

Information from the German National Helpdesk on

"Once an Article - Always an Article" Fulfilment of the notification and information obligations concerning candidate substances in articles

as at: September 2012

This information is intended to provide a specific guide to article importers and producers in implementing in practice the "Once an Article – Always an Article" approach supported by Germany. It is concerned primarily with the information and notification obligations for substances of very high concern in the case of assembled (complex) articles consisting of single articles.

REACH-CLP Helpdesk

National Helpdesk of the Federal Authorities

Two Regulations – One Helpdesk

established at the Federal Institute for Occupational Safety and Health (BAuA)

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Introduction

With coming into force of the REACH Regulation (EC) No. 1907/2006 information and notification obligations were introduced for producers, importers and suppliers of articles. These obligations relate to substances of very high concern (in short: **SVHC**) which have been identified as candidates for the authorisation procedure (hereinafter called candidate substances).

A **notification obligation** becomes necessary under Article 7 (2) towards the European Chemicals Agency (ECHA) if a company produces or imports articles which contain candidate substances in concentrations above 0.1% and with which the quantity of one tonne per year totalled for all articles is exceeded.

In addition **information obligations** apply under Article 33 towards customers if such a substance is present in concentrations of more than 0.1%. This applies regardless of the tonnage.

The meaning and purpose of these regulations, especially of the information obligations pursuant to Article 33, is to create transparency with regard to the candidate substances placed on the market in the whole supply chain and to ensure a safe use of the articles.

There are two core questions that arise from the obligations mentioned:

- When is an object an article?
- What is the reference for the 0.1% threshold in the case of assembled articles which consist of different/individual articles?

The first question can normally be answered on the basis of the definition of an article in the REACH Regulation and the decision-making aids in the ECHA guidance¹. On a European level there are hardly any differences here, at least between the member states.

The situation is different with respect to the reference to be used for the identification of the concentration of the candidate substance in assembled articles. The European Commission and the majority of the EU/EEA member states consider every article, including assembled ones, as a single article. In contrast a number of member states², including Germany, take the position that an article which has been incorporated into an article does not lose its character as an article due to the incorporation ("Once an Article – Always an Article"). This means that the concentration of the candidate substances in the first case is related to the assembled article and in the second case to each single article incorporated.³

In some cases the practical implementation is difficult with regard to the reference for the concentration of candidate substances and how the single article can be distinguished in

¹ Guidance of requirements of substances in articles published 1 April 2011 (http://guidance.echa.europa.eu/docs/guidance_document/articles_en.pdf)

² Austria, Belgium, Germany, France, Sweden, Denmark and Norway

³ Note: In the case of restrictions according to Annex XVII of the REACH Regulation the specific entry in Annex XVII is crucial in determining the reference.

relation to the assembled article. This information is intended to describe possible ways of dealing with this question and to indicate possible approaches to concrete implementation, which must be adapted to the individual case however. Furthermore there will be cases where strategies other than those described here are needed.

"Once an Article – Always an Article"

First of all the principle of "Once an Article – Always an Article" will be scrutinised more closely.

The REACH Regulation defines an article as "*an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition*". More detailed definitions are not available. **Germany** as well as **Denmark, Austria, France, Belgium, Sweden** and **Norway** therefore take the position that an article produced does not lose its character as an article after it is incorporated in an assembled article (see "Note to the Reader" in the ECHA Guidance⁴). In brief one speaks of the principle of:

"Once an Article – Always an Article" = 1O5A

This interpretation applies to each single article within an assembled article which fulfils the definition of article. And in this way the single article is the reference for the 0.1 % threshold which triggers the information and notification obligations in relation to candidate substances.

The following are examples of single articles:

- belt buckles
- bicycle grips
- shoe soles
- computer casings

The ECHA guidance holds the view that the article as supplied is the reference for the 0.1% threshold, regardless of how many articles and of which single articles it is made up. This means with regard to the examples mentioned that the concentration of a candidate substance relates to the whole belt, the bicycle, the shoe or the computer.

In the view of the EU/EEA member states who do not share this position the principle of "Once an Article – Always an Article" and the resulting information transmission for single articles yields in a number of major advantages:

- The interpretation is in direct accordance with the legal text.
- Basic objectives such as the protection of people and the environment and transparency are achieved in the supply chain.

⁴ Guidance of requirements of substances in articles published 1. April 2011 (http://guidance.echa.europa.eu/docs/guidance_document/articles_en.pdf)

- The producer of an assembled article may pass on directly the information obtained on single articles (without additional calculations). A calculation relating to the assembled article is mostly not possible since a precise indication of the concentration of the candidate substance is not specified by law.
- Consumers who refer to Article 33 (2) obtain detailed information of the single article containing a candidate substance. Therefore it is substantially easier for them to make their own risk estimation and to make a purchasing decision.
- If for imported assembled articles the information available on candidate substances in the single articles is not adequate, a chemical analysis becomes necessary, which may be easier for single article compared to the one of the assembled article.
- Producers of articles and importers of articles resident in the EU are subject to the same obligations. The importer does not profit from the "dilution effect" with regard to the concentration of a candidate substance in an assembled article. In the supply chain it is known that an article contains a candidate substance. This means that the different actors involved along the supply chain are informed that after inclusion of the candidate substance in Annex XIV it is possible that no authorisation will be granted for a certain use of the candidate substance. The article concerned therefore does not simply "disappear" from the market without prior warning.

Fulfilment of the notification and information obligations for articles

The basic notion of the REACH Regulation is that the information on candidate substances is passed on within the supply chain (in the EU) by the substance manufacturer to the user of an article containing such a substance in. The substance manufacturer must provide a safety data sheet (SDS) and the formulator who uses this substance must also include appropriate information in his SDS. The producer of an article will thus obtain the information on the candidate substance via the SDS and can pass this to his customers.

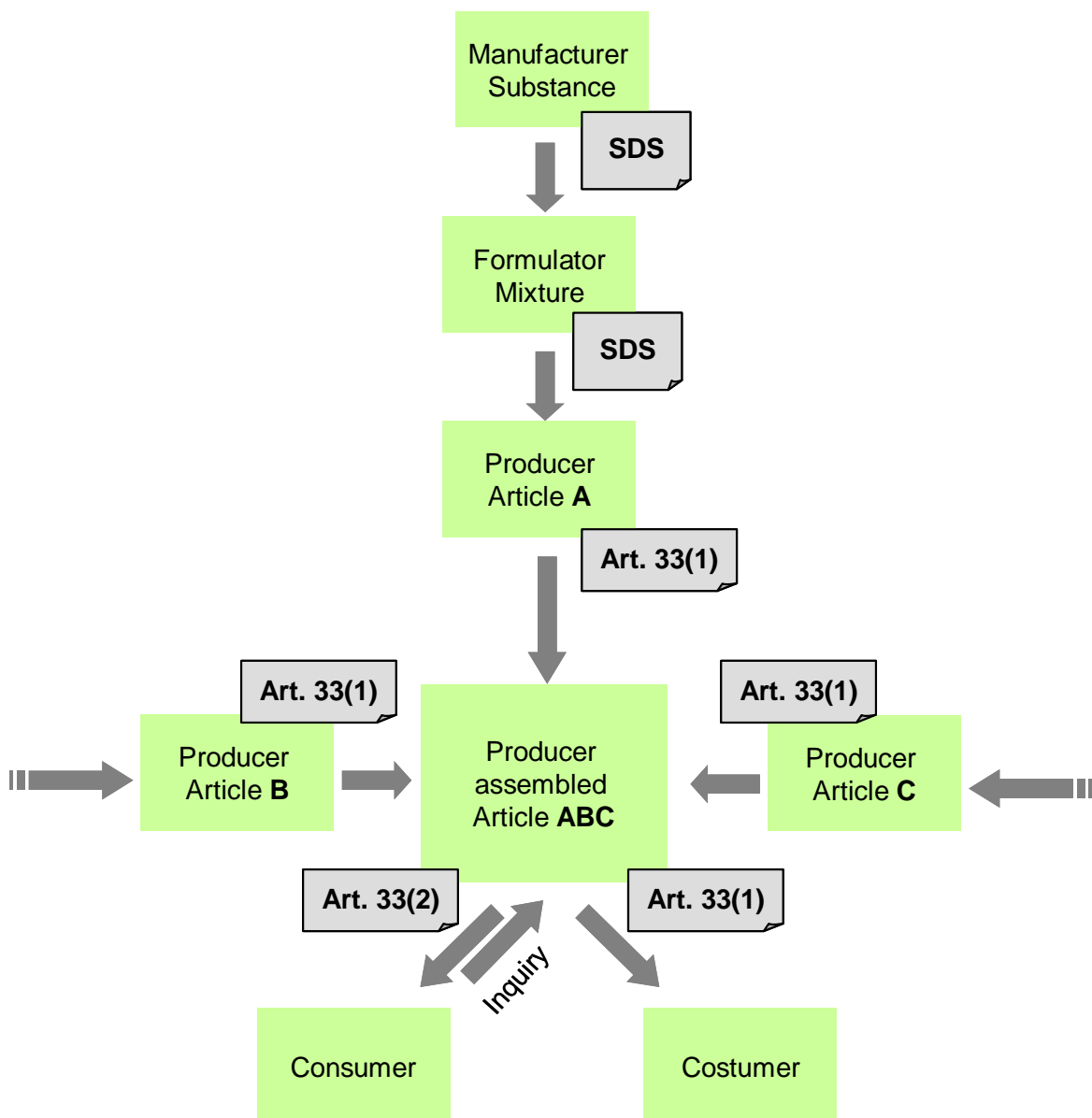


Figure 1: Information flow on candidate substances in a supply chain within the EU.

Under certain conditions, however, producers of assembled articles or importers may experience difficulties in passing on information and hence also in fulfilling the statutory obligations:

- Information obligations pursuant to Article 33 are not known in the supply chain.
- Supplies take place between EU member states with differing consideration of the reference for the 0.1% threshold.
- Import from outside the EU.

In the following, a possible procedure is described which from the point of view of the German REACH-CLP Helpdesk should be followed by an article producer or importer to fulfil the notification or information obligations with respect to articles. **This means that, on the basis of the principle "Once an Article – Always an Article", the single article is used as a reference and not the assembled article.** Additional cases are considered where no statement can be made about the presence of a candidate substance because:

1. There is no information available on candidate substances.
2. The information "no candidate substance >0.1%" is available, but it relates to the assembled article.

Import / production of articles

The question about the concentration of candidate substances in articles is unequally difficult to answer in relation to the different situations - **production** within Germany or **import** of the article into Germany.

A **producer** of an assembled article in Germany already obtains from his EU suppliers of the single articles the information whether a candidate substance is present in such an article. In a positive case he can pass this information, e.g. "candidate substance A >0.1% in the bicycle grip", to the customer of the bicycle. This information can also be passed on in this form if the producer supplies the finished bicycle to an EU member state which uses the assembled article as a reference. In this case he is possibly passing on information which the EU member state would not need. The important thing here is that the German bicycle producer does not have any extra work in generating information on the assembled article. This is a major advantage. It would only be possible to a very limited extent for him to formulate statements on the assembled articles from the information of the pre-suppliers of the single articles. Since only the presence of the candidate substance >0.1% but **not its exact concentration** has to be communicated, he will normally only obtain from his suppliers the information that a candidate substance is present in the relevant quantity.

This means it would only be up to him to conduct the calculations of the concentration in relation to the assembled article and he may also have to rely on his own conducted tests on the single articles.

An **importer** of an assembled article may on the other hand be faced by major challenges. Import encompasses two different situations:

1. Import within the meaning of Article 3 Nr. 10 of REACH, i.e. import into the EU
2. Import of an article from another EU member state.

In the case of an import from outside the EU the importer might not receive any information on the candidate substances contained, unless he has settled this contractually with his supplier. The gathering of information is especially difficult if an assembled article is imported and it has already passed through a complex supply chain outside the EU.

In the case of an import from another EU member state the supplier is subject to the information obligations according to Article 33. But difficulties will arise when the assembled article is taken as the reference in this member state. So if the German importer only receives the information that there is no candidate substance with a concentration greater than 0.1 % in the imported article, he does not know whether this statement is also valid for the single articles.

Regardless of this, an importer of assembled articles should in any case check these articles for the **plausibility of the information given** by his supplier for these articles. In particular, he should consider the question of whether no information from the supplier on candidate substances or the supplier information "no candidate substance in the assembled article" can also be plausibly applied to the single articles contained within it.

In cases of doubt, if he obtains no further information or if he cannot exclude the possibility that candidate substances are present, there remains only an analysis of the incorporated articles.

Basic procedure for importers/producers

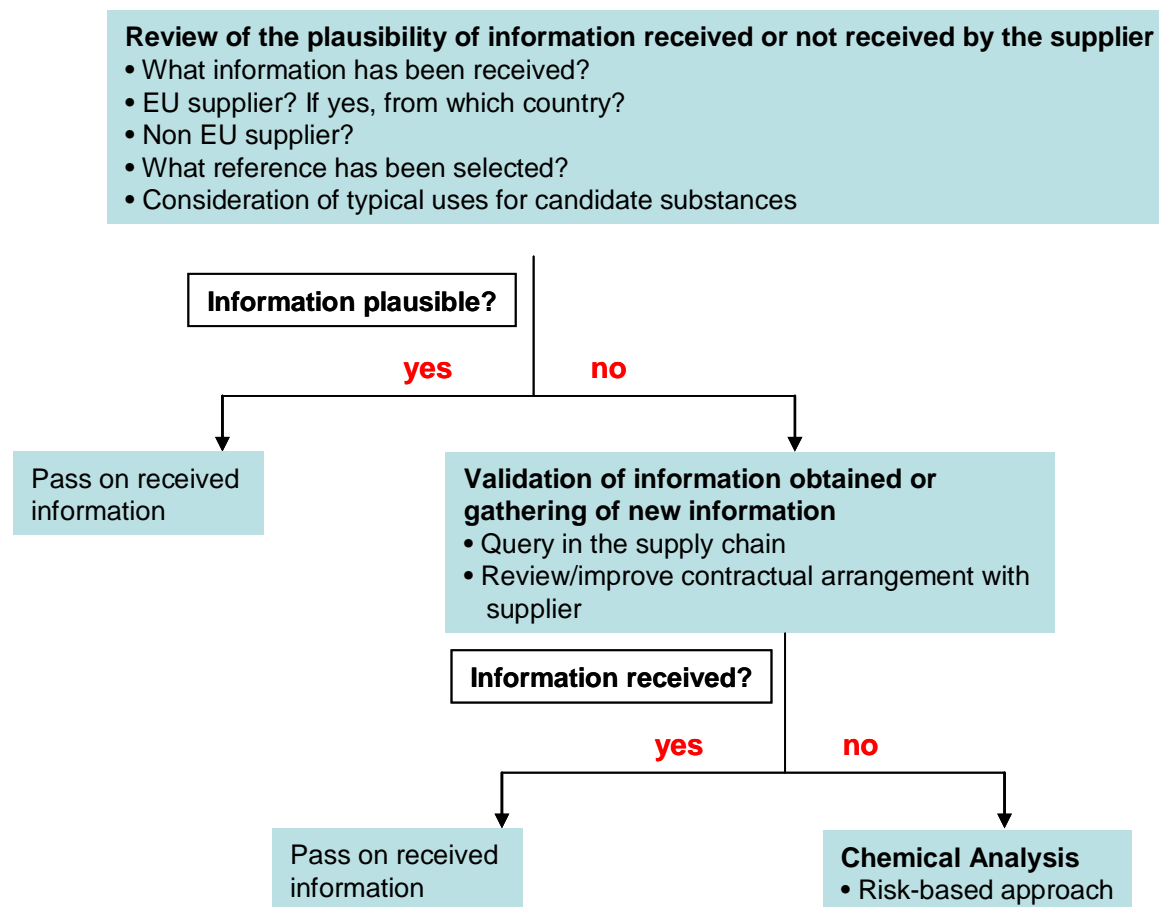


Figure 2: Outline of the principle procedure for the fulfilment of the notification and information obligations.

Review of information submitted by the supplier

- **Information on the concentration of candidate substances >0.1% is available** and the information is trustworthy. No need for further action, information can be passed on to the customer of the article.
- **Information on the concentration of candidate substances >0.1% is not available.** If no information is available, the producer/importer must decide whether this is plausible. It may mean that there are actually no candidate substances present in the article or the concentration in relation to the assembled article is <0.1%. But no information may also mean that the supplier himself does not have any such information, or he is not aware of his information obligations or does not comply with them.

Validation/gathering of information on candidate substances

If the article producer/importer concludes that the information he has received or the fact that he has not received any information is **not plausible** he must take actions. The first step should be to call on his supplier to make the necessary information available. The prerequisite for a legally compliant supply chain in the EU is - among other things - the fulfilment of the information obligations according to Article 7 (2) and Article 33 of the REACH Regulation. The non-EU supplier should also, in his own interest, make the necessary information available to the importer.

But since this does not work in every case the importer who passes on the article within the EU must take more efforts. For this purpose, he should first figure out the **probability** of the presence of a candidate substance in the single articles (**probability approach**). To avoid unnecessary analyses it is useful to obtain an overview of the possible uses of the substances in the current candidates list. This is because the uses of the candidate substances render their presence in certain materials highly probable. For instance, a plasticiser is possibly present in a bicycle grip of soft PVC, but not in the bicycle's metal frame. In particular, individual experience, researches, justified suspicions or indications of the presence of candidate substances will also play a role here.

The German REACH-CLP Helpdesk has drawn up a list of examples of typical uses for the candidate substances identified to date. This can be found using the link⁵ below. A certain use given in this list for a certain substance may, for example, justify further investigation or even the performance of an analysis where there is a suspicion. **However, if a use is not listed, it cannot be assumed that the candidate substance concerned cannot be present in the article.**

If there are ultimately justified suspicions (e.g. plasticiser in the bicycle grip) and there is no definitive answer to the question of whether a candidate substance is present to the extent of >0.1%, the article producer/importer has only the possibility of conducting his own analysis to fulfil his information obligations.

Analysis of candidate substances in articles

If the supplier of the article does not provide any satisfactory information on the possible presence of candidate substances or there is a suspicion that a candidate substance is present, an analysis is necessary.

If, as in Germany, the single article is taken as reference, this article is also analysed as such (e.g. bicycle grip of soft PVC). The analysis will then provide the value of the candidate substance in this article and **not** in the assembled article 'bicycle'.

⁵ <http://www.reach-clp-helpdesk.de/reach/de/Themen/Kandidatenliste/Kandidatenliste-Verwendung.html>

In the case of assembled articles which cannot be broken down into single articles without "destroying" them, a decision must be made in the **individual case** as to whether the possible presence of a candidate substance relates to the single articles which have, for example, been glued together, welded together or soldered together, or whether in this case the assembled article can also be taken as a basis. One example of this is the printed circuit board of a PC (see Figure 4 and explanatory notes). One possible procedure here could be to analyse the article separated according to materials. Furthermore, the concentration of candidate substances in relation to the respective material, such as plastic (where relevant, separated into rigid and soft plastics), metal and ceramics etc could be determined. Another strategy for certain assembled articles may be to compile components with identical function and to draw a conclusion about this group.

Possible procedure for the analysis:

- **Complete analysis:** All articles are examined for all candidate substances. This implies a high effort.
- **Probability analysis:** An approach where only the candidate substances which might probably be present in the single articles are analysed. It must be considered whether certain candidate substances may be present in view of the article's material properties, and also whether their use renders their presence probable.

Examples

Garden chair of plastic

A plastic garden chair cast in one piece is a single article. Candidate substances which may be present in it are, for example, plasticisers or flame retardants. In a positive case a declaration must be given to the purchaser that the concentration of a candidate substance present in the chair is >0.1%.

Sheath cable

This normally involves an article consisting of two materials, the actual copper wire and a PVC sheath. During manufacture the molten plastic is sprayed on the wire, which means that the question of a "PVC sheath" as an article in its own right does not arise. The reference for the concentration of plasticizer present in the PVC is therefore the **wire with the plastic sheath**.

If a plastic sheath is manufactured separately as an article and it is then pulled over a wire or cable (e.g. shrink-on tube), this is considered to be an assembled article of wire/cable and tube.

Bicycle

The situation is more difficult when considering an assembled article (e.g. a bicycle) which consists of a large number of articles made out of different materials. In such a case it seems to be useful to identify the different articles and divide them into material groups to obtain an initial overview:

- plastics/rubber: grips, tyre, hose, rear light etc.
- metals: frame, handlebars, rim etc.

For example, rubber/plastic articles are produced on their own, are clearly defined or visibly distinguished and can normally also be removed reversibly and remounted without "destroying" the bicycle. Therefore, information can be given about these articles (see Figure 3).

This approach does **not provide any hard criteria** for a decision whether something can be regarded as a single or assembled article. But in cases of doubt these delimitations can help answer the question of the reference.

The **painted metal frame** is an article. Regarding the question whether a candidate substance is present, a number of basic matters have to be considered first. There are two different materials present: 1. metal 2. paint. If candidate substances are present it is unlikely, in view of the material properties, that the same candidate substances will be present in both materials. A differentiated procedure is therefore advisable, which will be explained using the example of the bicycle frame. The general considerations however can also be applied to the other articles in the Figure.

In the **metal frame** (without paint) no candidate substances are to be expected at the present time (20.6.2011).

This means that mainly the **coat of paint** has to be considered. Here is a simple model calculation:

Assuming a frame with a total tube length of 2.5 m and a circumference of 10 cm, a surface area of 0.25 m² covered with paint is obtained. With an assumed thickness of this coat of paint of approx. 0.2 mm and a density of 2 g/cm³ a mass of approx. 100 g will be obtained for the paint. With a frame weight of 2.9 kg the percentage of paint present is approx. 3.5%.

Paints themselves normally consist mainly of polymers (e.g. polyester), inorganic and organic pigments and dyes, additives and fillers. Possible solvents should no longer be present in the hardened product in relevant quantities. Close attention is therefore paid to the constituents of the paint which may be candidate substances. The following questions should be considered here:

- Are pigments or dyes included in the candidate list? Are they used in such paints?
- What additives are used in paints? Are they included in the candidate list?
- Fillers are often inorganic or mineral substances. Are such substances included in the candidate list and are they also used for these applications?

- Can concentrations of > 0.1% be expected for the individual substances with respect to the painted frame?

The polymers present in the paint should be stable, inert and insoluble in water. In view of these properties, polymers, which make up a major portion of the paint, are not to be expected as possible candidates. Thus, the question remains if - from the other groups mentioned - there are still substances which may be present in the paint in relevant quantities, giving rise to an information obligation. In our sample calculation above this means that an analysis can be dispensed if it has been shown by the prior examination that less than 3 g of a candidate substance is to be expected (<0.1% in the article painted frame).

In many cases such questions can be answered theoretically, i.e. the presence of candidate substances can be discounted with a high probability and without analysis.

If these questions cannot be answered theoretically, however, or there is no information available whether the paint used may contain a candidate substance, an analysis should be conducted if there is any doubt.

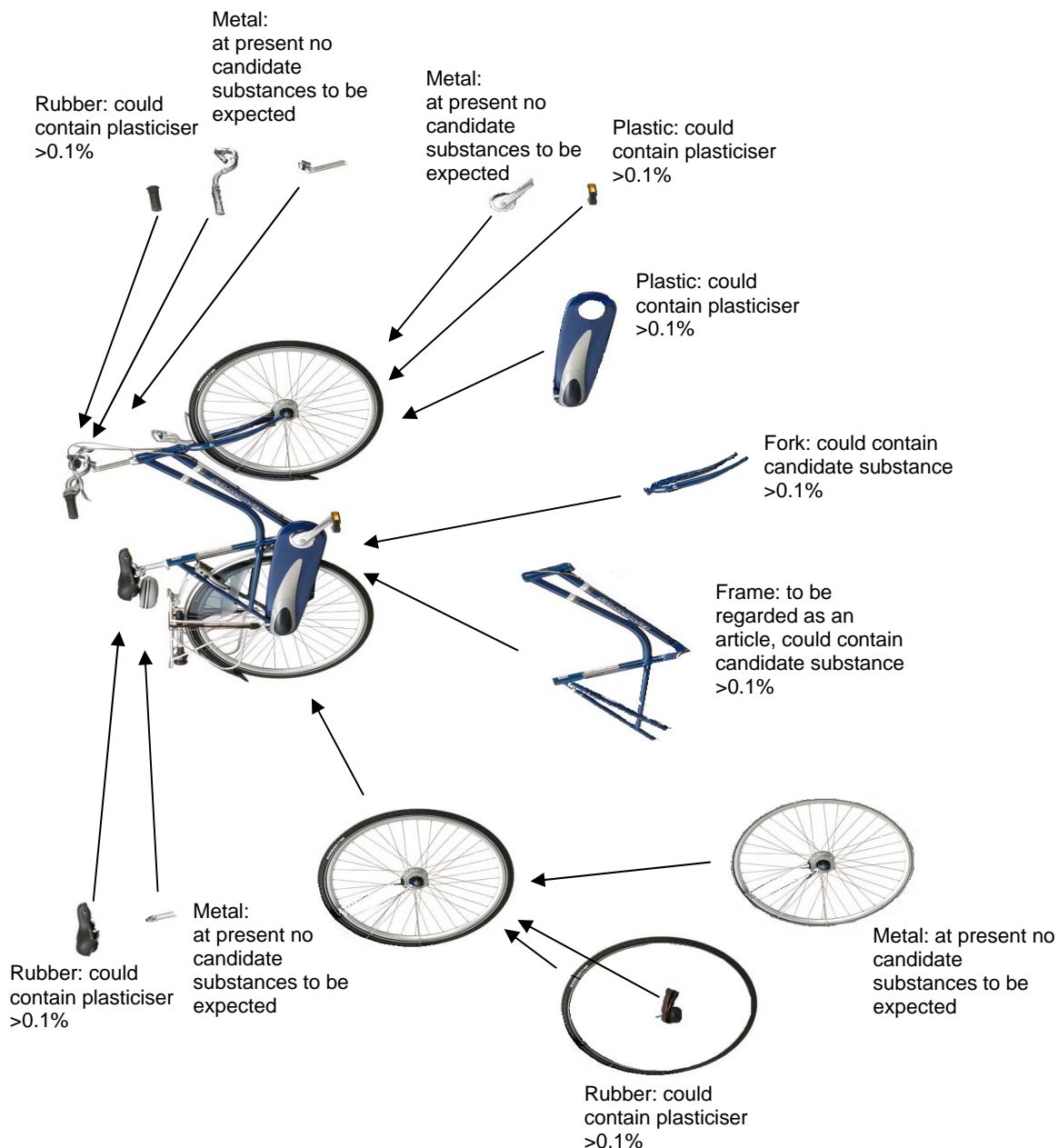


Figure 3: Bicycle as example for an assembled article

Electronic components

Electronic components are mostly assembled articles where single articles have been combined (glued, soldered etc.) more or less irreversibly to build another article. In such cases the question must be answered to which degree of detail such an article has to be assessed. There are limits under which a breakdown into smaller articles is no longer practicable. The question of the concentration of candidate substances present in the single articles should be answered in this case with reference to the material. Once again it should be taken into account that these are no generally valid criteria, but strategic approaches.

A laptop will now be taken as an example. In a laptop the single articles are relatively easy to identify, e.g. display, keys, casing, cables, boards, plugs etc. Information on the concentration of candidate substances present can therefore also be passed on.

Many of these articles themselves already consist of single articles. An example which illustrates this problem well is the **printed circuit board** (PCB, see Figure 4). Does a possible concentration of a candidate substance have to relate to each individual capacitor or each individual resistor plugged into or even soldered onto the PCB, or can the whole PCB be taken as a reference?

To answer this question there is no generally valid recipe. There are cornerstones, however, which can be taken for orientation purposes. A PCB consists of a series of different materials, e.g. rigid and soft plastics, metals, ceramics, glass etc. In addition there are articles which are easy to remove reversibly from a PCB, such as a plugged processor or a screwed-on fan which should be considered separately. If these articles are removed, there remains a PCB which cannot be easily broken down into further articles without being "destroyed".

With this reduced PCB (without the articles that can be easily removed reversibly) it is possible, for example, to identify the individual materials of the PCB and to say something about the quantity of candidate substances in relation to the material. This could mean that plastic parts can be dissolved and analysed as a representative sample. A statement on the candidate substances found in it could be as follows, for example: in the reduced PCB the plasticiser A is present with >0.1% and the flame retardant B with >0.1%.

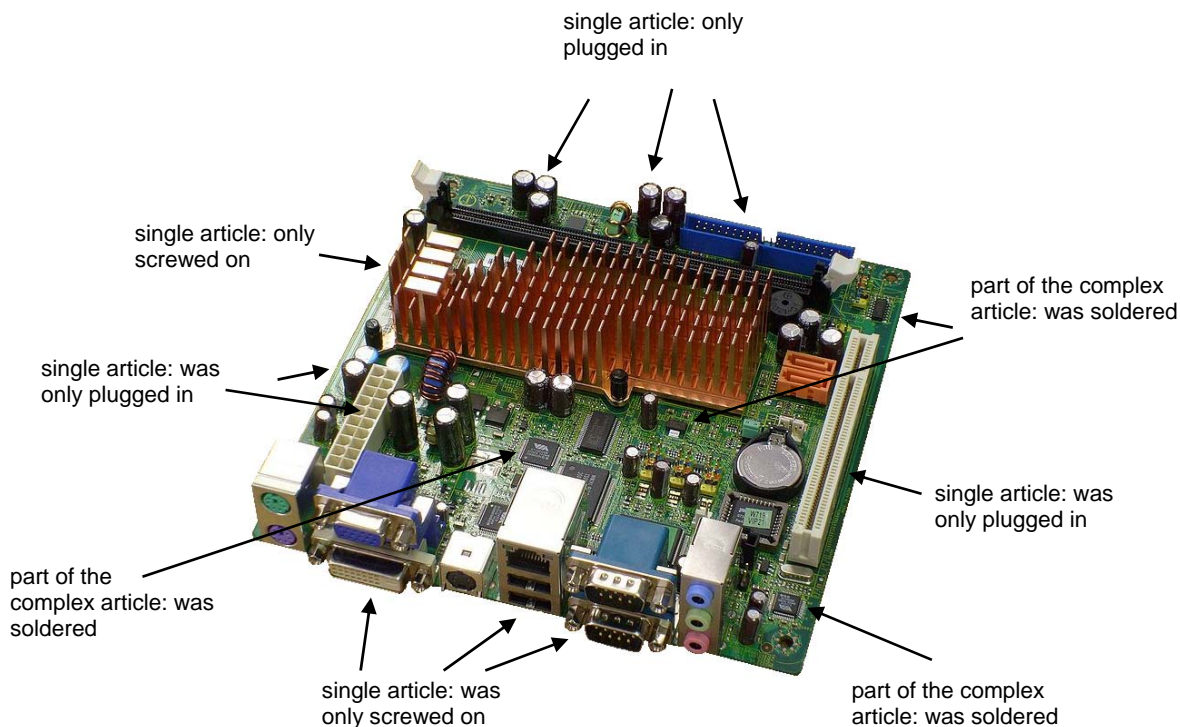


Figure 4: The PCB as an example for an assembled article.

Concluding remarks

The candidate list and the corresponding provisions for articles set under REACH are a milestone for the European chemicals policy: the aim is to adequately control the risks emanating from substances of very high concern and to create greater transparency for these substances in the supply chain. In practice, it can already be seen that many retailers would like to place **only products on the market** which do **not contain any candidate substances**. For this reason alone the notification and information obligations represent a major challenge to distributors, article importers and article producers. Furthermore, consumers are also finding increasingly that their enquiries to the retailer are not or only inadequately answered. In our view this is an indication of knowledge shortcomings and a lack of implementation guidance for the REACH actors concerned.

We have used these knowledge shortcomings as an opportunity to write the present information. At the same time we wish to show that the approach of "Once an Article – Always an Article" supported by Germany can be implemented in practice and even implies essential advantages.

This information is intended to be a **concrete aid** for article importers and producers. For the first time strategies are presented on how to handle the 0.1% threshold for an assembled article and the related obligations.

On the other hand this information does **not contain any generally valid criteria** for the procedure, i.e. the questions concerning candidate substances in articles must always be answered on a case-by-case basis. One major approach, for example, involves initially considerations regarding the possible presence of a substance where no information on candidate substances is available (keyword: **probability procedure**) before an analysis of all candidate substances in the single articles is conducted.

It is therefore the responsibility of the article producers and suppliers to establish from which point it makes no sense to break down an assembled article into even smaller articles or to exclude the presence of a certain candidate substance in an article due to the material. This responsibility cannot be assumed by the authorities or the REACH-CLP Helpdesk.

If, in the supply chain, the strategies applied and basic considerations are responsibly communicated and presented to the consumer and the enforcement authorities, and if no negligent action is involved, a major step will have been taken towards fulfilling the objective of the REACH Regulation, namely to control the **risks of substances of very high concern**.

Disclaimer

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