

Guidance for Suppliers of Articles

THE REACH DUTIES TO INFORM ABOUT CANDIDATE LIST SUBSTANCES



This guidance is aimed to help suppliers of articles – i.e. producers, importers, wholesalers and retailers of articles, to understand how to get information and provide information in order to fulfill their REACH obligations on articles.

© BELGIAN FEDERAL PUBLIC SERVICE, HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT,
GERMAN FEDERAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH,
DANISH ENVIRONMENTAL PROTECTION AGENCY,
FRENCH MINISTRY OF ECOLOGY, SUSTAINABLE DEVELOPMENT AND ENERGY,
NORWEGIAN ENVIRONMENT AGENCY,
SWEDISH CHEMICALS AGENCY.

ISBN 978-91-7932-066-X

COVER PHOTOS: THINKSTOCK

GRAPHIC DESIGN: AB TYPOFORM

Guidance for Suppliers of Articles

THE REACH DUTIES TO INFORM ABOUT
CANDIDATE LIST SUBSTANCES

JULY 2013

Contents

1. Introduction 6

2. REACH and the duties to provide information about Candidate List substances in articles 7
 - 2.1 REACH 7
 - 2.2 Articles in REACH 8
 - 2.3 The Candidate List substances 8
 - 2.4 The duty of all suppliers to inform customers 9
 - 2.5 The duty of producers/importers to notify ECHA 9
 - 2.6 How Candidate List substances may be further regulated by REACH 10

3. Applying the information duties 11
 - 3.1 When to provide information – application of the 0.1% trigger limit 11
 - 3.2 Accessing information using a probability based approach 13
 - 3.3 A stepwise work 15
 - 3.4 Validating information received from own suppliers 15
 - 3.5 Performing analyses to complement or check the information received 16
 - 3.6 Providing information to allow safe use of the article 16

4. Examples demonstrating how to apply the information duties 18

- 4.1 Article consisting of one single article 19
- 4.2 Articles consisting of several articles 20
- 4.3 Articles consisting of an article and a mixture
- 4.4 Very complex articles consisting of several assembled articles as well as mixtures 24
- 4.5 Applying the duty to notify ECHA (art. 7.2) 28

5. Routines and tools to access, store, and provide information 30

- 5.1 Routines and tools to access information 30
- 5.2 Systems for storing data 31
- 5.3 Tools and formats for providing information 32

6. Concluding remarks 34

- 6.1 Summary 34
- 6.2 Benefits from following the approach in this Guidance 35

Annex 1. Differences between the approaches to apply the 0.1% trigger limit 37

Annex 2. Glossary 40

1

Introduction

This Guidance document provides practical advice for suppliers of articles on how to carry out their legal duties to inform about contents of chemical substances listed on the so called Candidate List.

Both professional customers and consumers must be provided with such information. These duties are included in the EU Regulation REACH¹.

The Guidance document has been elaborated in co-operation between authorities responsible for REACH in Belgium, Denmark, France, Germany, Norway and Sweden.²

First, the Guidance describes REACH, the information duties for Candidate List substances, and some other aspects of REACH. Secondly, practical advice is given, focusing on how to fulfill the duty to inform customers, including how to apply the trigger limit (for when to provide information), how to first access information from up the supply chain, and what information to provide.

A number of illustrative examples are given.

Thirdly, some advice is given about routines and tools for the work to access, store, and provide information. Finally, short summaries are given of important pieces of advice for the work, and of why suppliers may benefit from implementing the duties in line with this Guidance.

A crucial message given is that *the same information on contents of Candidate List substances shall be provided irrespective of if the article is sold separately or as a part of an article assembled from several articles*. By fulfilling the duties in this way, suppliers will ensure compliance with these duties on the entire EU market³. It will also enable simpler and more efficient working processes and lead to more relevant, consistent and useful information.

It is also crucial that suppliers take note of the fact that Candidate List substances are inclined to be subject to further REACH measures that may severely limit or stop their uses in articles. Clear information from up the supply chain allows preparing for this, avoiding late and potentially costly surprises.

-
- 1 Regulation (EC) of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20121009:EN:PDF>
 - 2 A basis for the guidance was first developed in a project financed by the Nordic Council of Ministers.
 - 3 The interpretation in the corresponding guidance from ECHA is not accepted by the above mentioned Member States, neither by Austria. ECHA's interpretation means that the duty to inform about the content of a Candidate List substance in an article may be lost if the article is assembled with other articles http://echa.europa.eu/documents/10162/13632/articles_en.pdf.

2 ■

REACH and the duties to provide information about Candidate List substances in articles

The duties described in this Guidance are outlined in the EU Regulation REACH. This chapter introduces REACH, the definition of “article” in REACH, the REACH Candidate List, the duties to inform about Candidate List substances, and how such substances are further regulated under REACH.

2.1 REACH

REACH is an abbreviation of Registration, Evaluation, Authorisation and Restriction of Chemicals.

The overall aim of REACH is to ensure a high level of protection of human health and the environment against risks from chemicals, as well as to ensure free circulation of the chemicals on the market, while enhancing competitiveness and innovation.

Most of the provisions in REACH concern chemicals and manufacturers and importers of chemicals.

However, a few of the provisions in REACH directly affect suppliers of articles: the information duties with regard to Candidate List substances and restrictions of the use of certain chemicals in articles.⁴

Since articles – for example furniture, textiles, electronic equipment – normally contain or are treated with chemicals, suppliers of articles may also be indirectly affected by REACH provisions.

For example, if a supplier of a chemical chooses to discontinue the supply instead of registering the chemical, this will affect any producer of articles who at present use the chemical.

⁴ In addition, there is an obligation on importers and producers of articles to register substances which are intentionally released during normal and foreseeable use of the article.

2.2 Articles in REACH

Products other than chemical substances and mixtures of substances are called “articles” in REACH. Articles are for example products such as textiles, kitchenware, tools, toys, electronic equipment, and vehicles.

REACH (in Article 3(3)) defines “article” as:

[Article] “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”

According to REACH, “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. “Recipient of an article” means an industrial or professional user, or a distributor, being supplied with an article. Consumers are not defined as “recipients”.

Any article may contain hazardous chemical substances that can be (unintentionally) released. Some substances may be released already during use, for example from clothes while in contact with the skin. Other substances may potentially be released later on during recycling or waste handling.

2.3 The Candidate List substances

Listed substances are identified as “Substances of Very High Concern” (SVHC) since they have very hazardous intrinsic properties. The Candidate List is published on the website of the European Chemicals Agency (ECHA) ⁵. To be identified as an SVHC, a substance needs to fulfil one or more of the following criteria:

- ▶ substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR)⁶
- ▶ persistent, bioaccumulating and toxic substances (PBT)
- ▶ very persistent and very bioaccumulating substances (vPvB)
- ▶ substances for which there is evidence for equivalent level of concern, such as endocrine disruptors

Please observe that there is no need for evidence of exposure and risks, to be identified as a SVHC.

5 Link to the full candidate list on ECHA’s website: [The Candidate List, http://echa.europa.eu/web/guest/candidate-list-table](http://echa.europa.eu/web/guest/candidate-list-table)

6 Only the most hazardous CMRs (called categories “1A” and “1B”) may be identified as SVHCs

New substances for the Candidate List are identified continuously, and the list is currently updated twice a year. As soon as the substances are listed on the Candidate List suppliers must inform customers, and in some cases also ECHA (six months after inclusion), about the presence of these substances. The substances may, however, still be used, unless they have been subjected to further measures – see 2.6.



2.4 The duty of all suppliers to inform customers

REACH requires suppliers to provide information *to their customers* if an article contains a substance listed on the Candidate List in a concentration exceeding 0.1 % weight/weight. This duty is described in Article 33 in REACH, and applies *as soon as a substance has been included* in the Candidate List. Guidance on how to apply this duty is given in chapters 3–5.

Article 33 in REACH:

- ▶ Applies to all suppliers of articles that contains more than 0.1% of any substance on the Candidate List;
- ▶ Requires the supplier to provide recipients of the article with sufficient information to allow safe use of the article. As a minimum, the name of the substance has to be provided;
- ▶ Requires the supplier to provide such information to consumers on request, within 45 days from the date of the request.

2.5 The duty of producers/importers to notify ECHA

In addition to the above described duty, REACH Article 7.2 requires any producer or importer of articles to send a notification to ECHA if all his articles supplied during a year in all – irrespective of category – contain more than 1 tonne of a Candidate List substance. Only articles where the content exceeds 0.1% have to be considered. The duty applies from *six months after a substance has been listed*.

However, no notification to ECHA is needed 1) if the use of the substance in the article is covered by a REACH registration⁷ for the substance (Art 7.6), or 2) If the supplier can exclude exposure to humans or the environment during normal or reasonably foreseeable use and disposal (Art 7.3).

⁷ For information on registration, consult ECHA'S webpage: echa.europa.eu, or a national REACH helpdesk: <http://echa.europa.eu/web/guest/support/helpdesks/national-helpdesks/list-of-national-helpdesks>

2.6 How Candidate List substances may be further regulated by REACH

It is important to be aware of the fact that Candidate List substances are inclined to be subject to further REACH measures that may severely restrict or stop their uses in articles.

“Sunset” or time-limited authorisation: Candidate List substances are progressively listed also in Annex XIV of REACH via a prioritisation procedure – with a latest application date, and a “sunset” date. After sunset, no marketing and use of that substance is allowed, unless the European Commission has granted a time-limited authorisation. Applications for authorisation must be sent to ECHA. Manufacturers and importers of the substance may apply, as well as users of the substance such as producers of articles who use the substance in articles or in other ways. An important aim with authorisation is substitution.

REACH restrictions: If an unacceptable risk has been identified based on a particular use of a substance, this may lead to a Commission decision to restrict or even stop marketing and use of the substance, including in articles. New restrictions are added to Annex XVII of REACH.

It is possible to restrict some uses of a Candidate List substance, and assign the other uses to authorisation.

3

Applying the information duties

This Chapter gives guidance on how to apply the 0.1% trigger limit for when to provide information to customers. It also gives guidance on how to first access the needed information from own suppliers, and what information to provide. In Chapter 4, examples are given to demonstrate how the work can be carried out. In Chapter 5, advice is given on routines and tools that may be used for the work.

3.1 When to provide information – application of the 0.1% trigger limit

THE “ONCE AN ARTICLE, ALWAYS AN ARTICLE” PRINCIPLE

Application of the 0.1% weight/weight limit that triggers the duties to provide information is straightforward if the article is a simple article formed directly from a substance or a mixture.

Most articles, however, are assembled from some or many other articles. Application of the limit with respect to assembled articles in this Guidance document is based on the “*Once an article – always an article*” approach supported by Belgium, Denmark, Germany, France, Norway and Sweden.

This principle is in accordance with how an article is defined in REACH (in Article 3(3)) and reads:

“ Once an object during production has become an article of its own, it will remain an article until it eventually becomes waste after end use”.

This means that

- ▶ When two articles are joined to form an assembled article, they both maintain their status as articles.
- ▶ The 0.1% trigger limit thus apply to each object – within an assembled article – that fulfils the definition of an article in REACH, and that was an article already before the assembly.⁸

⁸ This is different from what is said in ECHA’s “Guidance on requirements for substances in articles” which is based on the Commission’s interpretation which implies that the trigger limit should be applied on the whole assembled article. In Annex 1, the differences between the approaches to apply the 0.1% trigger limit are further explained.

This principle was developed through in-depth studies of the legal text, and has by the above mentioned countries been found to be in line with the REACH Regulation.

According to this principle, the trigger limit does not apply to an object – within an assembled article – that is a substance or a mixture, or was that before the assembly. Thus, with respect to any Candidate List substance contained in e.g. a paint or a glue (which are mixtures) added during production, the trigger limit must instead be applied to the article to which the paint or the glue was added, e.g.

- ▶ to the painted article, if paint was added to only one of the articles in an assembled article
- ▶ to the whole painted assembled article, if paint was added to the whole assembled article
- ▶ to the assembled article formed by gluing two articles together

A FEW BASIC RULES FOR HOW TO APPLY THE PRINCIPLE

The following basic rules are useful when applying the “once an article always an article” principle on objects within assembled articles:

1. If an object within an assembled article was an article before it was included, it will remain an article on which to apply the trigger limit, also after assembly.
2. If an object within an assembled article was a substance or a mixture before it was included, the trigger limit with respect to any Candidate List substance in that object must be applied to the assembled article.
3. The complexity of the article does not change these two rules. In case of doubt, comparison with the REACH definition of an article (in REACH Article 3(3)) may help to conclude whether the object is an article or a substance or a mixture.⁹

How to apply the limit is also demonstrated, for a number of cases, in the examples in Chapter 4. In other cases, suppliers need to use their own judgment of how to apply the information duties in a reasonable way, taking account both of the guidance given, and the intentions behind the duties: that information shall be passed on along the supply chain to reach the final user.

FURTHER EXPLANATION OF THE PRINCIPLE

Many different simple articles are sold commercially first as individual articles, then as integrated in an assembled article and sometimes finally as second-hand spare parts after disassembly. According to the principle, they

⁹ The indicative questions in Chapter 2.4 of ECHA’s Guidance may offer further help on how to determine if an object is an article or a substance or a mixture.

are articles all along their service life – also when integrated – until finally disposed of as waste. This applies for example to springs, inner shields, strips, and hub-caps used for cars and to rims, chain rings and seat posts used for bicycles.

Certain articles, for example some computers, bicycles, and pieces of furniture, may be purchased either as assembled, or as a package of individual articles for self-assembly. According to the principle, the articles are articles irrespective of if they are included in a package of individual articles for self-assembly or in an already assembled article.

This principle is, however, *not* applicable if the object was a substance or a mixture before production of an article, e.g. the handle of a screw driver if formed by molding plastics directly onto the metal part.

3.2 Accessing information using a probability based approach

When the trigger limit is applied in line with the “once an article – always an article” principle, it is sufficient to learn from an own supplier that a certain article – whether purchased as an individual article or included in an assembled article – contains more than 0.1% of a certain Candidate List substance.

This information – *as it is* – can be passed on down the supply chain to own customers.

For suppliers who supply a large number of articles or very complex articles, it may be a challenge to find out in which articles which substances are contained, since the number of listed substances is relatively large and increasing. However, many listed substances are not even used in articles – for example due to physical state. Moreover, a specific substance is often mainly or only used in certain materials such as certain plastics, which in their turn are mainly used in certain article categories.

Therefore, a “probability based approach” can be used to focus the work. The idea is first to assess which articles may likely contain Candidate List substances – based on the materials used – and then consider which substances they may likely contain. For example, a plastic handlebar grip of a bicycle may contain softeners often used in the plastics. After that assessment, questions to own suppliers can be targeted to those articles and substances. This will increase the possibility of relevant answers, compared to if very general questions about all articles and substances are sent up the supply chain.

With time, provided correct implementation of the duties in Article 33 in line with the “once an article – always an article” principle, suppliers should normally *automatically* obtain the needed information on contents of Candidate List substances in articles they purchase from own suppliers, especially from EU-suppliers.

FINDING OUT WHICH SUBSTANCES ARE ALREADY ON THE CANDIDATE LIST – OR MAY SOON BE ON THE LIST

Since the list is regularly updated, there is a need to regularly check which further substances have been added to the list. This can be done via the following link on ECHA's webpage: [The Candidate List](#)¹⁰.

It may also – because the duty to inform customers applies immediately after a substance has been listed – be useful to know which substances may soon be listed:

- a) Substances already proposed for inclusion in the list ([Public consultations](#)¹¹)
- b) Substances where a dossier for identification as a SVHC will be prepared ([Registry of Intentions](#)¹²)

CHECKING WHICH SUBSTANCES MAY LIKELY BE USED IN THE ARTICLES CONCERNED

Information on uses of Candidate List substances in articles is so far not very abundant, but the following may offer a starting point:

- ▶ A few EU countries have published certain information on common uses of such substances.
- ▶ Cooperation within a sector can help to identify the Candidate List substances most commonly used in the articles of that sector. For example industry associations may potentially be able to provide information about commonly used Candidate List substances.

Knowledge of which materials that are used in a particular article category can be combined with knowledge of which Candidate List substances that might be used in such materials. For example, knowing that an article is mainly produced using specific plastics and also knowing that a special kind of plasticiser is used in such plastics helps answering the question whether this plasticiser is probably present in the article.

Once the supplier has made a probability analysis, he can send targeted questions to his own suppliers. He can also, where appropriate, direct any complementary analyses towards the articles/substances for which the probability to find contents is comparatively high.

However, care when using this approach is advisable. Indications from a probability analysis must not be used to finally conclude that no other Candidate List substances than the most probable ones are present, especially not with respect to imported articles. If, after all, “less probable” substances are contained, the supplier is still responsible for providing information about these.

10 <http://echa.europa.eu/web/guest/candidate-list-table>

11 <http://echa.europa.eu/web/guest/proposals-to-identify-substances-of-very-high-concern>

12 <http://echa.europa.eu/web/guest/registry-of-current-svhc-intentions>

3.3 A stepwise work

If a supplier starts from no or very limited knowledge about whether Candidate List substances are contained, the work may be challenging to find out whether any such substances are contained, and if so, which ones and where. This applies especially to suppliers who supply a large number of articles from different article categories, or who supply very complex assembled articles. This is valid irrespective of how the limit will then be applied.

In such a case, it may be helpful to combine a probability approach with a stepwise work procedure.

A first step might for example be to apply the probability approach on the larger included articles, and search for information where presence of Candidate List substances is probable. In the following steps, the same can then be done for smaller and smaller included articles.

To collect all data for assembled articles containing many different articles might take time, but will give the necessary knowledge. This has already been shown in some sectors such as the car industry and parts of the mobile phone industry (c.f. section 5.2).

Questions concerning Candidate List substances in articles must always be asked and answered on a case-by-case basis. It is the responsibility of the supplier to judge when to stop when he considers that it is no longer relevant to look for information by breaking down an assembled article into even smaller articles, or to exclude the possibility of a presence of a certain substance due to the material used. It must, however, be kept in mind that the information duties apply to all articles irrespective of size or weight, since no lower limit is given in REACH.

3.4 Validating information received from own suppliers

Information from own suppliers of articles normally need to be validated: Is the information sufficient? Is the information plausible? Did the supplier apply the 0.1 % trigger limit to articles included in the assembled articles? For example, the following may be appropriate to consider:

- ▶ Information received that a Candidate List substance is contained, which, and where

Probably no need for further action, the information can be passed on to customers.

- ▶ No information received on whether a Candidate List substance is contained

The recipient must consider what is most plausible since

- ▶ No information may mean *no contents* of any Candidate List substance.

- ▶ No information may also mean that the supplier so far *does not have any such information*, or *is not aware* of his obligations, or *does not comply* with them.
- ▶ No information may also – for assembled articles – mean that the supplier knows that a Candidate List substance *is present* in a high concentration in an included article. Though, the supplier has applied the trigger limit on the whole assembled article, and this happens to be so heavy that the calculated “fictive” average concentration of the substance is below the trigger limit.

In cases of such doubt or insufficient information, further actions are needed, such as further questions to own suppliers, or even having chemical analyses made where possible and appropriate.

3.5 Performing analyses to complement or check the information received

Analyses can be used to complement insufficient information from suppliers, or if there is a suspicion that the article contains a Candidate List substance, or to check the information received. Because of the costs and difficulties involved, analyses are normally used only for such purposes.

It is not useful to analyse a whole assembled article – made from many articles and possibly many materials – for contents of any Candidate List substance. Instead, analyses should be directed towards checking whether one or a limited group of substances is present in a specific article, such as the plastic handle bar of a bicycle. This fits well with application of the “once an article, always an article” principle.

Where a company has a general quality management system in place, it often includes certain factual checks – by tests or analyses if needed – of how suppliers to the company comply with the company’s quality requirements.

3.6 Providing information to allow safe use of the article

Article 33 of REACH simply states suppliers “*shall provide ... sufficient information.... to allow safe use of the article including, as a minimum, the name of that substance*”. The supplier must thus at least provide the name of the substance and must assess if the customer needs further information to decide on measures to allow safe use. It is clear that it is not always sufficient only to provide the name of the substance¹³.

13 This is pointed out also in ECHA’s guidance: http://echa.europa.eu/documents/10162/13632/articles_en.pdf

“To be able to ensure safe use, it is crucial to have information on where in the article any Candidate List substance is present.”

To be able to ensure safe use, it is crucial to have information on where in the article any Candidate List substance is present.

Such information will “automatically” be provided when the information duties are applied in line with this Guidance document. Without such information, it may be hard or impossible to decide on measures in an appropriate way.

REACH further states that consumers shall receive a response no later than 45 days after a request.

For recipients, no such “on request only” and “45 days delay” is stated.

The information is to be provided to recipients automatically, as soon as a substance has been included in the Candidate List.

Information on the name of the substance and where it is present might for a bicycle be expressed:

“The handle grips contain bis (2-ethylhexyl) phthalate (DEHP).”

4

Examples demonstrating how to apply the information duties

The examples demonstrate the aspects dealt with in Chapter 3. They are mainly intended to show how to apply the 0.1% trigger limit on articles of various complexities. Hints are given on how to access information, and which information to provide. The following is presented in each example:

1. *Preconditions*: a short description of the article, and facts on which Candidate List substance the article contains and in which percentage. This is normally not known when the work starts.
2. *Applying the 0.1% limit*: Practical use of the "Once an article always an article" principle.
3. *Accessing information*: In the examples only some hints of what to do are given, where appropriate by using a probability approach and working stepwise.
4. *Providing information*: In the examples only a core of what to provide is given. Suppliers will have to consider what more to provide in order to enable customers to ensure safe use.

Please note that the examples are not exhaustive, since the aim is to focus on certain substances and articles, to clarify the principles. More Candidate List substances may be contained than those mentioned, and the assembled articles may consist of additional individual articles than those mentioned.

Examples of the following "categories" of articles are presented:

- (4.1) Article consisting of one single article (plastic chair)
- (4.2) Articles consisting of several articles (bicycle, sofa)
- (4.3) Articles consisting of an article and a mixture (cable, T-shirt)
- (4.4) Very complex article assembled from many other articles as well as mixture(s) (table top PC)
- (4.5) Example of application of Article 7.2 (kitchenware)



4.1 Article consisting of one single article

Plastic garden chair

Preconditions:

- ▶ The chair is casted in one piece. It is made from polyethylene plastic pellets.

Not known when the work to access information starts:

- ▶ The pellets contain 0.12 % lead chromate molybdate sulphate red (C.I. Pigment Red 104).

APPLYING THE TRIGGER LIMIT

Here, the application is straightforward, the limit has to be applied to the chair, since it was casted in one piece.

ACCESSING INFORMATION

According to REACH (Article 31), suppliers of any substance that is classified as hazardous, or is a PBT/vPvB, or is included in the Candidate List for other reasons, must provide a Safety Data Sheet (SDS). The same apply to mixtures classified as hazardous. In this case, according to the SDS from the supplier of the plastic pellets – which is a mixture – the added pigment contains lead chromate molybdate sulphate red (C.I. Pigment Red 104) with CAS No 12656-85-8. The concentration in the pellets, and thus in the chair, is 0.12 %, i.e. above 0.1%.

PROVIDING INFORMATION

As a minimum, the name should be submitted to the recipient/consumer:

“This garden chair contains lead chromate molybdate sulphate red (C.I. Pigment Red 104)”

4.2 Articles consisting of several articles

The following two examples demonstrate articles assembled from a number of articles on which the 0.1% trigger limit has to be applied individually.



Bicycle

Preconditions:

- ▶ The bicycle is assembled from several articles that may contain Candidate List substances. Some of the articles are also frequently sold as spare parts.

Not known when the work to access information starts:

- ▶ The handlebar grips contain more than 0.1 % Bis (zethylhexyl) phthalate (DEHP) with CAS no 117-81-7.
- ▶ The seat covering contains more than 0.1 % of Dibutyl phthalate (DBP) with CAS No 84-74-2.

APPLYING THE TRIGGER LIMIT

Both the handle grips and the seat covering were articles before assembly of the bicycle and are still articles. The “once an article, always an article” principle is thus applicable to them. If any of them contain more than 0.1% of a Candidate List substance, information about this must be provided.

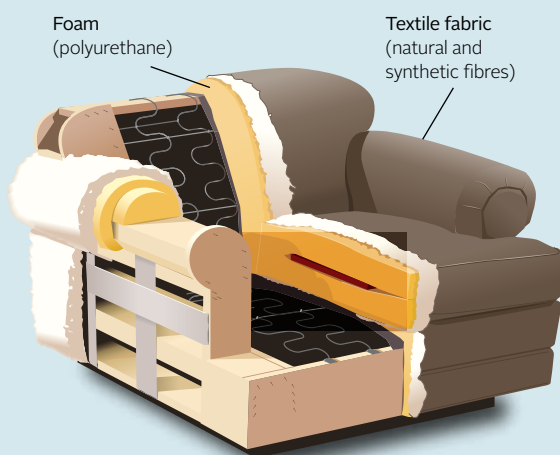
ACCESSING INFORMATION

A probability analysis might tell e.g. the following: *The saddle, handle bar grips, cables and pedals* can be produced from soft plastics which may contain e.g. plasticisers (e.g. phthalates). *The tyres, pedals and friction pads* can be produced from rubber which may contain plasticisers, flame retardants and other substances from the Candidate List. *Frame, wheels and gears* are produced from metallic materials. Some of those articles are painted. The pure metal articles are less likely to contain a Candidate List substance. Coating paints could however contain such a substance, or it might be used in the surface treatment process, for instance for corrosion inhibition (such as sodium chromate, potassium chromate, and acids generated from chromium trioxide). *Prism reflectors* produced from rigid plastics may also contain Candidate List substance, for example in the pigment used. After the probability analysis has been made, questions can be sent up the supply chain with special focus on the most probable articles and substances.

PROVIDING INFORMATION

The information obtained from the supplier can be passed on. As a minimum, the names of the substances and of the articles in which they are contained must be submitted:

“The handle grips contain bis (2-ethylhexyl) phthalate (DEHP).
The plastic cover of the seat contains dibutyl phthalate (DBP).”



Sofa

Preconditions:

- ▶ The upholstered sofa is assembled from a few articles produced from different materials.

Not known when the work to access information starts:

- ▶ The sofa covering is cut from textile fabric that contains 0.17 % hexabromocyclododecane (HBCDD) with CAS no 25637-99-4.
- ▶ The cushion foam block is cut from a bigger polyurethane foam block that contains 0.2 % tris (2-chloroethyl) phosphate with CAS no 115-96-8.

APPLYING THE TRIGGER LIMIT

Before assembly of the sofa the fabric was already an article. Cutting the fabric into pieces with different shapes does not change the function as an article. Thus, information about any contained Candidate List substance can be submitted for the fabric as specific article. The same apply to the cushion foam, which also was an article before the assembly.

ACCESSING INFORMATION

The first step is a probability analysis. The materials used can help to identify which Candidate List substances that are most likely to be found in the articles of the sofa. It may also lead to the conclusion that some Candidate List substances are very unlikely to be found. For example, the textile fabric and the cushion foam may contain flame retardants such as HBCDD. Textiles or synthetic skin may be based on polymers such as PVC, which may for example contain pigments, and plasticisers such as phthalates. The probability analysis may lead to questions up the supply chain on whether the textile fabric or the cushion foam contain any Candidate List substances with special focus on HBCDD, Tris (2-chloroethyl) phosphate, or phthalates, which all are on the Candidate List.

PROVIDING INFORMATION

The information obtained from the supplier can be passed on. As a minimum the following information must be submitted:

“The cushions of the sofa contains tris(2-chloroethyl)phosphate and the fabric contains hexabromocyclododecane (HBCDD)”

4.3 Articles consisting of an article and a mixture

A substance or a mixture, which is added to an article during production, does not fulfil the definition of an article. Thus, the trigger limit with respect to any Candidate List substance in an added substance or mixture applies to the article that has been treated (coated, painted, etc.) with the substance or mixture. The examples below of a coated cable and a printed t-shirt are used to demonstrate this.



Coated cable

Preconditions:

- ▶ The cable is for professional use and consists of a core of copper wire with a PVC coating. The copper wire is an article before production of the cable, while the PVC is a liquid mixture.
- ▶ The cable is in this case produced by spraying the liquid PVC on the copper wire.

Not known when the work to access information starts:

- ▶ The PVC used in the coating contains 40% Benzyl butyl phthalate (BBP) with CAS no 85-68-7.

APPLYING THE TRIGGER LIMIT

The PVC coating contains BBP but the coating was a mixture before production of the cable. The first article that contains BBP is the cable. The first article that contains BBP is the cable. Thus, in this case the 0.1% limit should be applied to the whole cable. If the PVC coating constitutes 10% of the weight of the cable, the fictive average BBP concentration in the cable will be 4% ($40\% : 10 = 4\%$), that is above 0.1%. Information thus has to be provided for the BBP content in the cable.

ACCESSING INFORMATION

The producer of the cable should automatically obtain a Safety Data Sheet (SDS) from the supplier of the liquid PVC. The SDS should inform about the content of BBP, including a concentration interval. A small probability analysis may lead to the conclusion that it is unlikely that also the copper wire contains a substance on the Candidate List.

PROVIDING INFORMATION

As a minimum the following information must be submitted to recipients:

“The cable contains benzyl butyl phthalate (BBP).”



Printed t-shirt

Preconditions:

- ▶ The t-shirt has a print. The raw material for the print is delivered to the production site as liquid paint in different colours.

Not known when the work to access information starts:

- ▶ The paint contain 30 % Bis (2-ethylhexyl) phthalate (DEHP) with CAS no 117-81-7. The content of DEHP in the t-shirt is 0.15 %.

APPLYING THE TRIGGER LIMIT

The paint was a mixture and not an article before production of the T-shirt. The first article that contains DEHP is the T-shirt. Thus, in this case the 0.1% limit with respect to the DEHP content has to be applied to the T-shirt with the print. The weight of the paint is 0.5% of the weight of the T-shirt. The average DEHP concentration in the T-shirt thus will be 0.15%, which is still above 0.1%.

ACCESSING INFORMATION

If the T-shirt is produced in the EU, the producer should automatically obtain a Safety Data Sheet (SDS) from the supplier of the liquid paint, telling that it contains DEHP and giving a concentration (interval). If the T-shirt is imported, the importer will have to ask his non-EU-supplier for information. A probability analysis may e.g. lead to the importer asking whether the print contains any Candidate List substances and specifically any pigments or phthalates on the Candidate List.

PROVIDING INFORMATION

As a minimum the following information need to be submitted to recipients/consumers:

“The t-shirt contains bis (2-ethylhexyl)phthalate, (DEHP).”

4.4 Very complex articles consisting of several assembled articles as well as mixtures

A Desk top computer (PC) is used here as an example. The example starts off with 1) the electronic articles, goes on with 2) a printed circuit board (PCB), and finishes with 3) the whole PC. In this way, the example considers certain segments of the production chain of the PC.



Electronic articles

Preconditions:

- ▶ a) Hole mounted capacitor. It is covered by a plastic layer made from a polymer mixture with additives and is later on soldered or glued to a PCB.

Not known when the work to access information starts:

- ▶ The covering plastic layer contains dibutyl phthalate with CAS No 84-74-2.

APPLYING THE TRIGGER LIMIT

The covering plastic layer has never existed as an individual article. The trigger limit must thus be applied to the whole article; i.e. the capacitor.

ACCESSING INFORMATION

If the article is produced in the EU, the producer should automatically obtain a Safety Data Sheet (SDS) from the supplier of the mixtures, providing information on if it contains a Candidate List substance and giving a concentration (interval). If the article is imported, the importer will have to ask his non-EU-supplier for information. A probability analysis may e.g. lead to that the importer focus on whether the article contains any of some named substances.

PROVIDING INFORMATION

For the capacitors, at least the name should be submitted from the producer to his customer:

“The capacitor contains dibutyl phthalate”



A printed circuit board

Preconditions:

- ▶ The printed circuit board (PCB) consists of a plain layered board with printed wires, electronic articles, operational facilities which often are fastened with solders or glue.
- ▶ Both the PCB and the added articles and mixtures consists of a series of different materials. E.g. rigid and soft plastics, metals, ceramics, glass etc.

Not known when the work to access information starts:

- ▶ The hole mounted capacitors (same as above) contain dibutyl phthalate with CAS No 84-74-2.

APPLYING THE TRIGGER LIMIT

The fact that the PCB is assembled from many small articles does not change the requirement that the trigger limit must be applied to any object within the PCB that is identified as an article. The large number of articles (such as various electronic articles, the fan, the board itself, etc.), and that many of them are soldered and/or glued to the PCB, may, however, make it a challenge to determine which of them that existed as articles already before production of the PCB.

For some electronic articles it may be possible to identify the individual mixture(s) used for its production (c.f. above) and the quantity of a Candidate List substance in the mixture(s), and by this know the concentration, or be able to calculate it. The limit will have to be applied to the electronic article (component) to which the mixture(s) was added.

PROVIDING INFORMATION

In this case any information often relates to more than one article (component) of the same kind. As a minimum the name of the Candidate List substance should be provided:

“The capacitors contain dibutyl phthalate”

Desktop computer

Preconditions:

- ▶ The computer is assembled from a large number of assembled articles with different functionality. There are larger articles as the screen, the casing, the cables etc. There is also a large amount of smaller articles mainly used for the electronic parts in the computer and the accessories (mouse, keyboard).
- ▶ Candidate List substances may potentially be present in several of the articles within the computer (as well in the electronics, as in the housing and cables).

Not known when the work to access information starts:

- ▶ In this case, the hole mounted capacitors (same as above) on the mother board as well as the mouse cable contain dibutyl phthalate (DBP) with CAS no 84-74-2.



GENERAL ABOUT VERY COMPLEX ARTICLES

In essence, such articles should be handled by the same principles as other assembled articles. The trigger limit is applicable to all objects identified as articles, since there is no lower limit in REACH regarding size of the article. The practical difference is the large amount of articles and the time that may be needed to obtain the relevant information. To find reasonable starting and end-points for gathering information on complex articles like the PC, the solution is to proceed applying a systematic strategy. Below, an example of such a strategy is presented.

APPLYING THE TRIGGER LIMIT

It must be applied to any objects within the PC identified as articles.

ACCESSING INFORMATION

A systematic strategy for accessing (and providing) information: Such a strategy may be rather similar for producers and importers. A producer of a PC, however, often has a stronger position to demand full information (for all the articles he purchases separately), while an importer may initially have only one (non-EU) supplier to contact.

EXAMPLE OF CONTENTS OF A SYSTEMATIC STRATEGY:

1. Make a list of the articles in the computer.
2. Make a probability analysis, that is for each article consider the material(s) used, the probability of that it may contain Candidate List substances, and if so, which one(s).
3. Send appropriate requests to the contact person(s) of the supplier(s)

4. Collect incoming data in an appropriate system/first make one if not already in place¹⁴
5. Validate and where needed complement or check the information
6. Provide information on contents of Candidate List substances to customers
7. Regularly check each step in the strategy, and revise if needed.

EXAMPLE OF WHAT A PROBABILITY ANALYSIS MAY TELL:

Such an analysis may comprise considerations on which articles may probably contain which materials, which of these may probably contain Candidate List substances, and which ones (c.f. Chapter 3):

Materials	Substances/mixtures that may be expected	Examples of Candidate List substances that may be contained (not exhaustive)
Metal (mostly)	Several substances used for metal surface treatment	Sodium chromate, potassium chromate, acids generated from chromium trioxide (such as chromic acid and dichromic acid)
Plastic, rubber and resins	Flame retardants and plasticisers	HBCDD, short chain chlorinated paraffins (alkanes, C ₁₀₋₁₃ , chloro), bis(2-methoxyethyl) phthalate, BBP, DBP, DEHP
Electroplating/coating		Cobaltdichloride

EXAMPLES OF POTENTIAL QUESTIONS TO SUPPLIERS ON CONTENTS OF CANDIDATE LIST SUBSTANCES:

1. Do plastic articles, e.g. internal cables, cords or connectors contain more than 0.1% (w/w) of any substance on the [Candidate List](#), such as flame retardants or plasticisers?¹⁵
2. Does the coated or surface treated casing or other metal articles contain more than 0.1% (w/w) of any substance on the [Candidate List](#)?
3. Does any of the electronic articles on the system board contain more than 0.1% (w/w) of any substance on the [Candidate List](#)?
4. Does the system board itself contain more than 0.1% (w/w) of any substance on the [Candidate List](#), such as flame retardants or plasticisers?

¹⁴ Note that producers of computers often already have in-house information systems for substances in their articles and their own sector specific guidance.

¹⁵ Since the "Once an article always an article" principle is applied, there is no need to know factual concentration of the substance and the weights of the articles, nor to calculate a fictive average in the whole PC. This may save a lot of efforts.

PROVIDING INFORMATION

Passing on information is handled in the same way as for more simple articles.

Any information on contents of Candidate List substances should be passed on as soon as it is obtained. As a minimum, the name of the substances and where they are contained need to be provided, e.g.:

“The capacitors (on the mother board) and the mouse cable contain dibutyl phthalate (DBP)”

4.5 Applying the duty to notify ECHA (art. 7.2)

Checking of if the 1 ton trigger limit is exceeded¹⁶



Kitchenware

Preconditions:

- ▶ A company imports kitchenware into EU, in this case 200 000 frying pans and 450 000 sauce pans per year. The pans have a non-stick layer.

Not known when the work to access information starts:

- ▶ The pans contain more than 0.1% PFOA with CAS No 335-67-1, which is still (May 2013) on the registry of intention list, why at this moment there is no obligation to provide the name of this substance or to notify ECHA. Though since PFOA might soon be added to the Candidate List, the company may prefer to do the work below in advance.

THE FOLLOWING STEPS NEED TO BE TAKEN:

1. Check which article of the frying pan and sauce pan that contains more than 0.1% of the Candidate List substance.
2. For each such article check the weight of the Candidate List substance. If this information cannot be obtained from the supplier, it may be necessary to conduct an analysis as a last resort.
3. Calculate total weight of the substance for each article of the frying pans and sauce pans and add up to a total weight:

¹⁶ Art. 7.2 requires any producer or importer of articles to send a notification to ECHA if all his articles – irrespective of category – taken together contain more than 1 ton/year of a Candidate List substance. Only articles where the content exceeds 0.1% have to be counted, however. The example with kitchenware is a simple one.

THE WEIGHT OF THE PFOA IN THE ARTICLES, THE TOTAL WEIGHTS, AND THE PFOA CONCENTRATIONS ARE:

- ▶ Frying pan as individual article without the grip – PFOA 3 grams;
Total weight 1,8 kg; Concentration $3/1800 = 0,17\%$
- ▶ Sauce pan without the lid and the grip – 1 gram; Total weight 0,5 kg;
Concentration $1/500 = 0,2\%$

The total amount of PFOA in these articles is:

- ▶ Frying pan (200 000 pcs) * 3 grams = 0.6 tonne
- ▶ Sauce pan (450 000 pcs) * 1 gram = 0.45 tonne

Total amount in all articles = 1.05 tonne. Thus, a notification to ECHA must be made no later than six months after the date when and if PFOA is included in the Candidate List, unless an exemption in Article 7.3 and 7.6 can be applied.

Remarks: It is up to the supplier to check whether a notification to ECHA must be done because the 1 ton trigger limit is exceeded, or if any of the exemptions (in Articles 7.3 and 7.6) apply. It should be noted that it will often be less burdensome to make a notification, than to check if the 1 ton trigger limit is not exceeded and/or document that the exemption in Article 7.3 (no exposure) or 7.6 (the use in the article is already registered) applies.

5 ■

Routines and tools to access, store, and provide information

The work to keep track of contents in articles will increase with more substances on the Candidate List, and with increased complexity of the articles. Many companies and sectors would most certainly benefit from establishing systematic approaches for applying the REACH information duties. This Chapter gives some advice on systems, routines and tools that may be used for this.

5.1 Routines and tools to access information

GENERAL QUALITY MANAGEMENT SYSTEMS

The single most important action to ensure workability of the REACH information provisions is to have a general quality management system. If such a basic system is already in place of other more general reasons, it may be relatively easy to add or adapt a part of it to include also the REACH information provisions. Less effort will then be needed to obtain the required information.

Such quality management systems can be more or less advanced and may for example include supplier audits, third party certifications and product tests performed in-house.

ROUTINES AND TOOLS FOR REQUESTING INFORMATION FROM SUPPLIERS

In the absence of a general quality management system it is crucial to establish specific routines and tools for accessing information on Candidate List substances in purchased articles. It is beneficial to apply such routines already during planning, procurement and contract writing stages. At those stages, suppliers – in the role of customers to other suppliers – will normally have the best position to access the needed information.

Product development is an extra reason to ensure access to clear information on Candidate List substances in substances and mixtures (e.g. such as a certain plastic material) and articles considered for the new products. This is because such substances are inclined to be subject to REACH authorisation or possibly restrictions, which may result in that the present use will no longer be allowed in the near future. Checklists for product development may be advantageous.

Criteria and standard letters can be used as tools in procurement and purchasing situations. Simple tools in the form of standard letters or templates for suppliers' declaration of Candidate List substances in articles have been developed by some industry associations and are available online and in guidance documents. Any company can also develop its own standard letter. Contracts or other written agreements can also be used, as well as product tests and third-party information. Conducting broader supplier audits – as part of quality management – may help to ensure that information provided by suppliers will be correct.

If EU-suppliers seem unaware of their obligations and do not automatically provide information on whether Candidate List substances are contained, it may be necessary first to inform them about their obligations. Non-EU suppliers have no such obligations, but would often for business reasons be willing to provide information. However, they may need to be informed about the obligations that EU companies must comply with.



EXAMPLES OF TOOLS FOR THE WORK:

- ▶ Checklists for product development
- ▶ Criteria and standard letters to use in procurements
- ▶ Contracts/written agreements
- ▶ Third party certifications
- ▶ Supplier audits
- ▶ Product tests from suppliers

5.2 Systems for storing data

Some sectors with very complex articles, such as cars and electronics, have already developed data systems and tools to obtain, store, and communicate information about substances in articles. Such systems help the companies within the sector to manage the information in the supply chains, and may facilitate work caused by inclusion of more substances into the Candidate List. Most probably also many other sectors (and companies) may benefit from developing some kind of information system on an appropriate scale, especially where many and/or very complex articles are handled.

Sector specific industrial organisations may certainly help their members by developing sector specific templates for obtaining, storing and passing on information and also by publishing lists of the most probable Candidate List substances in their sector.

5.3 Tools and formats for providing information

REACH do not specify how the information for safe use shall be transmitted and presented. More tools for this are available for communication of information to recipients, than to consumers. Besides, recipients have the right to automatically obtain the information, while consumers have a right to obtain it on request only. These differences may affect which tool is most suitable.

RECIPIENTS

Which tool or format that is most appropriate for transmitting or presenting the information may vary a great deal. It may depend on factors such as who is the recipient, what information needs to be provided, specific questions submitted by the recipient. The following are some examples:

- ▶ Standard response letters
- ▶ Modification of existing documents (*such as use instructions, packaging inserts*)
- ▶ Material declarations
- ▶ Product data sheets (*not to be mixed up with safety data sheets*)
- ▶ Product catalogues
- ▶ Link to a company website with specific and up-to-date information
- ▶ Information in databases with certain external access (*can be shared within a sector*)
- ▶ RFID tags/chips to be read electronically at a distance¹⁷

The example below of a simple standard response letter contains only a minimum of information.

As already said in section 3.6, the recipient may need more information than that to be able to decide on measures for safe use, as required by REACH. Suppliers must thus in the individual case assess whether further information needs to be provided.

¹⁷ *Remark:* can be extremely small and are used extensively by certain companies. However, standardisation problems remain.

Customer information on the REACH Regulation & The Candidate List

Dear Sir or Madam,

With respect to the so-called Candidate List with substances of very high concern as published by ECHA, we hereby confirm as follows:

The following listed substances are used in our articles:

- ▶ *The textile contains a flame retardant called HBCDD (hexabromocyclododecane).*
- ▶ *The bed mattress contains DEHP (bis (2-ethylhexyl) phthalate) in a covering sheet.*

Yours sincerely

XXXX

CONSUMERS

To fulfil the duty to provide consumers with information that allow safe use, it is important to ensure that it will be understood by individual consumers. It is also important to observe the maximum 45 days response period. For example, the following will be important:

- ▶ Confirmation of receipt of a request from a consumer
- ▶ Responding in the same language as the request was made
- ▶ Avoiding technical language and terms as far as possible

Some examples of possible formats:

- ▶ Standard response letters (via e-mail or surface mail)
- ▶ Modification of existing documents (e.g. use instructions, packaging inserts)
- ▶ Information on labels

6.

Concluding remarks

6.1 Summary

The following is a shortlist of some of the most important pieces of advice to remember:

- ▶ If there is more than 0.1% w/w of a Candidate List substance in an article, information about this must be provided irrespective of if the article is sold separately or is included in an assembled article.
- ▶ The information will communicate where the substance is contained, if it is contained in an article within an assembled article, and can simply be passed on down the supply chain.
- ▶ When accessing information from own suppliers it will help to use a probability approach. This enables focusing on the articles that most probably contain Candidate List substances, and on the substances most probably used in those articles.
- ▶ A stepwise work procedure may also help. This applies particularly if the supplier deals with many and/or very complex articles.
- ▶ The information received needs to be validated, and where needed complemented via further questions to own suppliers, or even analyses.
- ▶ Cooperation within sectors will facilitate the work triggered by the REACH information duties, not the least to find out which substances may most probably be contained.
- ▶ It is crucial also to have good routines and tools for the work triggered by the REACH information duties. The benefit of this increase with more substances on the Candidate List. It also increase if the supplier deals with many and/or very complex articles.
- ▶ To have a general quality management system facilitates any work triggered by the REACH information duties, and is the single most important action to ensure workability.
- ▶ It is crucial to observe closely the substances continuously added to the Candidate List, since the duty to inform customers enter into force immediately at listing.

6.2 Benefits from following the approach in this Guidance

This is a summary of benefits for suppliers if the trigger limit – in line with this Guidance – for assembled articles is applied on included articles, and not on the whole assembled article¹⁸.

The benefits apply especially to the many suppliers that in fact are recipients of articles as well, such as most producers of assembled articles, wholesalers, and retailers.

REACH-COMPLIANCE ON THE ENTIRE EU MARKET

By fulfilling the duties in this way, suppliers will ensure compliance with the information duties on the entire EU market.

SIMPLER WORKING PROCESSES AND INCREASED EFFICIENCY

For assembled articles, there will be no need to access the exact concentration of the substance in included articles, or to know the weight of the included as well as the assembled article, and calculate averages. Instead, received information can normally just be passed on as received along the supply chain. Routines for checking compliance may be made more similar to those in place for various restrictions of substances in articles. For those, limits normally apply to included articles or materials. In summary, this allows for simpler and more robust systems for accessing and passing on information, and for checking compliance within the supply chains.

PREPAREDNESS FOR COMING USE LIMITATIONS/BANS

Clear information on contents of Candidate List substances in articles, including those included in assembled articles, allows preparing for coming use limitations/bans, to which such substances are inclined. Suppliers can take steps towards applying for authorisation or finding alternatives. Late and potentially costly surprises can be avoided by reliable access to information.

MORE CONSISTENT AND RELEVANT INFORMATION

If a Candidate List substance is contained in an article in a concentration above 0.1%, information should always be received, *irrespective* of if the article is purchased separately or is included in an assembled article, and *irrespective* of the weight of the assembled article. For assembled articles, the information will tell in which included article the substance is present. This allows the recipient to in a meaningful way consider exposure, risk, and suitable measures, leading to reduced risks for health and the environment.

¹⁸ See Annex I, which demonstrates the differences between the approaches, including why application of the limit on included articles results in a number of benefits.

MORE FAIR COMPETITION

The duties will in practice apply in the same way to all suppliers, irrespective of if they sell a certain article separately or in a package with other articles or included in an assembled article. In every case they need to pass on information if there is more than 0.1% of a Candidate List substance in the article. The duty to inform will not be influenced by irrelevant factors such as the weight of the other articles with which the article has been assembled, i.e. there will be no “dilution” effect causing information about the presence of a Candidate List substance to disappear somewhere on its way along the supply chain.

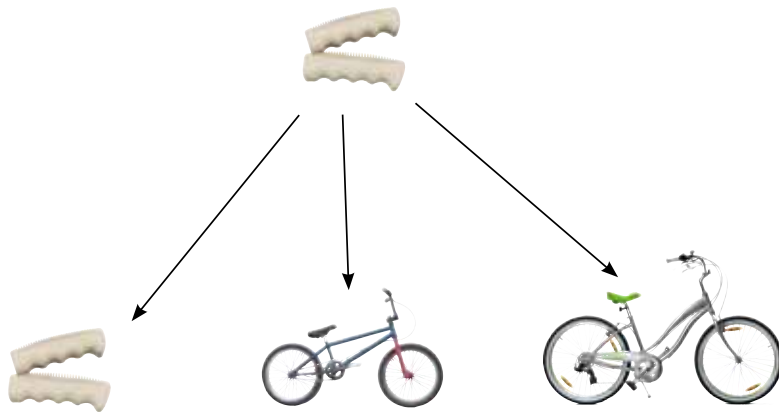
Annex 1.

Differences between the approaches to apply the 0.1% trigger limit

With the help of a bicycle the example below explains why application of the trigger limit in line with this Guidance (following the “once an article, always an article” principle) makes a major difference compared to application in line with the interpretation in ECHA’s Guidance.

Example: Differences between the approaches in the case of a bicycle (apply the limit according to this Guidance or to ECHA’s Guidance)

Preconditions: The bicycle weighs 13 or 16 kg depending on e.g. frame model. The two handlebar grips on the bicycle are always the same. Together they weigh 70 g and contain 14 g DEHP (20%).



INFORMATION THAT NEEDS TO BE ACCESSED BY SUPPLIERS

The most work consuming and difficult task is to first access information on if any Candidate List substance – and if so which – is contained in any of the articles purchased. There are clear indications that there are small differences between the approaches for that first task.

After that task, there are differences:

If the trigger limit is applied to included articles (i.e. according to the “once an article, always an article” principle)

Information from an own supplier of bicycles that the grips contain DEHP (more than 0.1%) can just be passed on to own recipients of the bicycles.

If the limit is instead applied to the whole assembled article (i.e. according to the interpretation in ECHA’s Guidance)

Extra work has to be done:

- ▶ access data on exact concentration of the substance in the grips (to access such information may often be difficult and sometimes even impossible for confidentiality reasons)
- ▶ access data on the weights of the grips and of the bicycle
- ▶ calculate average¹⁴ concentration in the bicycle, to be able to check if this is above 0.1%

The extra work may result in that no information has to be provided (i.e. the recipient or the consumer will not be informed), or that after all, information must be provided in spite of the extra work to check if this potentially might be avoided.

19 This will be a quite imaginary average concentration. In reality, DEHP is present only in the grips.

INFORMATION THAT MUST BE PROVIDED TO RECIPIENTS AND CONSUMERS

If the trigger limit is applied to included articles (i.e. according to the "once an article, always an article" principle)

- ▶ If the grips are sold separately as spare parts, information about the DEHP must be provided.
- ▶ If the grips are attached to a bicycle, information about the DEHP must be provided for all bicycles, irrespective of their weight.
- ▶ The information will for all bicycles tell where the DEHP is contained (in the grips). This opens for considering exposure/risk and suitable measures in a meaningful way.

(Remark: that the grips contain DEHP is relevant information when considering exposure)

If the limit is instead applied on the whole assembled article (i.e. according to the interpretation in ECHA's Guidance)

- ▶ If the grips are sold separately as spare parts, information about the DEHP must be provided.
- ▶ If the grips are attached to a bicycle, information about the DEHP must only be provided for the light bicycle, but not for the heavy bicycle. This is in spite of the fact that the grips are the same, and thus leads to random information.
- ▶ Where information is given (i.e. only for the light bicycle), it will not tell where the DEHP is contained. This makes it much harder or impossible to consider exposure/risk and suitable measures in a meaningful way.

(Remark: the weight of the bicycle and the average¹⁵ concentration of DEHP is totally irrelevant information when considering exposure, but in this case steers whether information will be provided or not).

Remark: Most suppliers are also recipients of articles. In their role as recipients they will get less, and less useful, information if their own suppliers choose to apply the limit on whole assembled articles.

²⁰ This will be quite an imaginary average concentration. In reality, the DEHP is of course not evenly distributed in the whole bicycle, but all remains in the grips.

Annex 2. Glossary

Annex XIV	Annex XIV of REACH lists all substances which are subject to authorisation under REACH.
Annex XVII	Annex XVII of REACH contains a list of restrictions on the manufacture, placing on the market, and use of certain dangerous substances, mixtures and articles.
BBP	Benzyl Butyl Phthalate. BBP is mainly used as an additive for plasticising PVC or other polymers.
CAS no	CAS registry numbers are unique numerical identifiers for chemical elements, compounds, mixtures etc. Registration numbers are given by the Chemical Abstract Services (CAS), Columbus, Ohio.
C.I.	Colour Index. The Color Index (C.I. or CI) is a list of identification numbers and names given to individual substances used as pigments and dyes.
CMR	Chemical substance that is Carcinogenic, Mutagenic and toxic to Reproduction.
DBP	Di-Butyl Phthalate. DBP is mainly used as an additive for plasticising PVC or other polymers.
DEHP	Di-Ethyl Hexyl Phthalate. DEHP is mainly used as an additive for plasticising PVC or other polymers.
ECHA	European Chemicals Agency
HBCDD	HexaBromoCycloDoDecane. HBCDD is a flame retardant mainly used in foam based polymers and textile materials.
MS	Member State in the EU/EEA.
PBT	Chemical substance that is Persistent, Bioaccumulating and Toxic.
PCB	Printed Circuit Board. A PCB is a thin board with electrical wires “printed” on the surface. Electrical components are mounted and connected to each other on the board.
PFOA	PerFluoroOctanoic Acid. PFOA is a synthetic chemical substance with special properties and hundreds of manufacturing and industrial applications. It is very persistent in the environment.
PVC	Poly Vinyl Chloride. PVC is a polymer in which more than half of the content by weight consists of chlorine. Plasticisers are often added to PVC to make it soft and pliable.
RFID	Radio Frequency Identification: Any method of identifying unique items using radio waves. Typically a transponder, which holds digital information.
SDS	Safety Data Sheet.
SVHC	Substance of Very High Concern
vPvB	very Persistent and very Bioaccumulating substance.



BELGIUM
Belgian Federal Public Service, Health,
Food Chain Safety and Environment



GERMANY
Federal Institute for Occupational
Safety and Health



Danish Ministry of the Environment
Environmental Protection Agency

DENMARK
Danish Environmental
Protection Agency



FRANCE
Ministry of Ecology, Sustainable
Development and Energy



NORWAY
Norwegian Environment Agency



SWEDEN
Swedish Chemicals Agency