

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

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

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

695	Based on experience from tests it is known that most of the buckles contain much less than 0.1% of lead, however, it is
696	not documented by chemical analysis or certificates from the supplier.
697	Concentration above 0.1% (w/w)?
698	YES. Conclusion after this step: communicate information according to Art. 33 and continue to the next step in
699	the assessment.
700	2. Is the SVHC (lead) intended released?
701	NO. Continue
702	3. Has the substance already been registered for that use?
703	To be checked once REACH has entered into force. It is assumed that lead isn't registered for that use: → NO.
704	4. Determine the amount of the SVHC (lead) present in all articles?
705	The buckles are the only articles brought into the EU by the company with a lead concentration above the threshold
706	limit at 0.1%. The total amount of lead brought into the EU per year by all the buckles is:
707	The import of buckles in 2005: 13,000,000 items
708	The weight of one buckle: 100 g
709	The maximum lead concentration in a buckle: 0.3% (w/w)
710	<i>Calculation of the total lead amount in the buckles in 2005:</i>
711	• The total amount of lead: $(0.3 \cdot 0.01) \cdot (100 \cdot 10^{-6}) \cdot 13,000,000 = 3.9 \text{ t per year}$
712	5. Is the total amount of the lead > 1 t/a?
713	YES. The total amount of lead brought into the EU-market is 3.9 t/a. This amount exceeds the threshold limit at 1 t/a.
714	6. Can exposure be excluded during normal or reasonable foreseeable conditions of use?
715	<i>The function of the substance in the articles:</i>
716	Small amount of lead lowers the melting point of the alloy. Lead would almost certainly be present as discrete particles
717	in the matrix of the alloy and as such it would retain its own intrinsic properties.
718	<i>The use(s) of the article:</i>
719	Normal use(s): The importer sells the belt buckles to companies, which are producing belts of e.g. leather for both chil-
720	dren and adults.
721	Reasonable foreseeable use(s): If the producer of the belt treat the buckle in such a way that particles are emitted from
722	the buckle e.g. at grinding or sand papering, appropriate protection has to be used. If soldering or welding is used, lead
723	will be emitted in the form of gas and appropriate protection has to be used. Furthermore, children can suck on the
724	buckle in the end-use situation.
725	<i>Potential for emission during use(s) and disposal – Look at the routes of exposure:</i>
726	The routes of exposure in the case of metallic lead are by inhalation and by ingestion. Inhalation can be discounted in
727	this case. However, it is within the realms of possibility that lead may be transferred from the buckle to the hands of the
728	consumer and subsequently ingested.
729	Furthermore, it can not be excluded that there will be an emission of lead from the metal buckle after disposal.
730	Lead has been used in articles for many years. Therefore, it would be obviously to look for further information for 'that
731	use' of lead in sector organizations, the open literature and databases. Look for emission of lead from buckles and simi-
732	lar materials and exposure of humans and the environment.
733	<i>Can exposure to humans or environment be excluded?</i>
734	NO
735	Conclusion: Notification is required
736	Go to Section 6.11
737	Communicate information to the recipients according to Art. 33

738 Comment on the case

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

747 The results obtained completing the workflows 1 and 2 in this guidance could be documented in a
748 table e.g. as in the example above either on paper or electronically. Certificates from suppliers of
749 the articles stating the limits of the SVHC, results of possible chemical analyses and data of the im-
750 ported articles volumes could be annexed. Documentation procedures to be followed during the as-
751 sessment of obligation under Article 7 and 33 could be implemented e.g. as a part of a possible ex-
752 isting quality management system.

CASE 2: Automotive tyres

Description of the case

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

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

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

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

Criteria for selecting tyres

- User groups and application: Wide spread use.
- Supply chain pattern: Represent a supply chain with a considerable part (70%) of the production located within the EU.
- Exposure scenarios: Exemplifies exposure to environment and a case where substances are contained in wear off from the article.
- Documentation: Existing knowledge from a former project performed by KemI, Sweden (1994)¹⁵ and information delivered by BLIC (The European Association of the Rubber Industry).

Producer/Importer of articles

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

Substance identity

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

¹⁵ KemI (1994). Nya hjulspår – en produktstudie av gummidäck (New Wheel Tracks - a product study of rubber tyres). Report 6/94

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

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

Several of the individual PAHs contained in HA oils are classified as category 2 carcinogens in the Community wide classification list (KIFS 2001:3). The PAHs' classified according to this system are listed in Table 8. Several of them are also included in the Water Framework Directive and international conventions due to their inherent hazardous properties.

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

Table 13 Some important properties of some of the PAHs in HA oil

Substance	Persistent	Bioaccumulative	Carcinogenic ¹⁶ (Cat. 2)
Antanthrene			(+)
Benzo(a)anthracene	+	+	+
Benzo(a)pyrene	+	+	+
Benzo(b)fluoranthene	+	+	+
Benzo(e)pyrene		+	+
Benzo(g,h,i)perylene	+	+	-
Chrysene	+	+	+
Dibenzo(a,h)anthracene	+	+	+
Fluoranthene	+	+	-
Indeno (1,2,3-c,d)pyrene	+	+	-
Pyrene	+	+	-
Benzo(j)fluoranthene			+
Benzo(k)fluoranthene			+

The criteria for persistence and bioaccumulation originate from the TGD¹⁷

The criteria for persistence and bio-accumulability originate from the TGD¹⁸.

+ = persistent, bioaccumulative or classified as category 2 carcinogenic in the Community-wide classification list (KIFS 2001:3).

(+) = has caused cancer in experimental animals but is not classified as carcinogenic.

? = too few studies are available to assess whether the substance is carcinogenic.

- = negative result.

Blank box = studies lacking.

¹⁶ Source IPCS, 1998.

¹⁷ Technical guidance document in the program for existing chemicals

¹⁸ Technical Guidance Document/Technical guidance document in the programme for existing substances in the EU.

Check for existing registration

To be done when REACH enters into force.

Information on concentration of the substance

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

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

Table 14 Calculation of amounts of PAHs in average passenger car tyres on the EU market

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

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

Information on amount of the substance produced per company and year

Not relevant as concentration limits are not exceeded. This case does not provide any company specific data on production volumes.

Illustration on the decision process for one company checking his obligation according to Articles 7 and 33)**Example: Tyres containing high aromatic extender oils**

Consult Chapter 1:

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

YES

2. Is the object an article?

YES, tyres are articles

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

3. Is there an intended release from the article?

NO

Conclusion on registration: No need for registration

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

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

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

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

5. Determine the concentration of the SVHC?

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

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

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

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

Comment on the case

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

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

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

CASE 3: Bath mattress**Description**

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

Criteria for selecting Bath mattresses

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

Producer/Importer of articles

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

Substance identity

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

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

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

Check for existing registration

To be done when REACH enters into force.

Information on concentration of the substance

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

928 **Information on amount of substance used**

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

933 **Illustration of the decision process on registration**

934 **Example: Company B – DEHP in bath mattresses**

935 *Consult Chapter 1*

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

937 YES, we import bath mattresses

938 **2. Is your object an article?**

939 YES, the bath mattress is an article

940 *Use Chapter 4 “Checking if requirements under Article 7 or 33 apply”:*

941 **3. Is there an intended release from the article**

942 NO

943 **Conclusion for registration: No need for registration**

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

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

948 *Go to Chapter 6: “Check if Article 33 applies and if notification is required”*

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

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

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

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

955 **Conclusion for this step: “Communicate information according to Art. 33” and continue to the next step in the**
 956 **assessment.**

957 **7. Communicate information according to article 33**

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

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

8. Is the SVHC intended to be released?

NO. Continue

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

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

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

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

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

Calculation of the total DEHP amount in 2005:

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

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

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

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

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

The use(s) of the article:

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

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

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

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

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

Can exposure to humans or environment be excluded?

NO

Conclusion: Notification is required

Go to Section 6.11

Communicate information according to Art. 33

999 **Comment on the case**

1000 The case shows how information from the suppliers may be used in the assessment. Notification of
1001 the use of the substances in the article as well as communication of information is required. The
1002 case gives examples on the information to be communicated to the recipients of the article.

1003 The results obtained completing the workflows in this guidance could be documented in a table e.g.
1004 as in the example above. Certificates from suppliers of the bath mattress stating the identity and
1005 concentration limits of the SVHC, potential results of chemical analyses, and the data of the yearly
1006 imported volumes of bath mattress could be annexed. The documentation procedures to be applied
1007 during the assessment of the obligation under REACH could be implemented e.g. as a part of a pos-
1008 sible existing quality management system.

1009

1010 APPENDIX 5: INFORMATION SOURCES ON SUBSTANCES IN ARTICLES

1011 The list contains examples of available information sources on substances in articles. They provide
 1012 various information, e.g. which substances to expect in certain types of articles, which substances
 1013 can be ruled out from presence in certain articles, which type of substances can be expected to be
 1014 released from articles etc. It is not a complete list of information sources.

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

Name	Address	Content
Information sources on substances in plastic articles – food contact material		
Food contact material – practical guide	http://cpf.jrc.it/webpack/ http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/practical_guide_en.pdf	Rules for substance in food contact material according to European Directives
Food contact material	http://bfr.zadi.de/kse/	Germany: Recommendations for substances in polymers
Directives on food contact material	Directive 2002/72/EC	Lists specify the use of substances and possible restrictions for usage 78/142/EEC: limits for the content of vinyl chloride in a finished material or released by this material
Information sources on substances in textiles		
OekoTex 100	www.oeko-tex.com http://www.oeko-tex.com/en/start/start.html	Requirements for substances in textiles
Information sources on substances in vehicles		
ELV and IDIS	Directive 2000/53/EC of 18 September 2000 on end-of life vehicles (ELV) and International Dismantling Information System (IDIS)	Database/software on car components containing restricted substances

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

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

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

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

Product	Identification of substances	Determination of substance content	Determination of substance release
Directives on food contact material		In Germany: recommendations for substances in polymers: http://bfr.zadi.de/kse/	Release in the context of the directives means a migration of substances from material to the foodstuff. Overall migration limit (in mg/dm ² as a measure for inertness of the material or mg/kg): Specific migration limits (SML, in mg/kg or mg/l)
Directive 2002/72/EC	Lists specify the use of substances: monomers and starting substances additives (Annex III) and products obtained by means of bacterial fermentation (Annex IV) possible restrictions (Annex V, VI) for usage.	Another possible method to exclude a relevant migration is to measure the quantity (Q) of a substance in the finished material or article and to compare it with the value of its specific migration (SM) known from experimentation or valid diffusion models 78/142/EEC: limits for the content of vinyl chloride in a finished material or released by this material	General analysis of overall migration For detailed information on analytical methods the directive refers to other documents like: 82/711/EEC: basic rules necessary for testing migration of the constituents of plastic materials and articles 82/572/EEC: simulates to be used in migration tests 97/48/EEC (temperature and time) Standards EN 1186 (global migration) Standards EN 13130 (specific migration)
ESD on additives used in Plastic Industry			Estimation: Potential release as emission or loss factors over service life: 10 additive types (e.g. antioxidants, anti-static agent, colourants) according to their function identified. The loss is estimated as a percentage of the amount of additives used (dependent on particle size (threshold value 40 µm) and volatility (related to the vapour pressure)). It depends on the application of the additives and the values of service life.
EURO-CAD	Report formats were used to communicate Alert and EURASCP system: a report format to inform colleagues inspectors within the EU and Norway when products with an exceed limit value of cadmium are found and it seems possible that it is planned to transport them to other EU countries. Report form EuroCad company inspections.	Quantification methods for cadmium content in articles: INAA (instrumental neutron activation analysis) DIN V ENV 1122 AAS (atom adsorption spectroscopy), XRF (x-ray fluorescence spectroscopy) and others	
Labeling requirements:			
Nordic swan for writing instruments	Lists of substances excluded from use in these products are used. supplier has to provide a declaration of classification, content of named substances and product composition.	Only general (GLP) requirements for content analysis on substance identification and quantification are given	

Product	Identification of substances	Determination of substance content	Determination of substance release
Thai Green Label for writing instruments	lists of substances that are excluded from use in certain applications	To ensure product quality the following general standards and requirements must be passed: Thai Industrial Standards or Industrial Standard product quality test as TISI 346, ball-point pens TISI 650, black lead pencils TISI 822, oil based marking pens TISI 1147, colour lead pencils pens TISI 1149, wax crayons or an acceptable international /national standard or the International/national standardized test of product quality and manufactured, transported, disposed as required by legislation e.g. Factory Act 1992.	
Furnishing Blue Angel for furniture based on wood	substance lists exclusion from use in the product (with declaration from producer) Documentation of compliance:	Thresholds for Formaldehyde in the raw state of the wood product, i.e. prior to machining or coating: a steady state, concentration of 0.1 ppm in the test chamber Content of Formaldehyde and TVOC in the finished product Test Methods for Wood-Based Materials, Federal Health Bulletin 10/91 p. 487-483	Limit values of emissions from finished furniture Chamber test with a sample of the finished product or parts of the product Formaldehyde and VOC (substances are listed) after 24 h +/- 2 h Formaldehyde and VOC after 28 days (it is recommended to take samples on at least 3 days in between) Identification and quantification with GC-MS Official Journal of BAM (Federal Institute for Materials Research and Testing), vol. 29, 1999, p. 234-250

Product	Identification of substances	Determination of substance content	Determination of substance release
Blue Angle for wood panels	No use of: wood preservatives (fungicides, insecticides, fire protection agents) halogenated organic compounds Documentation of compliance: Recipe for the production of the wood-based material and of the coating.		Limit values for the emission of substances. Chamber test with product sample Formaldehyde, VOC and individual substances Phenol ("Phenol Measurement - p-nitroanilin process", VDI Directive 3485) MDI phenol-containing binding agents Identification and quantification with GC-MS
Label for upholstery and mattresses	The used materials (leather, textiles, upholstery and coating material, adhesives) must not contain substances that are toxic, CRM ¹⁹ , known as a strong contact allergen (leather) ²⁰ No use of certain dyes or pigments (substance list) The following documents are requested for compliance: recipe for the production of the wood-based material and, if the occasion arises, of the coating. test certificates statement or declaration of the suppliers product information for the used materials		Chamber test with product sample (according to RAL-UZ 76 wood products, DIN ENV 13419-1, VDA 276) LANXESS criticizes that the scenario chamber test is very expensive and time-consuming. They prefer other smaller scaled methods from the automotive industry: Headspace-method: RAL-GZ 479/VDA 277 (PV 3341), PB VWL 709/VDA 278 overall-emission, for leather used in cars, RAL-GZ 479/DIN EN 717-3/VDA 275 free formaldehyde in for leather used in cars, Fogging DIN 75201/ISO 6452 condensable emission for leather used in cars
Nordic Swan for Furniture and Fittings	Not allowed are: biocides classified by WHO as Type 1A or 1B (mandatory) for wood CMR, toxic, allergenic substances halogenated organic substances heavy metals individual substances (substance list) For documentation of compliances: The producer of wood material shall submit information on total amount (in g/kg panel) of chemical substances classified as environmentally harmful. The supplier has to classify the constituents.	Methods for detection and measuring of formaldehyde depending on material are: ENV 717 (perforator method) Finnish classification system: "Emission Classification of building material" ²¹ and Climate Chamber, method, ENV-717-1 Chamber method used for correlation of emission potential (EN 120) as mg/100, emission level expressed in ppm or mg/m ³ EN ISO 14184 (emission from padding materials and textiles) CEN standard 131 (for adhesives) Nitrosamines: chamber test (ENV 13419-1 after 24 h and 30 h) or ZH ISO 1/120.23 ²² for air sampling; Thresholds for <u>emission and content</u> : formaldehyde substances harmful to the environment aromatic solvents organic solvents and substances classified environmentally harmful (e.g. quantity per m ² surface	

¹⁹ According to Directive 67/548/EEC annex I, GefStV, TRGS, MAK- und BAT-Werte-Liste

²⁰ List of the German BfR

(https://gripsdb.dimdi.de/websearch/servlet/Gate?accessid=bfrKABasic&language=de#_DEFANCHOR_)

²¹ http://www.rts.fi/emission_classification_of_building_materials.htm

Product	Identification of substances	Determination of substance content	Determination of substance release
The IKEA way of purchasing	IKEA provides a negative list of substances, which must not be used by its suppliers. IKEA demands a minimum chemicals management of its suppliers including to list all chemicals used.	Content and release analysis is carried out to control whether products comply with IKEA specification on chemical compounds (see below).	Release analysis (e.g. chamber tests) are also carried out to identify potential risks related to long term exposure of substances
ESD on textiles			A total release is estimated for volatile substances to the atmosphere for biocides from indoor articles to wastewater through cleaning for biocides from outdoor articles to wastewater and soil.
Oeko-Tex 100	Testing methods for detection of banned substances (substance lists)	<u>Testing methods to control compliance with thresholds for:</u> content of pesticides and chlorinated phenols formaldehyde or containing trace amounts (significantly lower than the required legal limits)	<u>Testing methods to control compliance with thresholds for:</u> release of heavy metals under artificial perspiration conditions For pigment, vat or sulphurous colorants a minimum grade of colour fastness to rubbing of 3 (dry) is acceptable
EU-Flower for textiles	Documentation includes a manufacturing system diagram with flow diagram and list of all suppliers list of used chemicals, dyes and pigments in the product	Analysis of chemicals and emissions by laboratories which are accredited according ISO 17025. Test methods/standards are indicated in the criteria documents (content and release) Named substances are prohibited (substance list) Thresholds for individual substances	
ChemRisk		As a reference system ChemTest is part of the toolbox and provides available analytical methods suitable to close data gaps remaining in the knowledge based analysis. Development and validation of biomarkers are key issues of EIS-ChemRisks (low dose biomarkers). Tool working with ExpoScenarios as standard scenarios. The focus of EIS-CHEMRISKS will be to evaluate the feasibility of using data derived from modelling activities in the EU and in the world.	

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²² Hauptverband der gewerblichen Berufsgenossenschaften

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1023**APPENDIX 7: LEGISLATION RESTRICTING THE USE OF SUBSTANCES IN ARTICLES**

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

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

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

1025 **APPENDIX 8: PICK-LIST FOR ARTICLE CATEGORIES AS CURRENTLY IMPL-**
 1026 **MENTED IN THE IULCID 5 REGISTRATION SOFTWARE**

1027 *NB! Please refer to the Guidance on preparing the Chemical Safety Report and the IUCLID 5 guid-*
 1028 *ance for full information of the context in which the list is to be applied.*

- C04 - Electrical and electronic products (no intended release)
- C04 - Electrical batteries and accumulators (no intended release)
- C04 - Electrical and electronic products: Household appliances (white ware) (no intended release)
- Passenger cars and motor cycles (no intended release) (no intended release)
- Other vehicles: Railway, aircraft, vessels, boats, trucks, and associated transport equipment (no intended release)
- Machinery and mechanical appliances thereof (no intended release)
- C05 - Glass and ceramic products: dinner ware, pots, pans, food storage containers (no intended release)
- C06 - Fabrics, textiles and apparel: bedding and clothing (no intended release)
- C06 - Fabrics, textiles and apparel: curtains, upholstery, carpeting/flooring, rugs (no intended release)
- C08 - Leather products: apparel and upholstery (no intended release)
- C10 - Metal products: cutlery, cooking utensils, pots, pans (no intended release)
- C10 - Metal products: toys (no intended release)
- C10 - Metal products: furniture (no intended release)
- C10 - Articles for welding and soldering (no intended release)
- C11 - Paper products: newspaper (no intended release)
- C11 - Paper products: other (no intended release)
- C13 - Photographic and reprographic articles: cameras, video cameras (no intended release)
- C13 - Photographic and reprographic articles: films, printed photographs (no intended release)
- C15 - Rubber products: tires (no intended release)
- C15 - Rubber products: flooring (no intended release)
- C15 - Rubber products: footwear (no intended release)
- C15 - Rubber products: toys (no intended release)
- C17 - Wood and wood furniture: flooring (no intended release)
- C17 - Wood and wood furniture: furniture (no intended release)
- C17 - Wood and wood furniture: toys (no intended release)
- C18 - Other (no intended release); specify:**
- C19.1 - Constructional articles and building material for indoor use (no intended release)
- C19.2 - Constructional articles and building material for outdoor use (no intended release)
- C20 - Commercial and consumer plastic products (no intended release)
- Plastic products: Flooring (no intended release)
- Plastic products: Toys (no intended release)
- Scented articles: Clothes (intended release)
- Scented articles: Eraser (intended release)
- Scented articles: Candle (intended release)
- Scented articles: Toys (intended release)
- Scented articles: Paper articles (intended release)
- Scented articles: CD (intended release)
- Other scented articles (intended release); please specify:
- Articles releasing grease and/or corrosion inhibitors: Packaging material for metal parts (intended release)
- Other articles; specify:**

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