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Assessment of applications of the 0.1% limit in REACH triggering information on Substances of Very High Concern (SVHC) in articles

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Preface

This report is based on a project “Assessment of alternative applications of the 0.1% limit in REACH triggering information on Substances of Very High Concerns (SVHC) in articles” which received funding from the Nordic Council of Ministers (The Nordic Chemicals Group) December 2008 – September 2009.

The project was supported by a reference group with members from the Swedish Chemicals Agency, Sweden, the Danish EPA, Denmark, the Finnish Environment Institute (SYKE), Finland, the Norwegian Pollution Control Authority, Norway, the Lebensministerium, Austria, FPS Health, Food Chain Safety and Environment, Belgium, Ministère du développement durable, France, and Federal ministry for the environment, nature conservation and nuclear safety, Germany.

The project work was carried out by Ökopol - GmbH Institut für Ökologie und Politik, Germany and its subcontractor Öko-Institut e.V., Germany.

Summary

The new European chemicals regulation REACH 1907/2006/EC entered into force on 1st of June 2007. Thereby, new communication obligations concerning substances of very high concern (SVHC) in articles apply if a threshold of 0.1% (w/w) of SVHC listed on the candidate list is exceeded. How to apply this limit in the case of complex articles, however, is still under debate.

While in the current ECHA "Guidance on requirements for substances in articles" interpretation is given that the 0.1% threshold limit applies to a whole complex article as produced or imported, six member states have a dissenting view and question this interpretation.

Against this background the main objective of the project was to identify and describe examples of implications in different product sectors induced by the new information obligations.

By illustrating the diversity of existing applications and describing possible impacts of different applications of the 0.1% limit, the results of this project shall contribute to the review of the "Guidance on requirements on substances in articles" as announced by ECHA.

Case studies as assessment approach

Case studies of article categories were considered suitable to give a realistic view on how different industry sectors handle "problematic substances" in articles and some examples of implications induced by the information obligations of REACH Article 33.

The selection of article categories was based on a set of criteria, including presence of SVHC in the article as well as exposure potential for the substance, complexity of the article and a relevant share of import to the EU. Refinement in a second step was based on further criteria like supply chain characteristics, established contacts to industry and availability of market data. The final list of selected article categories included:

- Furniture (upholstered sofa)
- Shoes (sports shoe)
- Tools (pliers)
- Toys (cuddly toy)
- Electric installations (power distribution unit)
- Electronics (desktop computer)

About 70 actors from 58 companies, associations and institutes were contacted and interviewed for the case studies. A questionnaire was used as guideline with questions on the characteristics of the supply chain, the article and its components, parts and materials as well as on the informa-

tion flow along the supply chain. Data on import statistics, market values etc. was collected from publicly available information sources in addition.

The selection of cases has provided a variety of article complexity and a good overview on different supply chain characteristics as well as on implemented procedures to define, communicate and check substance related requirements.

Parts and components are addressed in other legislation

Existing legal requirements in EU relating to some specific article types have been analysed in parallel to the case studies.

The analysis showed that thresholds and limitations for dangerous substances do not relate exclusively to complex articles. A wide variety of substance related requirements are in place, making reference to different levels (parts, components or materials). Even within REACH there are a number of provisions in Annex XVII, where the threshold relates to articles which are part of a complex article, rather than to the whole complex article. Several other legislative acts require industry to apply specific standards on parts of a complex article. This shows that industry sectors already apply different standards on different parts of complex articles.

The analysis suggests that future guidance on how to apply the SVHC threshold should encompass also situations that may arise because of other legal requirements for a specific type of articles.

Requirements cease to apply during supply chain

The current interpretation in the ECHA guidance of how to apply the 0.1 % threshold implies that different requirements will apply to the same article when sold separately and when it is incorporated into another (complex) article. None of the analysed legislative acts presents such characteristics. Neither does any of them stipulate that provisions should cease to apply to the articles once they have been incorporated into more complex articles. Following the ECHA guidance, the requirements would cease to apply when a smaller article has been incorporated into a complex article.

Information may get lost

The case studies show that even with the low concentration threshold of 0.1% that triggers REACH information obligations, there will be considerable amounts of SVHC imported through large volume articles without any safety information.

For example every year, up to 900 tonnes of one individual SVHC could be imported into Europe as part of shoes without specific notice. A similar finding is illustrated in the case study of desktop computers, where the theoretical import of one SVHC could amount to almost 42

tonnes per year without triggering information requirements. Even for a comparably small product group like the pliers tool, a similar estimation indicates the possibility of an annual import of 3.5 tonnes of any particular SVHC contained in pliers. These estimations show the extent of SVHC import that possibly could be “escaping” the information provisions in REACH.

The case studies also demonstrate in practice that SVHC concentrations in parts and components of complex articles (desktop computers, pliers) exceed the 0.1% limit. But, applying the threshold to the complex article gives an apparent “dilution” of the SVHC concentration to below the triggering threshold and consequently significant information is lost for the supply chain. Thereby the level of protection may be affected.

With view to the general objectives of the REACH Regulation, it seems important to avoid or reduce any gaps and losses of information in the supply chain.

Loss of information occurs at random

Following the current interpretation in the ECHA guidance, the flow of information may stop when smaller SVHC containing articles are assembled into heavier complex articles as well as when SVHCs are used in concentrations close to the 0.1% limit in those smaller articles. In other words, loss of information will occur more often with large differences in weight between article part and complex article and also with lower SVHC concentrations in the article part. For large groups of articles used as parts or components of complex articles, the trigger for information requirement can vary widely, depending only on how the individual item is used or marketed. This leads to the situation where “dilution effects” and information gaps occur at random. It should be noted that information gaps occur without relation to exposure or risk.

Access to SVHC related information is key

To determine if information obligations following Article 33 of REACH are triggered and to ensure their „compliance”, article producers will have to ask in the supply chain for information on SVHC concentrations in materials/parts.

According to the findings of this study, the workability depends on how article producers and importers can get access to exact SVHC information and on the efforts they need to spend for that. This will be the main obstacle, irrespective of the application of the threshold to parts or to the complex article.

In relation to this, it was noted in the cases studies that the knowledge on obligations relating to substance and their content in the materials used is diverse and quite poor in some supply chains. This basic lack of knowledge has no direct bearing for the issue on how to apply the threshold,

but the situation needs to be significantly improved. Such improvement is a general objective for the REACH regulation.

Flow of substance related information is feasible

The case studies on shoes and toys, together with experience from implementing the RoHS directive in the electronics sector, show that market actors are able to implement routines to ensure the flow of substance related information. This illustrates that obligations linked to communication on substance related issues are not new to industry. Moreover, product specific legislation and surveillance may be an effective push for coordinated efforts in the supply chains to establish information routines.

It appears from the cases studied that quite different situations exist, even inside the same industry sector or product group. On the one hand there are supply chains with full design control, effective communication routines and established test procedures – on the other hand there are actors with fundamental lack of awareness regarding substance related requirements. Proactive actors have implemented suitable routines to define, communicate and control detailed product requirements not limited only to fulfill existing legal requirements but to ensure product quality in a wider sense. Especially the toys and electronics cases show that market actors are able to implement such routines on the level of materials.

Workability is driven by quality management

An overall conclusion from the findings is that workability mainly depends on whether quality management systems are in place or not.

Moreover it can be expected that the resources needed to fulfill the information obligations are lower if the concentration threshold is applied to articles as such instead of assembled complex articles. Under such conditions there is no need to calculate concentrations for the final complex article from all parts included, neither for any detailed communication with all suppliers of parts.

Changes in application of the threshold will on the other hand probably not significantly change the efforts needed for to establish basic management routines. The number of request for information from clients will probably remain the same as well.

According to the findings of this study, the workability depends on how article producers and importers can get access to exact SVHC information and on the efforts they need to spend for that. This will be the main obstacle, irrespective of the application of the threshold to parts or to the complex article. However, applying the threshold to the complex article will force companies to calculate the respective SVHC content. For such calculations more detailed information also on the exact concentrations of SVHC in articles will be necessary, but will not or not easily be available in most supply chains.

Interference with harmonized market is possible

EU-made and imported complex articles will to a certain extent be subject to different preconditions, if the limit is applied to a complex article. It may be easier to access information concerning SVHCs in parts of a complex article that is assembled inside EU, as such information will circulate within EU. This may put more pressure on EU producers of complex articles to substitute SVHCs than on importers.

As shown in the case studies (e.g. sofa, computer), the interpretation in the current ECHA guidance would as well lead to different requirements for suppliers of separate articles (spare parts) than for suppliers of more complex articles.

Such interference on the internal market may diminish if the triggering threshold should apply to all articles, irrespectively if sold separate or included into a complex article.

Lack of SVHC information may cause business risks

It is important to be aware of links between the Article 33 provisions and the authorization procedure under REACH. If a company is not informed about the presence of a SVHC in the parts for a complex article, there may be less preparation time for changing the article quality or composition if that SVHC use should become subject to authorization.

Efforts for enforcement may increase

Existing restrictions on the use of substances relate to materials and parts of articles. This has facilitated market surveillance, especially when laboratory analysis is performed. Often such analysis can only determine concentrations of a specific substance in a homogeneous surrounding.

When concentration limits are applied not to materials but to articles that consist of different materials the analysis becomes more complicated, as all components would have to be checked. The more complex the article is the more resources will be needed to check compliance.

Furthermore, exact weight ratios between the different materials or parts and the final complex article would be needed to recalculate the overall concentration in the whole complex article. This could be a problem for enforcement as for industry's internal compliance checks.

1. Introduction

1.1 Background

The new European chemicals regulation REACH 1907/2006/EC entered into force on 1st of June 2007. Thereby, new obligations concerning general information requirements on substances in articles have been introduced. The ultimate aim of these provisions is a high level of protection against adverse effects on human health and the environment from substances of very high concern. An appropriate flow of information through the supply chain will help ensure this.

However, these requirements do not extend to non-European supply chains. On the one hand this will cause difficulties for European importers of articles in obtaining the necessary information from their suppliers. On the other hand, Member State authorities will have difficulties to control conformity during import.

Furthermore, as REACH does not state in detail how the limit shall be applied, Member States authorities may control and enforce according to different interpretations.

1.2 REACH Information requirements on substances in articles

Article 7 of REACH is directed to article producers and importers. The provisions in Article 7(1) concerning substances which are intended to be released from articles are not addressed in this project.

Notification

Producers and importers of articles that contain substances of very high concern (SVHC) included in the candidate list, will be required to notify these to the Agency (ECHA) if both of the following conditions are met:

- The substance is present in those articles in quantities totalling over 1 t/y per producer or importer;
- The substance is present in those articles above a concentration of 0.1% weight by weight (w/w).

Notification will not be required in case the SVHC has already been registered for this use by any other registrant (Article 7(6)), or exposure to humans or environment can be excluded (Article 7(3)). The notification provisions in Article 7(2) will enter into force June 2011.

The obligation to notify SVHC to ECHA will create a source of information on uses of SVHC in articles on the EU market. This may be used for

- Closing gaps in the registration of a SVHC, when it is not covering uses in articles
- Setting priorities for the authorisation and restrictions procedures
- Initiating targeted control of compliance.

The obligation to notify SVHC may also lead to raised awareness of article producers and importers, to the effect of enhanced substitution of these substances by less dangerous ones.

Communication

In addition, Article 33(1) requires producers and importers of articles containing more than 0.1% w/w of an SVHC included in the candidate list, to provide sufficient information to allow safe handling and use of the article to its recipients. As a minimum, the name of the substance is to be communicated.

The provisions of Article 33(1) are currently in force. They apply regardless of the total amount of the SVHC used by that actor (no tonnage threshold) and regardless of a registration of that use. Furthermore, this information has to be communicated to consumers, on request, free of charge and within 45 days (Article 33(2)).

The obligation to inform customers about the SVHC content may

- Raise awareness on SVHC in articles in general
- Provide information to ensure safe use of the article
- Provide market incentives for substituting SVHC

Information trigger

So both notification and communication requirements on producers and importers of articles will be triggered by the 0.1% threshold. The way the concentration limit is applied will affect the level of protection for the human health and the environment with respects to risks from substances of very high concern in articles.

The outcome of the application of the 0.1 % threshold will depend on how the term article is to be understood in the context of article 7(2) and article 33.

The term “article” is defined in REACH Article 3 (3) 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”.

It follows from this definition that an object is considered an “article” as soon as the conditions in Article 3(3) are fulfilled. Such an object

could at some stage form part of a complex article, i.e. an article which is composed of one or more different components or parts which themselves are to be regarded as articles. Depending on the intended function, the components of such complex articles are composed of different materials. The number of these components or parts can range from only a few (e.g. battery) to hundreds (e.g. cars, electronic devices).

The ECHA “Guidance on Substances in Articles” describes this:

“An article is to be understood as the article as produced or imported. It may be very simple, like a wooden chair but could also be rather complex, like a computer, consisting of several parts, which are also considered articles when produced or imported”. (page 21)

According to the current interpretation in the guidance, the threshold should be applied in the following way:

“The substance concentration threshold of 0.1% (w/w) applies to the article as produced or imported. It does not relate to the homogenous material or parts of an article, as it may in some other legislation, but relates to the article as such (i.e. as produced or imported).” (page 16)

“The SVHC may be contained in different concentrations in different components of the same article, e.g. one concentration in the chassis of a computer and another concentration in the transformer. The concentration threshold of 0.1% (w/w) refers to the average concentration of the entire article as produced or imported.” (page 54)

Dissenting views questioning this application of the 0.1 % threshold to the entire complex article have been notified by six Member States (Austria, Belgium, Denmark, France, Germany and Sweden). These Member States are of the opinion that Article 7(2) and Article 33 can be interpreted in different ways and therefore must be read in its context, being the definition of article, the *ratio legis* in the recitals and the context of similar community legislation. Reading the relevant articles against this background, the dissenting Member States find that the limit value should relate to individual articles, parts or materials that complex articles consist of. According to said Member States the interpretation given in the guidance will lead to arbitrary differences in application, depending on whether the article is marketed as a separate part or integrated in a complex article. Furthermore, this interpretation will preclude effective dissemination of information by suppliers of articles containing SVHC throughout the supply chain to the final user, especially in the case of complex articles typically used by consumers.

1.3 A theoretical example

According to the current guidance, producers and importers of complex articles will apply the requirement to the entire article and thus sum up the amount of an individual SVHC included in all components of the complex article and divide it by the total weight of the entire article. This means that in complex articles the information trigger for SVHCs will be diluted away, as opposed to situations where the concentration is calculated in the part or component only. The latter is describing the case for producers / importers of article components, who will apply the 0.1% threshold to the component as they place it on the market.

A theoretical description on the information requirements is given in Figure 1.

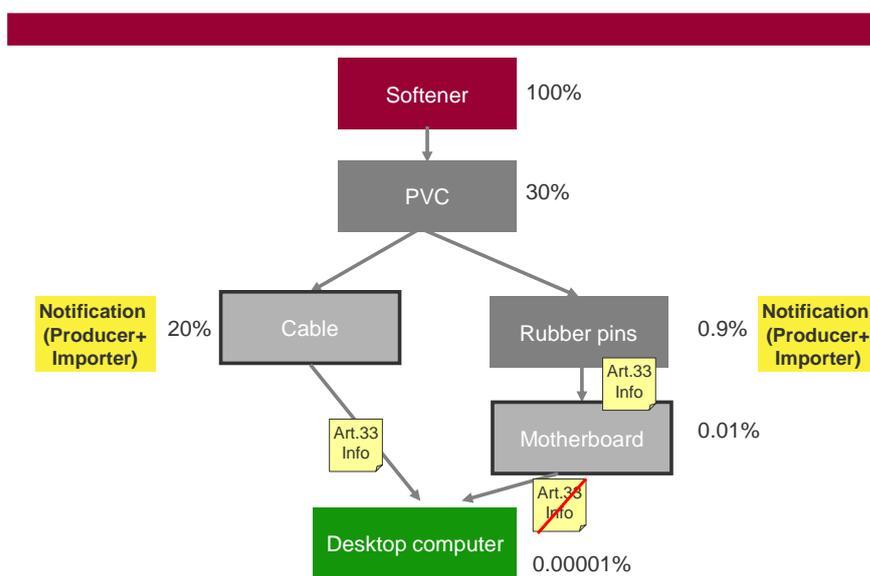


Figure 1: Notification and communication requirements under current interpretation – theoretical illustration

1.4 Objectives of the project

As described above, SVHC concentrations in articles exceeding the 0.1% threshold will trigger different substantial information requirements. How to apply this limit in the case of complex articles, however, is still under debate. ECHA has announced that the current “Guidance on Substances in Articles” will be reviewed and that new information is needed for changes. Against this background, this project was initiated. Funding has been granted by the Nordic Chemicals Group, on behalf of the Nordic Council of Ministers.

The main objective of this study is to identify and describe examples of implications in different product sectors induced by the application of the 0.1% limit. By illustrating the diversity of existing applications and impacts, the results shall contribute to the review of the “Guidance on Substances in Articles” as announced by ECHA.

The project work was carried out by Ökopol and its subcontractor Öko-Institut between December 2008 and October 2009. The project work has been followed and discussed by a reference group consisting of representatives from the six Member States who expressed dissenting views: Austria, Belgium, Denmark, France, Germany and Sweden. In addition, representatives from Finland and Norway have taken part in the reference group.

This report presents the findings of the work.

2. Terms used in EU legislation

The result of the application of the 0.1 % threshold will depend on how the term “article” is to be understood when used in Article 7(2) and Article 33. Since these Articles can be interpreted in different ways they must be read in their context, being the definition of article, the *ratio legis* in the recitals and the context of similar community legislation. In the following, relevant terms in REACH and similar community legislation are listed and analysed.

2.1 Definitions and explanations of the terms “article”

The term “article” is defined in REACH Article 3(3):

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

In the ECHA “Guidance on Substances in Articles” the article definition is described in more detail.

“In a general understanding, an article is an object composed of one or more substances or preparations given a specific shape, surface or design. It may be produced from natural materials, such as wood or wool, or from synthetic ones, such as polyvinyl chloride (PVC). Substances or preparations may be added to give an article its special properties. Most of the commonly used objects in private households and industries are articles, e.g. furniture, clothes, vehicles, books, toys, kitchen equipment, and electronic equipment.”

The guidance also contains a brief description of complex articles:

“An article is to be understood as the article as produced or imported. It may be very simple, like a wooden chair but could also be rather complex, like a computer, consisting of several parts, which are also considered articles when produced or imported”.

Originally, the former Limitations Directive (76/769/EEC), now in REACH Annex XVII, defined only the terms “substance”, “preparation”, and “childcare article”. Therefore, some MS may have included definitions in their national legislative implementation. These are, however, just valid on a national level.

However, the understanding of the term “article” seems to gradually become harmonised. Similar expressions are for instance found in the international context:

OECD

“An article is a man-made object which during manufacturing has been given a special shape, surface or form which determines its function to a greater degree than does its chemical composition”

US Occupational safety and health standard 1910.1200 hazard communication

“An article is a manufactured item which:

- is formed to a specific shape or design during manufacture;
- has an end use function(s) dependent in whole or in part upon its shape or design during end use; and
- either has no change of chemical composition during its end use or only those changes in composition which have no commercial purpose separate from the article of which it is a part.”

Canadian legislation

“Any manufactured item formed into a specific physical shape or design during manufacture that has, for its final use, a function or functions that depend, in whole or in part, on its shape or design.”

Environmental Risk Management Authority of New Zealand (definition equivalent to Australians NICNAS Handbook for notifiers)

“An item is an article if it satisfies each of the four following criteria:

- The item is deliberately formed to a specific shape or design during manufacture, and;
- The item has an end use function wholly or partly dependent on its shape or design, and;
- The item undergoes no change of chemical composition during end use, except as an intrinsic part of that end use, and;
- The item is not a particle or a fluid.”

2.2 Application on parts of articles – some examples

Annex XVII in REACH (the former 76/769/EEC Directive) lists restricted substances and the respective concentration limits may refer to different allocation bases. There are however a number of examples in Annex XVII where the threshold relates to articles which are part of a complex article, rather than the whole complex article.

In some cases the restrictions apply to the concentration in materials or migration from a material. The examples below show a variety of ele-

ments that clarify that parts of articles are also within the scope of the provisions.

18. Mercury: “Member States shall prohibit, as from 1 January 2000 at the latest, the marketing of batteries and accumulators, containing more than 0.0005 % of mercury by weight, including in those cases where these batteries and accumulators are incorporated into appliances. Button cells and batteries composed of button cells with a mercury content of no more than 2 % by weight shall be exempted from this prohibition.”

22. di- μ -oxo-di-n-butylstanniohydroxyborane: “Shall be prohibited in a concentration equal to or greater than 0,1 % in substances and constituents of preparations placed on the market. However, this provision shall not apply to this substance (DBB) or preparations containing it if these are intended solely for conversion into finished products, among which this substance will no longer feature in a concentration equal to or greater than 0,1%.”

23. Cadmium: Shall not be used to stabilise the following mixtures or articles manufactured from polymers or copolymers of vinyl chloride: (...) fittings for furniture, coachwork or the like, (...) Tubes and pipes and their fittings.

27. Nickel: Shall not be used (...) in articles intended to come into direct and prolonged contact with the skin such as: (...) wrist-watch cases, watch straps and tighteners, — rivet buttons, tighteners, rivets, zippers and metal marks, when these are used in garments,,

28. Nickel and its compounds: Refers only to release from article / article parts
 “1. in all post assemblies
 2. in products intended to come into direct and prolonged contact with the skin such as:

 3. in products such as those listed in point 2 where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such products coming into direct and prolonged contact with the skin will not exceed 0.5 $\mu\text{g}/\text{cm}^2/\text{week}$ for a period of at least two years of normal use of the product.”

44 / 45. Bromated Diphenylethers: “Articles may not be placed on the market if they, or flame-retardant parts thereof, contain this substance in concentrations higher than 0.1% by mass.”

50. Polycyclic-aromatic hydrocarbons (PAH): 1. refers to defined limits in extender oils which are banned for the “production of tyres or parts of tyres” and 2. refers to tyres and treads for retreading. The limits can be regarded as kept by measuring the content in the respective material: “These limits are regarded as kept, if the vulcanised rubber compounds do not exceed the limit of 0.35 %”

51 / 51a. Plasticizers (phthalates): “Shall not be used as substances or as constituents of preparations, at concentrations of greater than 0.1 % by mass of the plasticised material in toys and childcare articles.“

53. Perfluorooctane sulfonates (PFOS): “2. Shall not be placed on the market in semi-finished products or articles, or parts thereof, if the concentration of PFOS is equal to or greater than 0.1 % by weight calculated with reference to the mass of structurally or microstructurally distinct parts that contain PFOS or, for textiles or other coated materials, if the amount of PFOS is equal to or greater than 1 $\mu\text{g}/\text{m}^2$ of the coated material.”

The Directive 94/11/EC on labelling of materials used in footwear

According to the Directive 94/11/EC of the European Parliament and Council of 23 March 1994, on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer, manufacturers and importers are required to label the main components of footwear for sale to the consumer. The labelling shall be done according to the materials used in the three parts: the upper part, the lining / sock and the outer sole. Only materials covering at least 80% of the surface areas or 80% of the volume of the outer sole shall be labelled. If no one material accounts for at least 80%, information should be given on the two main materials used.

The Toys Safety Directive

The relevant legal requirements for toys are laid down in the newly revised Toys Safety Directive (2009/48/EC). Here the use of CMR substances in toys is restricted and substance thresholds for CMR 1, 2, 3 substances refer to 0.1 % concentrations in: toys, components of toys or micro-structurally distinct parts of toys.

The General Product Safety Directive

The restriction on use of dimethylfumarate (DMF) through the General Product Safety Directive (2001/95/EC) refers to the concentration in articles or parts of articles.

End of Life Directive

In the End of Life (ELV) Directive 2000/53/EC on dangerous substances in vehicles, the term vehicle is understood as “vehicles and end-of life vehicles, including their components and materials, as well as spare and replacement parts”. According to his Directive the use of four metals are prohibited in vehicles.

The exemptions for components and materials are given in Annex II for the four banned metals. The exemptions unsystematically apply to functional units (e.g. battery, parts of components (e.g. electrical components which contain lead in a glass or ceramic matrix compound and fluorescent tubes used in instrument panel displays), materials (copper alloys) or chemical function (e.g. stabilizer in paints).

In practice these terms are implemented in the material declaration tool of the automotive industry for the declaration of substances in materials: the International Material Data System (IMDS), VDA List 232-101, ISO 1043 and the respective Global Automotive Declarable Substance List (GADSL). Here, the terms are applied as follows:

“Products / articles: Materials, which have transformed during production to take a specific shape, surface or form, which has a greater influence on their function than their chemical composition does.”

“Parts: single component made up of one or more homogenous material(s).”

“Materials: Chemical elements, chemical compounds or preparations thereof in finished state used to manufacture products / articles.”

RoHS Directive (2002/95/EC), WEEE (2002/96/EC), and electronic industry

A revision of the RoHS directive is ongoing. Under the current regulation, six substances / groups of substances are banned in electric and electronic equipment: Pb, Hg, Cd, Cr (VI), PBB and PBDE. In contrast to REACH the concentration limits apply to homogenous material. This application base is defined as:

“Homogenous material means a material that cannot be mechanically disjointed into different materials. “

The concept “homogenous material” has been deeply thoroughly in this context. It is further explained in the respective document on Frequently Asked Questions:

The term “homogenous” means “of uniform composition throughout”. Examples of homogenous materials are individual types of plastic, ceramics, glass, metals, alloys, paper, board, resins, and coatings.

This document contains also examples for illustration:

- “A plastic cover is a "homogeneous material" if it consists of one type of plastic that is not coated with or has attached to it or inside it any other kinds of materials. In this case the limit values of the Directive would apply to the plastic.”

- “An electric cable that consists of metal wires surrounded by non-metallic insulation materials is an example of a "non-homogeneous material" because the different materials could be separated by mechanical processes. In this case the limit values of the Directive would apply to each of the separated materials individually.”

- “A semi-conductor package contains many homogeneous materials which include: plastic moulding material, tin-electroplating coatings on the lead frame, the lead frame alloy and gold-bonding wires.”

“The term “mechanically disjointed” means that the material can, in principle, be separated by mechanical action such as unscrewing, cutting, crushing, grinding and abrasive processes.”

Another explanation is found in a tool developed for Product Environmental Compliance (ROHs, WEEE) in the electronic sector. In this material data base report format Wizard www.goodbyechain.com the term “product/component” is described as:

“A manufactured item with a unique identification number (the part number). The item (as delivered) that the respondent is supplying (e.g., assembly, subassembly, component, raw material) is the product. All product declarations will have at least one substance, and frequently many materials and substances.”

Common rules in the field of civil aviation

Regulation (EC) No 1592/2002 of the European Parliament and of the Council of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency deals with

“aircrafts” and

“parts and appliances”, meaning “any instrument, equipment, mechanism, part, apparatus, appurtenance or accessory, including communications equipment, that is used or intended to be used in operating or controlling an aircraft in flight and is installed in or attached to the aircraft.

According to the Regulation products, parts and appliances shall comply with certain environmental protection requirements. For example there are certain requirements on emissions from engines.

Ecodesign Framework Directive

Directive 2005/32/EC of the European Parliament and of the Council of 6 July 2005, establishing a framework for the setting of ecodesign requirements for energy-using products mentions both

”parts” that are intended to be installed in the products, that are put on the market and / or are used separately by end users and can be assessed separately as well as

”components and sub-parts” that are intended to be installed in the products but are not put on the market or used separately by end users and cannot be assessed separately.”

It follows from this Directive that ”parts” that are intended to be installed in the products and are put on the market are considered as products.

Electromagnetic Compatibility Directive

Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC mentions “apparatuses” and ”components or complex parts intended to be installed in an apparatus by end users”. Such components and complex parts are considered as “apparatuses” within the meaning of the Directive. Each apparatus shall meet certain requirements with respect to electromagnetic disturbance. The manufacturer shall also provide information on any specific precautions that must be taken when the apparatus is assembled, installed, maintained or used, in order to ensure that, when put into service, the apparatus is in conformity with the protection requirements set out in the Directive.

2.3 Findings from examples on application of terms

This analysis of existing EU legislation restricting the use of chemicals in products and other legal environmental requirements with respect to products shows that thresholds and restrictions do not relate exclusive-

ly to complex articles. In general, also components or parts or materials of complex articles are included as products to which the environmental requirements apply.

Even in Annex XVII of REACH a number of provisions relate to articles which are part of a complex article, rather than the whole complex article. An example of this is the limitation regarding the use of cadmium, which applies to “mixtures and articles” such as, *inter alia*, “fittings for furniture” and “tubes and pipes and their fittings”. Another example is the restriction regarding nickel which stipulates that this substance shall not be used in articles such as, *inter alia*, watch straps and tighteners, zippers and metal marks. There are also other legislative acts which require industry to apply specific standards on parts of a complex article. This indicates that industry sectors already apply different standards on different parts of complex articles.

Furthermore, none of the legislative acts that were analysed stipulate that the provisions shall cease to apply once the articles have been incorporated into complex articles. On the contrary, it is obvious that the standards apply regardless of whether the articles have been incorporated into a complex article or not. This is true also for requirements to provide certain information on precautions with respect to the articles concerned (as in the electromagnetic compatibility directive 2004/108/EC).

3. Case study approach

3.1 Function and focus of the case studies

Case studies are seen as a suitable method to get a realistic view on how different industry and trade sectors handle “problematic substances” in articles for the time being and which effects might be triggered by different approaches applying the legal limits against that background. Therefore, the focus has been on the information requirements which are currently in force.

During the conceptual work for the case studies, four major impact areas were identified.

1. **Level of protection** (information dissemination)
 Knowledge about dangerous substances in an article is a prerogative for information about safe handling and use. Furthermore detailed information on SVHC contained in articles can stimulate substitution of such substances. Depending on the application of the 0.1% limit, more or less information might get lost during communication in the supply chains.
2. **Workability** (on level of industry and trade actors)
 Workability for industry actors is assumed to mean efforts needed to establish routines to gather information and check conformity regarding SVHC in the articles. Another aspect for workability is the effort for information dissemination and the benefit from receiving it.
3. **Enforceability** (on level of authorities and market surveillance)
 Regarding enforceability it is important whether more or less clear and easy to implement strategies for compliance assessment are interlinked with the application of the 0.1% limit.
4. **Market & competition**
 A level playing field among different actors (e.g. EU producers versus importers) in the same article sector is seen as important for reaching the aims of REACH.

Based on the experiences from the assessments performed the last impact area was included during study process under “workability” to avoid duplication of aspects.

So actors from different stages of the supply chain were asked by using a questionnaire as a guideline (see also Appendix 2) for a characterization of the contacted actor and the related supply chain; a characterization of the article including a detailed description of the article and its components, parts and materials; information on SVHC in the article as well as dissemination of this information along the supply chain

The case studies intended to get answers to questions like:

- How is information gathered on what SVHC is included in which amounts / concentrations in which “area” (part, material,...) of the respective articles?
- How are substance related requirements defined during design process, communicated during sourcing procedures and crosschecked during quality control?
- On which level do existing legal requirements and/or other “safety standards” address substance related risks and how are these requirements controlled by enforcement bodies?

Considering the limited time and personal resource constrains the case study assessments were limited to a more qualitative analysis.

3.2 Case study selection

In order to catch a broad picture of the realities in different product sectors, at least five cases were to be selected. The selection was performed in a two-staged procedure. In a first step, a list of product groups was set up comprising articles meeting the following criteria:

- Known presence of SVHC in the article
- Variety of complexity of the articles
- Relevant share of production within EU and of import into the EU-market
- Different possible exposure pathways from the SVHC contained (human health, environment)

The pre-selection lead to the following product groups:

- Cars and parts of e.g. seats, tyres
- Electronics
 - a) Computers
 - b) White goods
- Furniture
- Home trainer
- Roofing felt
- Shoes
- Textiles
- Tools
- Toys
- Windows

Based on short characterisations of these product groups, the selection was refined in a second step. Further criteria like supply chain characteristics, availability of market data and anticipated and established con-

tacts to industry, were applied. Table 1 provides an overview on the selection criteria and the respective reasoning.

Table 1: selection criteria for case studies

Selection criteria	Explanation
Relevant SVHCs content	Preferably at least exceeding threshold on the level of material
Good quality of industry cooperation and information access	<ul style="list-style-type: none"> • Access to sector information about material composition (incl. SVHC) • Basic economic data in the sector (e.g. about import ratio)
Different types of complexity: [order of magnitude of different materials / parts included]	<p>In relation to article or part of article considered in the specific case e.g.</p> <ul style="list-style-type: none"> • car: > 1.000 different materials/parts • white goods: > 100 different materials/parts • car seat: > 10 different materials/parts • textiles: < 10 different materials/parts
Different types of supply chain characteristics covered	<ul style="list-style-type: none"> • share of import • market dominance of big player “brands” and small companies (SME) • dominating organisation of the supply chain (System leader) demanding specifications in <ul style="list-style-type: none"> a) 1 step down (e.g. pre-product level – requirements for power supply unit) b) 2 steps down (e.g. component level – circuit board) c) 3 steps down (e.g. material level - components of plastics)
Type of exposure relevance	Exposure pathway: at least one case relevant for the environment

The following six product groups were selected for the case studies:

- Furniture (upholstered sofa)
- Shoes (sports shoe)
- Tools (pliers)
- Toys (cuddly toy)
- Electric installations (power distribution unit)
- Electronics (desktop computer).

3.3 Case study procedure

As basis for the case study assessment, a questionnaire was developed to be used as guideline for interviews with industry partners, associations, and in addition as well for laboratories and authorities. The last two groups have been included as first experience showed that these actors often have valuable knowledge regarding the objectives of this study.

Testing laboratories who perform product quality checks on a day-to-day basis for more proactive market actors - namely brand producers and retailers – have a quite detailed knowledge on where and in which concentrations SVHC and other “problematic” substances might be found in articles to be placed on the market. Unfortunately this “knowledge pool” is not accessible in a transparent manner, because the laboratories are bound to very strict CBI rules. But even with this limitation they were able to offer some very helpful information regarding testing strategies and more general problems.

Authorities involved in the market surveillance have as well gained lots of experiences about the status quo regarding product groups where already today substance specific legal requirements are in place to some extent comparable to the new REACH requirements.

The questionnaire (see Appendix 1) included questions on:

- 1. Role of actor and supply chain
 - a) Characterization of actor and supply chain
 - b) Market data
 - c) Quality management
- 2. Characterization of article
 - a) Detailed article description and
 - b) components/parts, materials
 - c) article and chemicals related regulations
- 3. Information on SVHC
 - a) In the article, in components / parts, materials
 - b) Information exchange with suppliers, customers and consumers.

For all selected cases, actors from different stages of the supply chain, industry associations and laboratories were contacted via e-mail and/or telephone.

Quite diverse reactions were received from the interview partners. Some actors provided full detailed information by filling in the whole questionnaire and granting the opportunity to use their input as reference for the work (e.g. B&Q (tools), Dell, Apple, Faber (VEG – association of electric installations, AVNET, Sony Ericsson). Other actors supported the project with information, but wanted to stay strictly anonymous.

Also, there was almost no reaction to the request at all or in some cases it was not possible to identify a person responsible for REACH im-

plementation. Furthermore some companies communicated that they were not interested in providing information because they

- did not feel affected from requirements under REACH
- were fine with the current situation and not interested in any further debate.

All in all about 70 actors from 58 companies, associations and institutes were interviewed in the case studies. In parallel, publicly available information e.g. market data like import statistics, market value of articles and relevant existing legal requirements was gathered for the respective article.

Details of the results from the individual case studies are included in Appendix 1. The summarized findings from all case studies are described in Chapter 4.

4. Findings from case studies

4.1 Furniture - upholstered sofa

The article complexity of an upholstered sofa is comparably low with about 10 - 100 parts (e.g. frame, back, arm rest, seat and back cushion, leg, cover). The number of different materials used is also quite low: wood based materials (particleboard, fiberboard, solid wood, and plywood), polyurethane foam, plastic, steel, and textile. Spare part supply for the consumers could include covers, pillows or legs but is only to a very limited extend part of the normal business.

The EU furniture market is – beside some multi-national companies – dominated by smaller independent specialists. The sector is divided into a premium segment at the top end and a discounting segment at the other end.

Beyond bans and restrictions for the use of substances in REACH Annex XVII and the General Product Safety Directive, there are no product specific regulations in place in the EU but some voluntary product labels are implemented (like Nordic Swan and Blue Angel, for the whole product and Ökotex 100 for the covering).

SVHC potentially used in upholstered sofas are e.g. brominated and phosphorous flame retardants (e.g. HBCDD already included in the first candidate list), formaldehyde, phthalates (DEHP, DBP, and BBP already included in the first candidate list), chromium, azo-dyes, pigments, and organo tin (TBTO already included in the first candidate list). The content of flame retardants in foams is typically between 5-10 %. In Great Britain upholstered furniture explicitly has to be furnished with flame retardants to meet the criteria of the national Furniture and Furnishings fire safety regulations.

Two aspects that are specific to this article type, “high volume” and “preservation during transport”, set some limits for the import of complete upholstered sofas from far away countries outside EU (mainly from Asia). But, on the other hand upholstery is a time consuming manual operation that is dominated by labour costs.

These aspects may lead to a supply chain situation where many parts (like the covering, the feet or the metal frame) are imported from non-EU countries. Prefabrication is made at the brand producers site and then the preassembled part is exported again for upholstery (e.g. to countries outside the eastern borders of EU). After re-import, final assembly and quality check, the sofas are marketed. In this situation, the 0.1% limit will apply to the different components and parts during the first import of the smaller parts.

The supply chain situation import – export and re-import of materials and parts – described above is more relevant in the segment of high price furniture. Here major brand producers have implemented full design and quality control routines ensuring safe products already on the level of the (imported) material.

On the other hand resellers in the low price segment importing complete upholstered sofas from non-EU countries do not have a quality management system. System routines implemented and awareness on REACH obligations seem quite low.

In summary, this case shows that the article selection was relevant, in particular since sofas are large volume articles that contain significant SVHC amounts and are used directly and long term by consumers. Also, potential complexities in the supply chain are illustrated.

4.2 Shoes – sport shoes

Sports shoes may be quite complex articles consisting of up to 250 parts (like sole, upper material, lining and interlining material, toe and heel caps, thread, pad cushion, bottom filler, glue, etc.). They can be made of up to 50 different materials (e.g. leather, textile, synthetic, plastic, cork, rubber, glue, fur and fleece). Only in very limited cases spare parts (like shoelaces or insoles) are available. The typical weight of a shoe ranges between 120 g and 250 g.

No information was made available by interview partners on SVHC of the candidate list or potential SVHC contents in materials or parts of entire shoes. However, identified and potential SVHC may be present in shoes depending on the used material:

- textile: e.g. azodyes, disperse dyes, formaldehyde
- leather: chromium (VI), PCP, chlorinated paraffines (short chain chlorinated paraffines are included in first candidate list)
- plastics: cadmium, lead, dimethylformamide, aromatic solvents, phthalates (DEHP, DBP, and BBP are included in first candidate list)

Therefore, as a general observation it should be noted that knowledge about the used materials will be essential for product quality assurance.

Almost 3 billion pairs of shoes were imported into the EU in 2007. The share of import is increasing steadily. The supply chains are complex with up to 50 suppliers mainly located in non-EU countries.

Taking the numbers of imported shoes and a typical average weight of 185 g per shoe makes it possible to estimate that up to 900 t per anno of a single SVHC can theoretically be imported without triggering REACH information requirements if the 0.1 % limit is applied to the complex article shoe.

In addition to bans and restrictions for the use of substances in REACH Annex XVII and the General Product Safety directive, legal requirements exist for labeling of the upper, inner and sole parts of a shoe regarding their main constituting material (e.g. textile, plastic parts, and leather).

In the shoe market there are on the one hand some few actors with full design control, giving stringent specifications on the composition of all materials included in the final article. This group has control of chemical content in the raw materials used for the final shoe. On the other hand there is also a suppliers market where the actors only choose to buy or not buy articles as offered off-the-shelf by the supplier. In the latter group, specified requirements are most likely to be related to the functional performance of the final article rather than to information on chemical substances. The producer specifications do not reach deeply into the supply chain.

Generally, test routines for banned substances are performed for materials and parts as well as for whole articles as placed on the market. Actors with full design control perform testing for a number of listed substances on material samples. Only approved materials can be used for the later production steps. Therefore these actors do not foresee any problems to address future SVHC requirements at the level of materials.

However, market actors in this product group expressed that they were not inclined to deviate from the current application of the 0.1% limit to the complex article. This could indicate that the application may be of relevance at material level (and thus influence the freedom in the selection of materials) but not at the level of the final article.

In summary, this case confirms the relevance of the article selection criteria, in particular since shoes are large volume articles, with a short and fashion dependent lifespan that are used by consumers.. The shoes case illustrates how much SVHC might escape the REACH information provisions yearly via shoe imports.

The materials used may be in close and long lasting contact with the skin Existing requirements in product specific legislation involve the labeling of parts of the shoe, based on their main material. Some few actors have control on the composition of materials included in the final article.

4.3 Tools - pliers

The pliers are articles of low complexity (<10 parts) consisting of less than 10 materials. The main material used is steel, contributing 50 to 95% of the weight of the whole pliers. The handles are usually made of rubber or plastic but sometimes different materials are combined for the handle. Typical pliers have a weight between 100 and 700 g. SVHC included in

the first candidate list (e.g. DEHP, DBP, Anthracene (PAH)) can be found mainly in the handles, while for example chromium (VI) can be found in the metal fraction of the tool.

Tools are produced in supply chains with only few actors. The market includes producers / importers with full design control and others just buying supplier offers with no control on product design and therefore no control on substance content at all.

Besides general requirements from the General Product Safety Directive and REACH Annex XVII, no specific obligations concerning dangerous substance exist for this product group. Therefore, up to now there was no need for actors to demand specific requirements or specific information on the materials included in the different parts of the final article.

A specific aspect to consider in this case is that pliers can be produced from semi-finished products: metal corpus and handle. Both are articles in the sense of REACH Article 3(3) if placed on the market separately. However, handles are not always produced as separate article. In some production chains, polymer handles are formed directly onto the metal grip. Here the handles cannot be considered as articles on their own.

Concerning the application of the 0.1% limit, a dilution effect is possible because of the weight differences between the main metal part and the handle that may contain a SVHC.

More than 8 million pliers are imported into the EU yearly, making up about 30-40% of the market. Thereby, it can be estimated that some 3.5 tonnes of any SVHC could theoretically be imported yearly through this tool, without triggering REACH information obligations. This shows as a general learning point, that considerable gaps in the flow of information may occur for SVHCs in concentration below 0.1% contained in articles that are traded in large volumes and significant share of import.

Also, in this case the correlation between weight differences and SVHC concentrations can be demonstrated. For softeners with a typical concentration >20% in the material, the information requirement will be triggered irrespective of the reference base applied. In contrast, for anthracene the information obligation will depend on whether the 0.1% limit is applied to the whole article or on the handle parts. This is shown in Table 2 for pliers with the weight 360-396 g in metal parts and 4-40 g in handle parts.

Table 2: Contents and dilution factors of SVHC in handles of pliers

SVHC	Reference	Typical SVHC content in final article	SVHC content related to final article (weight 360 - 396g)	Dilution factor	Information obligation
	Typical content SVHC in the material				
	Weight of material in final article				
DEHP / DBP	Plastic handle	0.8 – 8 g	0.2% - 2.2%	9-100	Yes, at all stages
	20%				
	4-40 g				
Anthracene (respectively PAH fraction)	Plastic handle	0.008 – 0.08 g	0.002% - 0.02%	10-100	- Not at stage of the complex article - Only at stage of the sub-part (=handle)
	0.2%				
	4-40 g				

The different actors interviewed in this case study showed no clear positions regarding different possible applications of the 0.1 % limit under REACH. In general they expected that another application of the reference unit would not cause significant changes in conformity costs due to the simple product structure and short supply chains.

In summary, this case confirms the relevance of the selection criteria and demonstrates important gaps in the flow of SVHC information. In particular, this case illustrates the correlation between large weight differences and SVHC concentrations close to the 0.1% concentration limit.

4.4 Toys – cuddly toy

The complexity of cuddly toys is quite low with less than 10 parts/materials like filling material (hollow fiber), covering (web plush, textile), yarn and paints. Accessory equipment (e.g. clothes) is often also available and can be made of multiple other materials e.g. plastics, metal, etc.

The toys sector is clearly dominated by import (about 80% of all traditional toys) from Asia, mainly China. EU production is only relevant in the specialized sector of high quality products. Two main situations in the toys supply chain may be distinguished:

- Brand producers or big brand retailers who produce or order according to detailed product specifications having (full) design control.
- Low price retailers choosing their products according to general product properties like e.g. size, type, colour and having no or only limited influence on product design.

Because of existing regulations and consumer pressure, this industry sector is used to restrictions of problematic substances in their products. Hence, information channels and knowledge on SVHC content is in place. Up to now all performance requirements, sourcing and testing routines relate to limitations on material level. Differentiation into e.g. parts, sub-parts, components of the article is not common.

The relevant legal requirements for toys are laid down in the newly revised Toys Safety Directive. Here the use of CMR substances in toys is restricted and thresholds for CMR (cat. 1, 2 and 3) refer to concentration in:

- toys,
- components of toys or
- micro-structurally distinct parts of toys.

These provisions are much stricter than the information obligations in REACH, as they restrict the use of all CMRs. The provisions apply to “placers on the market”, thus to producers and importers equally.

In the toys case, defined rules on declaration of conformity and CE marking exist. Such marking confirms that a product meets EU consumer safety, health or environmental requirements and the rules advice on how to ensure product quality. It was mentioned by interview partners, as well as in a study commissioned by the EU Commission¹, that final product testing alone is not sufficient to ensure product safety but it is necessary to ensure intensive communication within the supply chain.

Because of the sensitive and vulnerable user group, toys are subject to intensive market surveillance. This kind of market control forces actors to improve their quality management, as confirmed by interview partners. However, although rules and control procedures already exist, experience from the RAPEX system² shows that imported products are often identified as non-conform.

This case illustrates that current requirements pose higher demands on workability than the “new” information obligations under REACH. The workability of any consumer safety requirements are closely linked to the ability to communicate within the supply chain. It is shown that market actors are able to implement routines to ensure the flow of substance

¹ Evaluating Business Safety Measures in the Toy Supply Chain – Final report – European Commission, May 2008, Brussels

² RAPEX is the EU rapid alert system for all dangerous consumer products, with the exception of food, pharmaceutical and medical devices.

related information. Today, larger and brand toy companies are better placed in fulfilling their obligations than low price retailers.

4.5 Electric installations - power distribution unit

A power distribution unit (with about 6 kg weight) in electric installations has a complexity level of 10 to 100 parts. Preassembled parts of the article may also be bought as spare parts. Power distribution units are used in many industrial and professional applications but direct purchase by consumers is rare.

The supply chain is relatively short compared to the electronic's supply chain. No dominating "brand-producing" market leaders exist; instead the market is dominated by large retailers with limited inside knowledge of material composition of the articles.

Technical performance requirements defined on basis of harmonized standards (e.g. for electrical safety) are the main guiding factors in the design process. No specific requirements concerning problematic substances are included in design and material procurement routines.

Although the provisions in WEEE and RoHS do not apply to this article group, they have certain relevance as in many cases ubiquity standard components are used also in the electronic sector and the component producers do not differentiate between the two sectors. So as a general tendency it can be observed that some big part-producers in Asia declare to substitute SVHCs on the candidate list. Nevertheless, SVHC already included in the candidate list may still be present in power distribution units. For example the phthalate DEHP may be contained in the PVC of conductor wires, and brominated flame retardants may be present in concentrations of about 20% in PBT/PC³ enclosures.

Although electrical installations are often installed in buildings they do not fall under the current Construction Products Directive (89/106/EEC) and its ongoing revision.

It can be expected that information on SVHC will have to be provided, independent of the way the 0.1% trigger is applied (to the power distribution unit as a whole or to its parts and components). The SVHC concentrations in plastic parts of the article will, although being diluted by the total article weight, remain above the threshold.

³ Polybutylene terephthalate / Polycarbonate

4.6 Electronics – desktop computer

Desktop computers are articles of very high complexity consisting of numerous parts, components and materials. Parts, modules, components and spare parts are imported on their own. They can be bought separately by recipients and consumers for repair, for upgrading (e.g. of the processor), and for “home” assembly of a computer. Moreover, a second hand market exists for parts (e.g. graphic cards) from consumers’ upgrading.

A desktop computer can be divided into about 10 sub-parts containing more than 100 components that are composed of > 1,000 materials. Electronics are produced in complex and wide spread global supply chains with > 100 - 1,000 suppliers from the raw material to the final product. Normally big producers order from several alternative suppliers at each stage of the supply chain. Desktop computers, due to their modular design, are very often assembled close to the market in Europe, from parts produced in South East Asia.

SVHCs on the first candidate list and likely to be found in electrical and electronic equipment are:

- 3DBP: 15% w/w in flexible PVC
- DEHP: 30 - 45% w/w in flexible PVC
- BBP: 30 - 45% w/w in flexible PVC
- HBCDD: 5% - 7% w/w in high impact polystyrene (HIPS), expandable polystyrene (EPS) and extrudable polystyrene (XPS))
- SCCP and TBTO⁴.

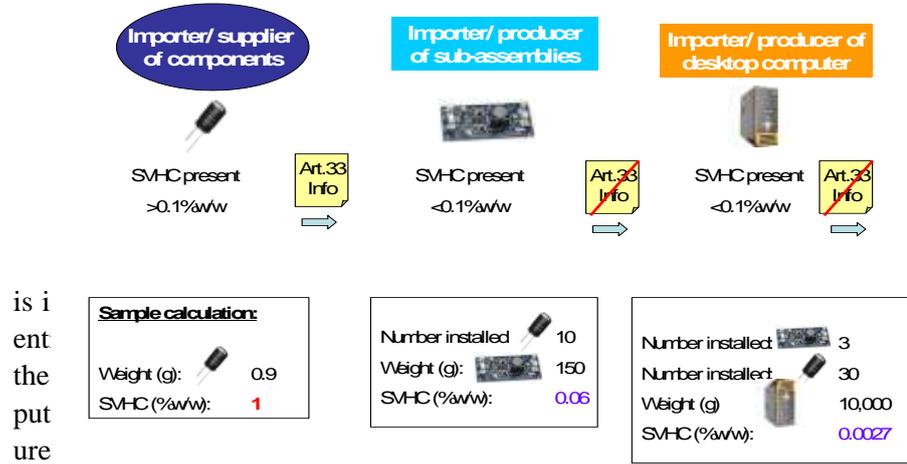
Based on the weight of a desktop computer (approximately 10 kg), up to 10 g of an individual SVHC could be present without triggering the information requirements for the article. Extrapolated to the total import per year (4,181,000 units in 2005 for EU25), theoretically up to 41.8 tonnes of SVHC could be present in desktop computers without information requirements.

One producer of desktop computers stated that individual SVHC concentrations are below 0.1% in the entire computer but they may, however, be above the 0.1% limit in parts and accessories like external rotating media storage device, external power adapter, cables, wired keyboard, wired mouse etc.

It was also stated by a producer that the existing product specific legislation has made it easier to get information from suppliers because they have become aware of issues around substance use. In some EU countries these regulations are subject to national market surveillance.

⁴ DBP: dibutyl phthalate; DEHP: Bis (2-ethyl(hexyl)phthalate); BBP: benzylbutyl phthalate; HBCDD: hexabromocyclo dodecane; SCCP: short- chain chlorinated paraffins) and TBTO: tributyltin oxide

Information dissemination within the supply chain:
Application of the 0.1% limit to the complex article



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Information dissemination within the supply chain:
Application of the 0.1% limit to the complex article

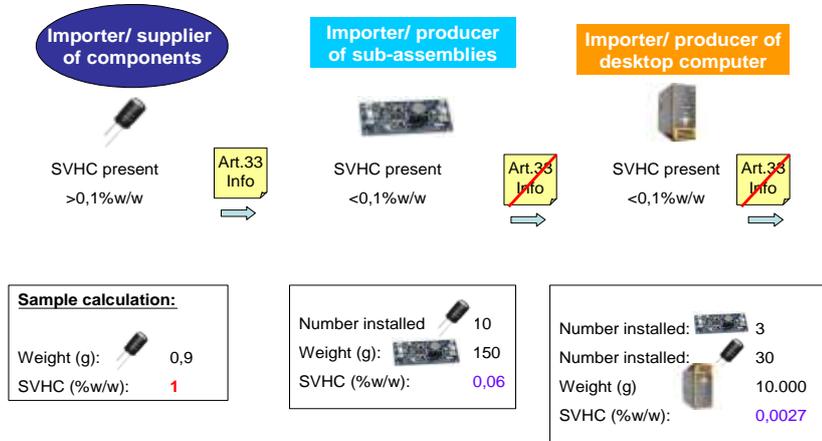


Figure 2: Application of the 0.1% threshold to the entire complex article

Applying the threshold to the entire computer would mean that only for components placed on the market as such and containing SVHC in concentrations above 0.1% would information be required according to Article 33. In case the threshold is applied to components the information would have to be forwarded until the final customer as shown in Figure 3.

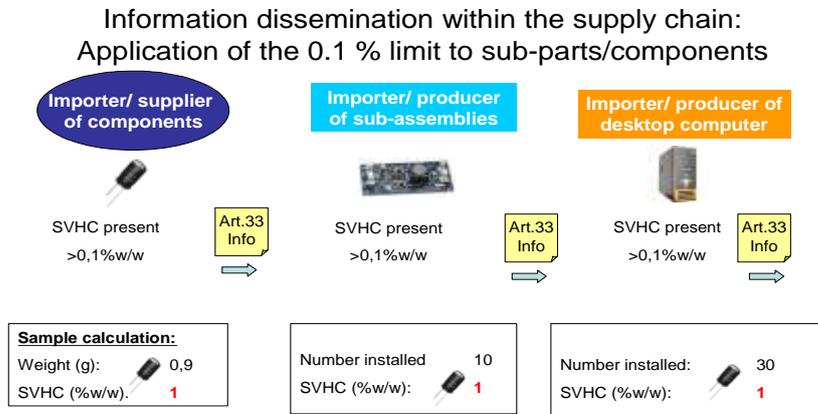


Figure 3: Application of the 0.1% limit to parts or components

Another effect is that information will get lost in cases of re-use of parts taken from complex article (Figure 4). Parts for repair and upgrade can be bought at almost any stage of the supply chain. If the flow of information is interrupted, information about SVHC will be lost for subsequent users of the part or component.

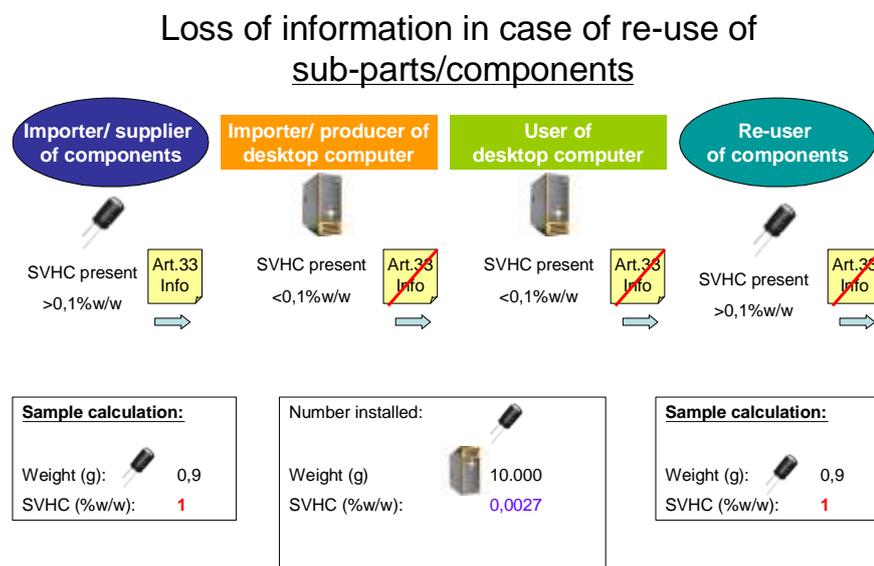


Figure 4: Loss of SVHC information when parts and components are reused

There are several units of reference in product related legislation as well as in industry sector internal terminology, attempting to define homogeneous materials, components, parts etc. The concept of applying restrictions and thresholds for dangerous substances in homogenous material exists in the RoHS Directive and applies to four substances resp. two groups of substances.

Producer of desktop computers have design control in the sense of technical performance, functionality, and RoHS-compliance but not to the far end of the supply chain. Sub-parts are ordered on simple performance specifications.

Furthermore the point was made by interview partners from industry that due to the wide spread structure of the supply chain and the limited market share of EU producers it is difficult to get completely the relevant information from the suppliers in the global market. For illustration it was mentioned that in the last months about 50% of the suppliers (mainly located in Asia) responded to the requests on SVHC of the first candidate list.⁵

But there are also market actors that demand substance related specification from their suppliers.

Market actors interviewed during the case study expressed clear reservations regarding a more detailed application (e.g. component) on the 0.1% limit under REACH. Some actors argued that another application of

⁵ This leads to the situation, that currently some producers of electronic devices simply provide the general information that phthalates from the first candidate list may be included in concentration more than 0.1%

the 0.1% limit in conjunction with the dynamic concept of an expanding candidate list would make it necessary to establish a full material declaration to trace down the SVHC content on material level.

At the moment there are no standardized instruments implemented to support exchange of full material declaration information - comparable to the automotive instruments like IMDS and GADLS. But intense efforts are made today to define at least standard formats for an information exchange (e.g. JIG standard).

This case confirms the relevance of the selection criteria: desktop computers are sold in very large volumes with a significant share of import. Spare parts are supplied separately and there is a second hand market for disassembled parts. The computers are used directly by consumers also and they are known to contain SVHCs.

This case illustrates the amount of SVHC that may escape REACH information provisions each year. Furthermore, gaps in the flow of SVHC information are demonstrated to occur as the concentration limit is applied to the final assembled computer. It is also shown that these gaps can occur at random.

Current product specific legal requirements involve restrictions on the content of substances in the materials used and may be more demanding than information obligations under REACH.

It is shown that market actors are able to ensure the flow of substance related information in order to control the composition of materials included in the final article. It is stated by interview partners that these regulations have made suppliers aware of issues around the use of substance and have made it easier to get access to information from suppliers.

5. General discussion of findings

While findings from the single case studies are presented in Chapter 4 (together with more detailed findings in the article fiches in Appendix 1), the following chapter discusses the findings against the overall objectives of the project.

5.1 Comparison with other legislations

An analysis of existing EU legislation restricting the use of chemicals in products and other legal environmental requirements with respect to products has been performed in parallel to the case study work. The analysis shows that thresholds and restrictions do not relate exclusively to complex articles. In general, more often components, parts or materials of complex articles are addressed as reference to which the requirements apply. Components and parts are clearly articles in most of these cases.

By incorporating the former Directive on marketing and use restrictions of dangerous substances (76/769/EC) into Annex XVII, a number of provisions are part of REACH itself. Here, the thresholds for dangerous substances relate to articles which are or might be part of a complex article, rather than to the whole complex article.

Several other legislative acts require industry to apply specific standards on parts of a complex article. This indicates that market actors of various industry sectors already apply different standards on parts of complex articles.

The current interpretation in the ECHA “Guidance on requirements for substances in articles” of how to apply the 0.1 % threshold implies that in practice different requirements apply to the same article when marketed separately and when incorporated into another (complex) article. This seems unique, as none of the legislative acts which have been studied presents such characteristics.

Neither do any of the analyzed legislative acts stipulate that the provisions should cease to apply once the articles are incorporated into a more complex article. On the contrary, it is made clear in other legislation that the requirements apply regardless of whether the articles have been incorporated into a complex article or not.

Also according to the current interpretation in the ECHA guidance, the obligation to inform on SVHC contents may cease to apply to an article when it is included in a more complex article while later it may reappear if the complex article is disassembled and the same part (article) is sold as a spare part e.g. for reuse.

The analysis suggests that future guidance on how to apply the SVHC threshold should encompass also situations that may arise because of other legal requirements for a specific type of articles.

5.2 Level of protection

The case studies show that even with the low concentration threshold of 0.1% triggering REACH information obligations, there will be considerable amounts of SVHC imported through large volume articles without triggering any safety information. For example every year, up to 900 tonnes of one individual SVHC could be imported as part of all kinds of shoes without specific notice into Europe by all shoe importers. A similar finding is illustrated in the case study of desktop computers, where the theoretical import of one SVHC could amount to almost 42 tonnes per year, without triggering information requirements. Even for a comparably small product group like the pliers tool, a similar estimation indicates the possibility of an annual import of 3.5 tonnes of any particular SVHC contained in pliers. These estimations indicate the extent of possible SVHC import “escaping” information provisions in REACH and consequently affecting the level of protection.

It is shown that through the increased weight of the assembled article, the final calculated SVHC concentration will be lower (“diluted”) than in the smaller part that contains the SVHC and is incorporated into the assembled article. Thus, SVHC concentrations can be decreased during article production to below the information triggering threshold. Consequently, gaps in information dissemination occur as information stops on the way to the recipients of the article.

On the level of practical experience information provided by market actors show very clearly that today in several parts of desktop computers SVHC are present in concentration above 0.1% while for the complex article “assembled desktop computer” the concentration is below this limit. In principle, the weight ratio is decisive for such dilution effects, but it needs to be considered together with the SVHC concentration in the respective part. For example, in the pliers case the weight ratio between the SVHC containing part - the handles – and the whole pliers tool is 1:20. Therefore, DEHP which is contained in a concentration of 40% in the handle is decreased to 2% in the final tool. Hence, there may be no difference in the triggering of information provision. In contrast to this, concentration of anthracene in a rubber handle close to the threshold – e.g. 0.2% - would be “diluted” to below the limit if reference is made to the complete pliers tool. Here the assessment will be sensitive to how the limit is applied.

In this context it needs to be stated that the SVHCs on the candidate list up to now are typically used in relatively high shares in the respective

materials. This is specifically true for the plastisers (DBP, BBP and DEHP, typically in concentrations between 20 and 50%, e.g. in plastics), and the flame retardant HBCDD (up to 30%). In the future SVHCs with lower “normal” use concentration may be included in the candidate list.

In summary, gaps in information will occur more often with large differences in weight between article part and complex article and also with lower use SVHC concentrations in the article part. This could be seen as a fictitious increase of the limit value for smaller articles when they get assembled into more complex articles and therefore, for any given part or component, the trigger for information requirement would vary widely, depending on how the individual item is used or marketed. This leads to the situation that “dilution effects” and information gaps will occur at random.

As mentioned already in section 5.1, such random application differs from how similar thresholds are to be applied according to other EU legislative acts. It is important to note that such arbitrary variations in the triggering of information obligations do not at all relate to the emission potential and possible exposure levels of the SVHC. The potential for exposure may be independent from whether an article is placed on the market as such or as part of another article, for example parts that are in direct contact with skin during use, like the textile cover of a sofa or the handle of a tool.

Applying the trigger to the whole complex article may lead to cases where safety measures would be relevant, (i.e. if exposure is likely) but the article producers/importers do not obtain information on the SVHC content in the article contained and therefore are not in the position to provide safety recommendations to the recipients of the complex article.

With view to the general objectives of the REACH regulation, it seems important to avoid or reduce gaps and losses of SVHC information in the supply chain. Several cases in this study illustrate that applying the threshold to the complex article may cause significant “dilution” to below the threshold in the assembled article and thereby loss of supply chain information. The application of the 0.1% limit to parts of the complex article on the other hand, would lead to more information and by that - indirectly - to a higher level of protection.

In all industry sectors covered by the case studies it was found that in general, knowledge on content of SVHCs in the materials used was fairly low. This will influence both the reachable level of protection as well as the workable implementation of the requirements. Such fundamental lack of knowledge is problematic, whatever way the triggering threshold will be applied and, hence, the situation will need to be significantly improved. Such improvement is one general objective of the REACH regulation.

5.3 Workability for industry

The case studies on shoes and toys show, together with experience from implementing the RoHS directive in the electronics sector, that market actors are able to implement routines to ensure the flow of substance related information. This illustrates that obligations linked to the task of communicating with the supplier about substance related issues are not new to industry. Furthermore, implementation of a product specific legislation and surveillance shows to be an effective push for coordinated efforts in the supply chains to improve the knowledge base in an industry sector. The efforts needed to fulfill information requirements according to Article 33 may therefore be less demanding for article categories with product specific legislation.

Following not only the legal obligations, e.g. in the shoes and toys cases, but as well practical considerations from quality management, the assessed established information routines are implemented on the level of materials and/or parts as main objects in the supply procedures.

It appears from all article categories studied that quite different situations exist, even inside the same industry sector or product group. On the one hand there are supply chains with full design control, effective communication routines and well established test procedures – on the other hand there are actors with fundamental lack of awareness regarding respective substance related requirements. Proactive actors have implemented suitable routines to define, communicate and control detailed product requirements not limited to fulfill existing legal requirements but ensure product quality in a wider sense.

Quality management

An overall conclusion from the findings is that workability largely depends on whether quality management systems are in place or not. In business reality, basic routines for “compliance” check are established to achieve core economic targets like technical/functional quality guarantees as well as contractual and pricing issues. If such basic routines are in place, they offer a suitable platform for addressing additional aspects like substance related requirements triggered by REACH.

Two approaches for market actors to ensure compliance with substance related requirements may be differentiated:

1. Inclusion of substance related aspects into the product
/information specifications communicated actively up the supply chain during sourcing activities
2. Implementation of a testing strategy for the final product.

The first approach can be observed in a full design control situation, typical for big brand producers and multinational companies. But as examples from big multinational companies in the shoes case and in the

computer case show, even such market actors need to complement their design control approach by testing materials and/or sources of parts at a certain level.

The second approach is mainly used by retailers and (other) importers buying case-by-case from a larger number of suppliers. Market actors in the latter situation report that testing the final product is not sufficient because the quality of components in these articles may vary between different batches or even within the same batch and might still cause non-compliance. Proactive market actors therefore tend to combine a testing strategy with other management tools e.g. like supplier ranking, supplier audits and/or blacklists to intensify the information exchange with their suppliers.

Access to SVHC related information

Article 33 of REACH states the duty to communicate information about SVHCs present in an article in concentrations above 0.1%. So in order to determine if the information obligations will be triggered and to ensure compliance producers will have to ask in their supply chain for information on SVHC content in materials/parts.

According to the findings of this study the workability of the information obligations will depend on how article producers and importers can get access to SVHC information and how much efforts they need to spend for that. This will be the main obstacle, irrespective of the application of the threshold to parts or to the complex article.

If the threshold applies to the whole complex article, for each incorporated part it is necessary to obtain information on the exact SVHC quantity, to add it up and to estimate the concentration in the final article. Communicating of such detailed information through a supply chain may be difficult for many reasons, for example because of business confidentiality.

If in contrast the threshold applies to the smaller articles (parts) of the final complex article only exceeding the limit would need to be communicated through the supply chain. No information on quantities would be necessary. This indicates that actually the workability increases, if the threshold is applied to the components.

In a way the same is true for industry's check of compliance (exceeding of the 0.1% limit). If the limit is applied on the level of a complex article, the SVHC content and weight of each component included needs to be analyzed as basis for the calculations. Only for small complex articles, shredding and testing of a sample is an alternative route. If the limit is applied to single parts, efforts for the analysis would remain the same, but the identification of weights and concentrations as well as calculations could be skipped.

According to the findings, it can be expected that the workability of Article 33 and the related resource needs to fulfill the information obliga-

tions are lower if the concentration threshold is applied to articles as such and not to the assembled complex article. This is mainly due to the loss of the need to calculate concentrations in complex article and the fact that changes in thresholds don't significantly affect management routines in the supply chains or requests from clients.

Business risks

It is important to bear in mind the links between the provisions of Article 33 and the authorization procedures under REACH. If a company does not receive information from its suppliers about the presence of a SVHC in the parts for a complex article, there may be an important lack of awareness to the fact that the article quality or composition may have to be changed in future because of that SVHC use being subject to authorization.

Such awareness would be needed for early action in particular by article producers and/or retailers, who depend on certain qualities of articles and parts, regarding supply contracts in the value chain and early reactions to customer demands.

The image of article producing companies has become more important, particularly for brand name owners. Companies may lose their good reputation if they are unaware of SVHC in their articles and cannot proactively manage their supply chain and prevent potential "bad will".

Competition aspects

The information gathered within the framework of this study does not allow an assessment of competitive effects, but nevertheless it may be used to identify some areas with potential implications.

EU-made and imported complex articles will to a certain extent be subject to different preconditions, if the limit is applied to the whole complex article. In practice, the access to information on SVHCs contained in different parts of a complex article assembled inside EU, as information on contents in such parts will circulate within EU. This may put more pressure on EU producers of complex articles to substitute SVHC than on importers of these articles. Furthermore, the EU producers of complex articles may indirectly have to carry the costs for information dissemination for the parts to be incorporated. On the other hand importers of complex articles would have to carry extra burden for their efforts to receive reliable information about SVHC contents.

The current ECHA Guidance's interpretation on how to apply the 0.1 % limit could also lead to disadvantages for suppliers of separate article parts. According to the current interpretation, the obligation to inform on SVHC contents may cease to apply for an article when it has been joined together with other articles into a complex article. For example, if a cover of a sofa which contains more than 0.1 % of a SVHC is sold separately an information obligation will arise, but this is not the

case when the sofa cover has been fitted on a sofa. So a supplier selling the cover directly to the consumers will have to provide information, while another supplier selling a whole sofa with the same cover fitted onto has no information obligations.

The effects described above might be seen as unfair and interfering with the attempt to create a level playing field for the actors on the European market. They might be diminished if the triggering threshold would apply to all articles, irrespective if sold separately or incorporated into complex articles.

5.4 Enforceability by authorities

Up to now, existing restrictions on the use of substances relate to materials and parts of articles. This has facilitated the market surveillance, especially when laboratory analysis is performed. Often the (chemical) analysis can only determine concentrations of a specific substance in a homogeneous surrounding, i.e. materials or parts of a complex article. When the concentration limit applies to these materials or parts, the compliance assessment becomes fairly simple. Furthermore, such enforceable provisions are also workable for industry.

When the concentration limit applies to a complex article that is assembled from several articles, parts and materials, the (chemical) analysis becomes more extensive. SVHC concentrations will have to be analysed in samples from a number of parts and materials. The more complex the article is the higher will be the efforts to check compliance. Furthermore the same problems already addressed in the context of “compliance checking” - like the need for exact weight ratios among the different parts and the final complex article - have to be faced here.

Using again the example of the sofa cover illustrates that confusing situations may arise when different requirements are in place for the same article depending only on how it has been placed on the market (as such or as part of a more complex article). This difficulty may lead to legal uncertainty for the market actors and enforcement bodies. Specifically in product groups placed on the market in lots of different configurations, like e.g. computers assembled from basic part in many different ways, this uncertainty is not easy to solve in a transparent manner. In addition, this confusion would raise criticism about the consistency of REACH obligations as well as the logics of relating requirements to levels of risk.

The difficulties in checking compliance with Article 33 may hamper efficient enforcement of producers and importers of complex articles and lead to difficult court cases.

Sammanfattning

Den nya europeiska kemikalieförordningen Reach (1907/2006/EG) trädde i kraft den 1 juni 2007. Genom förordningen gäller nya informationskrav för särskilt farliga ämnen (SVHC-ämnena) i varor, om gränsvärdet på 0,1 % (viktsprocent) överskrids för de SVHC-ämnena som förtecknas i kandidatlistan. Hur denna gräns ska tillämpas i fråga om sammansatta varor diskuteras dock fortfarande. I ECHA:s nuvarande vägledningsdokument "Vägledning om krav för ämnen i varor", ges tolkningen att haltgränsen 0,1 % gäller för en hel sammansatt vara, så som den är tillverkad eller importerad. Sex medlemsstater har en avvikande syn och ifrågasätter denna tolkning.

Mot denna bakgrund har projektets huvudsyfte varit att identifiera och beskriva exempel på konsekvenser av de nya informationskraven för olika varuområden.

Genom att exemplifiera olikheterna i nuvarande tillämpningar och beskriva vilken påverkan olika tolkningar av gränsen på 0,1% kan få, bör resultatet av detta projekt kunna bidra till den översyn av "Vägledning om ämnen i varor", som ska genomföras enligt ECHA.

Fallstudier som metod

Fallstudier för varukategorier ansågs lämpliga i denna studie, för att ge en realistisk uppfattning av hur olika industribranscher hanterar problematiska ämnen i varor och för att ge exempel på de följder som informationskraven i artikel 33 i Reach får.

Urvalet av varukategorier är gjort på basis av ett antal kriterier, inklusive innehållet av särskilt farliga ämnen (SVHC) i varan, liksom exponeringspotentialen för ämnet, varans komplexitet och en relevant andel import till EU. Ett förfinat andra urvalssteg gjordes på basis av ytterligare kriterier såsom egenskaper i leverantörsledet, upparbetade kontakter med industrin och tillgängligheten av marknadsinformation. Den slutliga listan med varukategorier innehåller:

- Möbler (stoppad soffa)
- Skor (sportskor)
- Verktyg (tänger)
- Leksaker (mjukdjur)
- Elektriska installationer (elfördelningscentral)
- Elektronik (stationär dator)

För fallstudierna kontaktades och intervjuades omkring 70 aktörer från 58 företag, organisationer och institut. Ett frågeformulär användes som vägledning, med frågor om kännetecknen för leverantörsledet, varan och dess komponenter, delar och material liksom frågor om informationsflö-

det i leverantörskedjan. Dessutom samlades importstatistik, marknadsvärde osv. in från allmänt tillgängliga informationskällor.

Urvalet av fallstudier gav en varierande varukomplexitet och en bra överblick över kännetecknen för olika leverantörskedjor och deras metoder för att kommunicera och kontrollera ämnesrelaterade krav.

Delar och komponenter i annan lagstiftning

Nuvarande regelkrav i EU för några specifika varutyper har analyserats parallellt med fallstudierna. Analysen visade att gränsvärden för och begränsningar av farliga ämnen inte uteslutande relaterar till sammansatta varor. En mängd ämnesrelaterade krav finns, som gäller olika nivåer (delar, komponenter eller material). Även i Reach finns det ett antal bestämmelser i Annex XVII, där gränsvärdet gäller för varor som är delar av sammansatta varor snarare än för hela den sammansatta varan. Flera andra lagstiftningar kräver att industrin ska uppfylla specifika standarder på delar till komplexa varor. Detta visar att industribranscher tillämpar olika standarder för olika delar av sammansatta varor.

Analysen visar att framtida vägledning om hur man ska tillämpa gränsvärden för SVHC-ämnen, också bör inbegripa situationer som kan uppstå på grund av andra regelkrav för en särskild typ av vara.

Kraven upphör att gälla i leverantörskedjan

Nuvarande tolkning i ECHA:s vägledning om hur gränsvärdet på 0,1 % ska tillämpas, innebär att olika krav kommer att gälla för samma vara när den säljs separat och när den ingår i annan (sammansatt) vara. Ingen av de analyserade rättsakterna har sådana särdrag. Ingen av dem innehåller heller regler som säger att bestämmelserna ska upphöra att gälla för varor när de satts in i mer sammansatta varor. Om man följer ECHA:s vägledning, skulle kraven upphöra att gälla när en mindre vara byggts in i en sammansatt vara.

Informationen kan gå förlorad

Fallstudierna visar att även med ett lågt tröskelvärde på 0,1 %, som utöser krav på information, kommer det att bli avsevärda mängder av SVHC-ämnen som importerats i stora mängder varor utan någon säkerhetsinformation.

Varje år kan till exempel upp till 900 ton av ett specifikt SVHC-ämne importeras till Europa som en ingående del i skor utan att detta särskilt uppmärksammas. Ett liknande fall illustreras genom fallstudien om stationära datorer, där den teoretiska importen av SVHC-ämnen kan uppgå till åtminstone 42 ton per år utan att kravet på information faller ut. Till och med i fråga om en jämförelsevis liten produktgrupp som tänger, pe-

kar en liknande uppskattning på en möjlig årlig import på 3,5 ton av ett av de SVHC-ämnena som ingår i tänger. Dessa uppskattningar visar på omfattningen av importen av SVHC-ämnena som möjligen kan ”undkomma” kraven på information i Reach.

Fallstudierna visar också i praktiken att koncentrationen av SVHC-ämnena i delar och komponenter i sammansatta varor (stationära datorer, tänger) överskrider 0,1 %-gränsen. Men att tillämpa tröskelvärden på den sammansatta varan resulterar i en tydlig ”utspädning” av koncentrationerna av SVHC-ämnena till under tröskelvärden och därmed går betydande information förlorad för leverantörskedjan. Därmed kan skyddsnivån påverkas.

Med tanke på de allmänna målen med Reach-förordningen tycks det viktigt att undvika eller minska luckor och informationsförluster i leverantörskedjan.

Sluppmässigt bortfall av information

Om man följer den nuvarande tolkningen av ECHA:s vägledning, kan flödet av information avbrytas när mindre varor med innehåll av SVHC-ämnena sätts in i tyngre/större, sammansatta varor, liksom även då SVHC-ämnena används i koncentrationer nära 0,1%-gränsen i mindre varor. Med andra ord kommer informationsbortfall att uppkomma oftare då det är stora viktskillnader mellan en del av en vara och den sammansatta varan samt med lägre koncentrationer av SVHC-ämnena i en del av en vara. Det betyder att för stora varugrupper som används som delar eller komponenter i sammansatta varor, kan kraven för information variera stort, beroende av hur den individuella varan används eller marknadsförs. Detta leder till en situation där ”utspädningseffekt” och informationsluckor uppkommer slumpmässigt. Det bör uppmärksammas att informationsluckor uppstår oavsett exponering eller risk.

SVHC-relaterad information är avgörande

För att bestämma om informationsskyldigheter i enlighet med artikel 33 i Reach gäller och för att försäkra att de efterföljs, måste varuproducenter efterfråga information i leverantörskedjan om koncentrationer av SVHC-ämnena i material och delar.

Av resultaten i denna undersökning att döma, beror användbarheten på hur varuproducenter och importörer kan få tillgång till precis information om SVHC-ämnena och på den möda de behöver lägga ner för att få det.

Detta kommer att vara det största hindret, oavsett om tillämpningen av gränsvärdet görs på delar eller den sammansatta varan.

I samband med detta, kunde det i fallstudierna märkas att kunskapen om skyldigheter i relation till ämne och ämnets innehåll i det använda materialet är ojämn och ganska dålig i vissa av leverantörsleden. Denna

grundläggande brist på kunskap har ingen direkt betydelse för frågan hur gränsvärdet ska användas, men situationen behöver förbättras avsevärt. En sådan förbättring är ett generellt mål för Reach-förordningen.

Flödet av ämnesrelaterad information är genomförbart

Fallstudierna med skor och leksaker, tillsammans med erfarenheter från tillämpningen av RoHS-direktivet inom elektronikbranschen, visar att marknadsaktörerna kan använda rutiner för att säkra ämnesrelaterad information. Skyldigheter som rör kommunikation om ämnesrelaterade frågor är således inte nya för industrin. Produktspecifik lagstiftning och tillsyn kan dessutom bli en effektiv press på att samordna insatser i leverantörsledet för att ta fram informationsrutiner.

Det verkar utifrån fallstudierna som om förhållanden kan var helt olika, även inom samma industrisektor eller produktgrupp. Å ena sidan finns det leverantörskedjor som har full kontroll på design, effektiva kommunikationsrutiner och fastställda testmetoder. Å andra sidan finns det aktörer med en grundläggande brist på medvetenhet när det gäller ämnesrelaterade krav. Proaktiva aktörer har använt sig av lämpliga rutiner för att definiera, kommunicera och kontrollera detaljerade produktkrav som inte begränsas endast till att uppfylla gällande lagkrav, utan också ger en försäkran om produktkvalitet i vidare mening. Speciellt fallstudierna med leksaker och elektronik visar att marknadsaktörer kan införa sådana rutiner på materialnivå.

Kvalitetshantering ger grunden

En övergripande slutsats från resultaten är att genomförandet huvudsakligen beror av om det finns kvalitetsstyrningssystem eller inte.

De resurser som behövs för att uppfylla informationskraven kan dessutom förmodas vara lägre om koncentrationsgränsvärdet tillämpas på varor som sådana, istället för på sammansatta varor. Då finns inget behov av att beräkna koncentrationer för den slutliga sammansatta varan utifrån alla ingående delar, och inte heller behövs någon detaljerad kommunikation med alla leverantörer av delar.

Ändringar i hur gränsvärdet tillämpas påverkar troligen inte de ansträngningar som krävs för att ta fram grundläggande rutiner för kvalitetssäkring. Antalet förfrågningar om information från kunder skulle troligen också vara detsamma.

Enligt denna studie beror genomförandet främst på hur varuproducenter och importörer kan få tillgång till information om SVHC-ämnen och vilka ansträngningar som krävs för att få denna information. Detta kommer vara det främsta hindret, oavsett hur gränsvärdet tillämpas. Tillämpas gränsen på den sammansatta varan kommer företagen tvingas beräkna innehållet av SVHC-ämnen i varje del och för varje sådan beräkning

krävs mer detaljerad information delens vikt och exakta SVHC-koncentration, vilket inte kommer vara lätt tillgängligt i de flesta leverantörskedjor.

Störningar på den inre marknaden

Om gränsvärdet tillämpas på sammansatta varor kommer sådana varor som tillverkats inom EU i viss utsträckning ha olika förutsättningar än importerade komplexa varor. Det kan vara lättare att få information om SVHC-ämnen i delar av en sammansatt vara som satts ihop inom EU, eftersom sådan information cirkulerar inom EU. Detta kan sätta mer tryck på EU-producenter av sammansatta varor än på importörer att byta ut SVHC-ämnen.

Som visats i fallstudierna (t.ex. soffa, stationär dator) skulle tolkningen i nuvarande vägledning från ECHA leda till olika krav för leverantörer av reservdelar och för leverantörer av mer komplexa varor.

Sådana störningar på den inre marknaden kan komma att minska om gränsvärdet gäller alla varor, oavsett om de säljs separat eller om de ingår i en komplex vara.

Riskfyllt för företagen att sakna information om SVHC-ämnen

Det är viktigt att vara medveten om relationen mellan bestämmelserna i artikel 33 och tillståndsproceduren i Reach. Om ett företag inte är informerat om förekomsten av ett SVHC-ämne i en sammansatt varas olika delar, kan föreberedelsestiden bli kort för att ändra varans kvalitet eller sammansättning om den användningen av SVHC-ämnet skulle bli föremål för tillståndskraven i Reach.

Insatser för tillsyn kan öka

Gällande begränsningar i användningen av kemikalier har att göra med material och varudelar. Detta har underlättad marknadskontrollen, särskilt när laboratorieanalyser görs. Ofta kan sådana analyser endast bestämma koncentrationerna av ett specifikt ämne i en homogen omgivning.

När koncentrationsgränser används för varor som består av olika material, blir analysen mer komplicerad eftersom alla komponenter måste kontrolleras. Ju mer komplex en vara är, desto större resurser måste användas för att kontrollera regelefterlevnad.

Dessutom skulle exakta viktförhållanden mellan de olika materialen eller delarna och den slutliga sammansatta varan behövas för att räkna om den totala koncentrationen i hela den sammansatta varan. Detta kan bli ett problem för tillsynen likaväl som för industrin vid interna kontroller.

Appendix 1: Article fiches

1.1 Furniture (upholstered sofas)

1.1.1 Rationale of selection

Sofas are found in almost all households and in many professional situations (e.g. offices). It is known, that several problematic substances are used in upholstered furniture⁶.

In terms of the case selection criteria, “upholstered sofas” have been selected as an example of upholstered furniture:

- An article that contains SVHC exceeding 0.1 % at least on material level
- An article with quite low complexity (10 – 100 materials/parts)
- A complex supply chain with market actors on each level inside and outside EU
- Exposure to humans may occur during production and use (inhalation and skin contact)
- Exposure of the environment occurs during the waste stage

Short description of construction and materials of the article

The case addresses upholstered sofas used indoors in private households. Sofas with leather covering are not subject of this study. Fabric upholstered sofas may consist of materials like:

- Coated or painted wooden frame
- Upholstery materials made of foamed material
- Covering made of dyed textile
- Metal parts

The weight of a sofa depends on the size of the parts. Table 1 lists the composition of parts and materials of a typical upholstered sofa whereas weights and weight shares are specified in Table 2 for one example.

⁶ KEMI (Posner, Stefan]: Survey and technical assessment of alternatives to decabromodiphenyl ether (decaBDE) in textile applications, PM Nr. 5/04.

KEMI [Posner, Stefan]: Survey and technical assessment of alternatives to TBBPA and HBCDD, PM Nr. 1/06.

Prioritisation dossier for Hexabromocyclododecane at:
http://echa.europa.eu/doc/consultations/recommendations/prioritisations/prioritisation_hbccd.pdf

Table 1: Description of parts and materials in a “two-seat sofa bed frame”⁷

Parts/ modules	Material(s) (weight)
Frame	Particleboard, Fibreboard, Solid wood, Plywood,
Back	Polyurethane foam 21 kg/m ³
Armrest	Polyurethane foam 25 kg/m ³ ., Polyester wadding Fire-retarding interliner/ mattress cover Total composition: 100% cotton
Seat cushion	Highly resilient polyurethane cold foam 40 kg/m ³
	Seat cushion: 100% waterfowl feathers
Back cushion	Polyester fibres
Leg	Polypropylene plastic
Bed mechanism	Steel Pigmented polyester powder coating
Elastic webbing	65% polypropylene 35% rubber
Mattress	Polyurethane foam 30 kg/m ³
Cover	100% cotton

Table 2: Specification of materials and weight shares in “EKTORP KD So2” (information provided by IKEA)

EKTORP KD So2		
Material	Weight (kg)	% weight share
Softwood	9,30	19,9
Plywood	0,79	1,7
Particle board	18,50	39,6
Hardboard	3,90	8,4
Cardboard	0,68	1,5
Foam PU	1,30	2,8
Foam HR	2,70	5,8
Cut foam	0,39	0,8
Polyester fibre wadding	0,74	1,6
Polyester fibre	4,50	9,6
PP	0,90	1,9
Metal fitting	2,60	5,6
Plastic leg	0,40	0,9
Total	46,70	100,0

1.1.2. Supply chain characterisation

The sector is divided into two major segments. The first one is dominated by large companies like IKEA or CONFORAMA that influence the complete supply chain, as they are in charge of design, selection of materials and use substance “black” lists to exclude substances from their products along the chain. But the bigger share of the sector is made up of small and mid-sized manufacturers. Their products are sold via small specialized stores or large retailers. They produce the articles basically by their own specifications, although there are large retailers involved, which provide similar “black” lists like those mentioned before for the large companies.

Supply chains are - as far as the smaller companies involved - not that complex. Small manufacturers buy their material on a local scale. Only relatively few direct imports from non EU countries are known.

General understanding within the furniture sector is that the 0.1 % limit refers to the article as placed on the market; therefore it is expected that dilution processes will lead to compliance in any case.

Production volumes and share of import

The European production of furniture components is worth about € 5.2 billion. Italy is a leading European producer, exporter and consumer, while Germany - being the main furniture producer in Europe - is a leading importer of furniture components⁸.

The production value of the entire furniture sector at the EU27 level reached € 105.1 billion in 2007. The value of export to non-EU countries was € 11.1 billion while import into EU was at € 12.6 billion. The largest share of import was generated by China, increasing the trade by 31 % to a total of € 6 billion. Other large imports to EU were from Indonesia (stagnating imports) and Vietnam (+16%). Turkey is also becoming a major supplier. No detailed data for upholstered furniture is available.

1.1.3. Information on hazardous substances

Potential SVHCs that may be used in upholstered sofas are brominated and phosphorous flame retardants (e.g. HBCDD on the first candidate list), formaldehyde, phthalates (DEHP, DBP, and BBP on the first candidate list), chromium, azo-dyes, pigments and organotin (TBTO on the first candidate list). The content of flame retardants typically is between 5-10% in foams. Phthalates may be present as softeners in artificial PU leather covers.

Exposure relevance

⁸ <http://www.worldfurnitureonline.com/showPage.php?template=reports&id=1826>

Exposure to humans may occur during production and use (inhalation and skin contact) whereas exposure to environment may occur during the waste stage.

Case specific dilution factor

Table 3 shows that even if the SVHC concentration limit is applied to the whole upholstered sofa, the information obligations will be valid at all stages. Data on weights in this table relate to information from Table 2. It should be noted however that IKEA does not in any case use SVHCs in their products.

Table 3: Influence of weight difference as dilution factor on information obligations

SVHC	Material	Typical SVHC content in final article	concentration of SVHC in final article (total weight 46.7 kg)	Weight difference as dilution factor	Information obligation
	Typical SVHC concentration in material				
	Weight of material				
Flame retardant (e.g. HBCDD)	Foam	0.2 – 0.4 kg	0.4% - 0.9%	ca. 10	At all stages
	5-10%				
	4.39 kg				
Phthalate (e.g. DEHP)	PU cover	0.8 – 1.2 kg	1.7% - 2.6%	ca. 10	At all stages
	20%				
	4-6 kg				

Legal requirements and other standards

In addition to restrictions for the use of substances in REACH Annex XVII and the General Product Safety directive, certain national safety requirements concerning fire safety exist. For example in the United Kingdom and Ireland, upholstered furniture explicitly has to be furnished with flame retardants to meet requirements of the national Furniture and Furnishings (Fire Safety) Regulations. Also in the US some states (e.g. California) require high fire safety standards. If these fire safety requirements are not met, the market is closed for the respective product.

Apart from legislative requirements, a CEN process is ongoing to work out standards for fire resistance in furniture. The objective of

CEN/TC 207 is to prepare European standards in the field of furniture, particularly on terminology, safety and health related aspects, test methods and dimensional co-ordination. For example:

- N 1021-1:1993: Furniture - Assessment of the ignitability of upholstered furniture - Part 1: Ignition source: Smouldering cigarette (ISO 8191-1:1987 modified)
- EN 1021-2:1993: Furniture - Assessment of the ignitability of upholstered furniture - Part 2: Ignition source: Match flame equivalent (ISO 8191-2:1988 modified)

Other instruments implemented on the market include eco-labelling schemes like the EU Flower, the Nordic Swan, the German Blue Angel for the whole product and Ökotex 100 for the sofa covering. The Blue Angel scheme bans the use of flame retardants in upholstered furniture.

Practical experience on substance content and information dissemination

Typical characteristics of the furniture sector include the two aspects “high volume” and “preservation during transport”. These aspects set some limits for the import of complete upholstered sofas from non-EU countries. On the other hand upholstery is a time consuming manual operation dominated by labour costs.

These aspects may lead to the following quite specific situation: Many components and parts (e.g. the covering, the feet, and the metal frame) are imported from outside EU. Pre-fabrication takes place at a brand producers’ site and then the pre-assembled parts are exported again for the upholstery (e.g. to countries outside the eastern borders of EU). After re-import, final assembly and quality check the sofas are put on the EU market. This means that the 0.1% limit already applies to the components during the first import. But still loss of information might occur due to weight difference as illustrated in Figure 1.

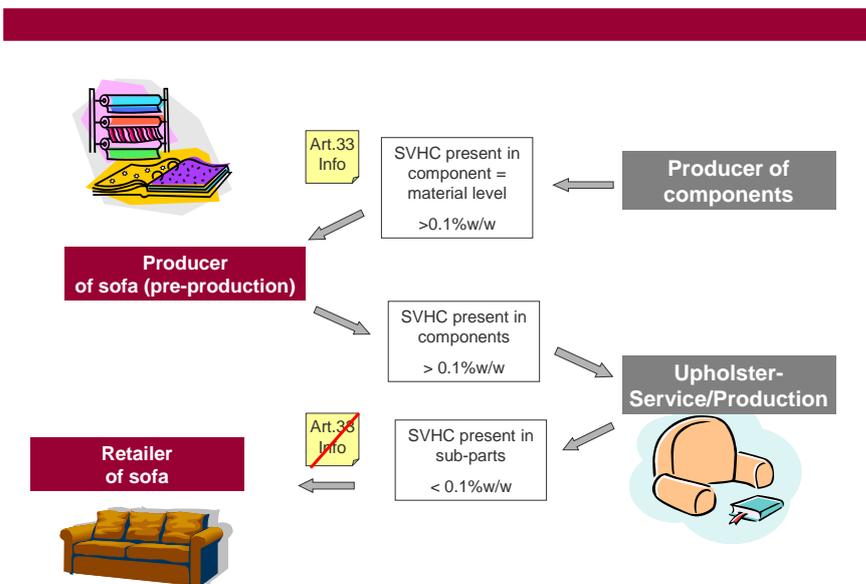


Figure 1: Loss of information due to weight difference between pre-assembled and finished sofa

The situation explained above is more relevant in the segment of high price furniture. Here major brand producers like IKEA have implemented full design and quality control routines ensuring safe products already on the level of the (imported) material.

On the other hand resellers in the low price segment importing complete upholstered sofas from non-EU countries do not have a quality management system. Implementation of system routines and awareness on REACH obligations seem quite low.

1.2 Shoes (sport shoes)

1.2.1 Rationale of selection

Shoes as article group have a large variability in complexity, covering both very simple shoes (e.g. sandals) as well as more complex ones with up to 250 parts and 50 materials (e.g. sports shoes). The present case study mainly deals with the more complex sports shoes.

In terms of the selection criteria the following aspects are fulfilled by sports shoes:

- SVHC content: shoes may contain various SVHCs exceeding 0.1% w/w at least on material level. Known hazardous substances used in shoes are e.g. phthalates in shoe soles, flame retardants in shoes used for certain jobs, chlorinated paraffins⁹.
- Complexity: the more complex the shoe is, the more complex is the supply chain. Members of all stages of the supply chain are located inside and outside the EU.
- Exposure: consumer exposure may occur via skin contact during use. Exposure of the environment occurs during the waste stage.
- Beyond requirements from general product safety control, producers and importers are required to label the main components of footwear for sale to the consumer according to the materials used.

Introductory note

In the preparatory phase of the study, contacts were established to various actors within the footwear supply chain (i.e. shoe producers, a footwear association, test and research institute specialised in the analysis of footwear). However, in the second phase of the study most of the actors did not show interest in any further cooperation and did not want to support the preparation of the case. As one of the main reasons, the actors mentioned that they are comfortable with the current interpretation of the 0.1% limit.

The data in this case is from publicly available information, information provided by one manufacturer of sport shoes, three fashion & shoe retailers and a testing institute, Bureau Veritas, Germany.

Short description of construction and materials of the article

In general, shoes are made up of the following parts: upper material, lining material (quarter lining, vamp lining, tongue lining, back lining), sock material, interlining material, toe cap, heel cap, vamp underlay, thread, stamp foil, label, pad cushion, lasting glue, last, orthopaedic sock,

⁹ KEMI PM 2/01: Chemical substances in shoes – a pilot study.

bottom filler, tack, insole material, outer sole, glue, shoe polish, heel seat padding, reinforcement, facing and shank. Sport shoes may additionally have lace or velcro, eyelet, eyelet strap. These parts can of course be found on the market but may not always fulfil the REACH definition of an article.

Typical materials are leather, textile (cotton, linen, nylon), plastic, cork, felt, rubber, fur and fleece. Some typical compositions and weight shares are shown in Table 4.

Table 4: Main parts and materials in some shoe types and their relative weight shares

Children trainers (~130g)			
Part	Material	Weight	
		[g]	[%]
Sole	TPR ¹⁰	70	53.9
Edging	textile	5	3.9
upper material	PUR ¹¹	40	30.8
upper material	stitchery	2	1.5
upper material	colour	-	-
insole material	EVA ¹² , mesh	10	7.7
Children trainers (~120g)			
Part	Material	Weight	
		[g]	[%]
Sole	TPR	70	58.3
upper material	leather/PUR	35	29.2
upper material	fibre	2	1.7
upper material	colour	-	-
insole material	EVA, mesh	12	10.0
Sneaker (~250g)			
Part	Material	Weight	
		[g]	[%]
Sole	TPR	80-120	32.0 – 48.0
upper material	leather/PUR	70	28.0
Lining	textile	30	12.0
Application	plastics	10	4.0
Shoelaces	textile	15	6.0

¹⁰ TPR = Thermoplastic Rubber, also referred to as thermoplastic elastomer (TPE), a physical mix of polymers with both thermoplastic and elastomeric properties.

¹¹ PUR = Polyurethane

¹² EVA = Ethylene vinyl acetate copolymer

1.2.2 Supply chain characterisation

The supply chain is quite complex with up to 50 suppliers from the raw material to the final product. They are located both within and outside the EU.

Production volume and share of import

Data on production volumes and share of import are available only for the footwear industry in general i.e. without distinguishing different shoe types.

An overview of production and external trade for the EU footwear market during 2004-2007 has been published¹³. The overview is presented in Table 5, showing that import (expressed in 1000 pairs) is increasing steadily whereas internal production is decreasing and export remains more or less constant.

Table 5: EU27 Production, consumption and external trade of footwear (Source: Eurostat + estimates by DG Enterprise & Industry)

Data expressed in 1000 pairs	2004	2005	2006	2007	% growth 2004-2007
Production	783 178	706 704	684 639	642 386	-18.0
Exports	168 929	160 563	164 793	170 472	0.9
Imports	1 661 659	1 929 858	2 096 155	2 504 729	50.7
Apparent consumption	2 275 908	2 475 999	2 616 001	2 976 643	30.8

Figure 2 illustrates the EU production volume (expressed in thousands of pairs) and the corresponding value (expressed in thousands of €)¹⁴. In

¹³ http://ec.europa.eu/enterprise/sectors/footwear/statistics/index_en.htm

¹⁴ Data from EUROSTAT "Statistics on the production of manufactured goods ANNUALS" and Montani (2008): Study for the footwear criteria revision; work package 1, preliminary report – 1st background report, Version 23 October 2008.

2006, the footwear production value reached approximately €13 billion. The main EU producers are in Italy, Spain, Portugal and Romania.

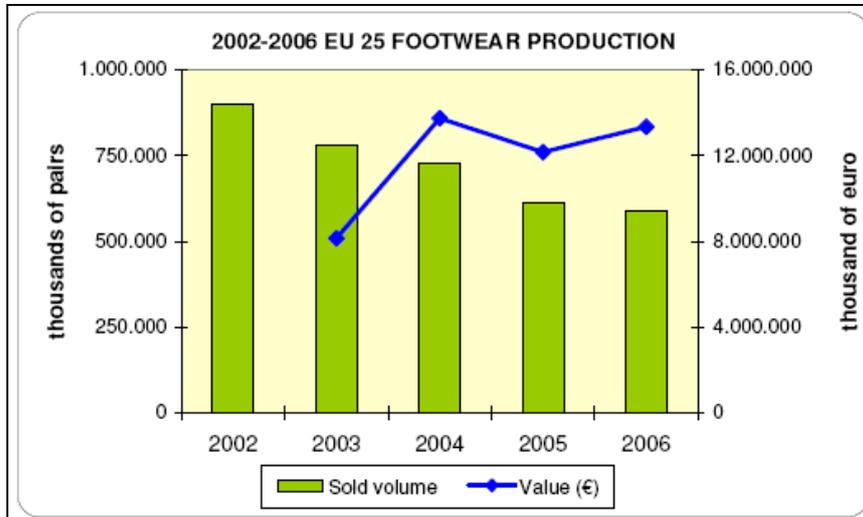


Figure 2: European footwear production in 2002-2006: sold volume and value (Source: EUROSTAT 2006; in Montani 2008)

Figure 3 illustrates the EU import of footwear (expressed in thousands of pairs) and the corresponding value (expressed in thousands of €). In 2005, the value of footwear imports reached a value of approximately €12 billion.

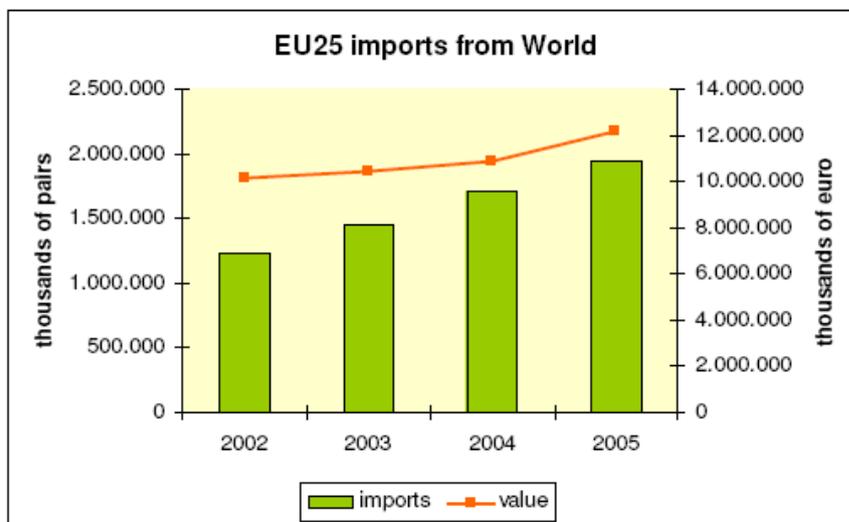


Figure 3: European footwear import in 2002-2006: number of thousands pairs and value (Source: EUROSTAT 2006, in Montani 2006)

1.2.3 Information on hazardous substances

No information was made available by interview partners on the use of SVHCs on the candidate list or potential SVHC in materials or parts of entire shoes. However, identified and potential SVHC may be present in shoes depending on the used material:

- textile: e.g. azodyes, dispersive dyes, formaldehyde
- leather: chromium (VI), PCP, chlorinated paraffines (short chain chlorinated paraffines are included in first candidate list)
- plastics: cadmium, lead, dimethylformamide, aromatic solvents, phthalates (DEHP, DBP, and BBP are included in first candidate list)

More information on hazardous substances that have been detected in materials used in shoes is shown in Table 6.

Table 6: Materials and hazardous substances and SVHCs measured in shoes [information provided by Bureau Veritas, 16/07/09]

Material	hazardous substances and SVHC
Textile	Azodyes Dispersive dyes Formaldehyde (in Germany: threshold is 1500mg/kg (→ 0.15%, in practice no exceeding measured)
Leather	Chromium VI PCP (but rare) Chlorinated paraffines (threshold: 10,000 mg/kg (→ 1%) in practice no exceeding measured, often companies have own limits of 100 - 1,000mg/kg (→ 0.01 – 0.1%) which is a value that is sometimes exceeded in practise)
Plastics	Cadmium Lead Dimethylformamide (only in PUR) Solvents (e.g. aromate, benzene as impurities, rare)

Therefore, it should be noted that knowledge about the materials used will be essential for product quality assurance.

Exposure relevance

Consumers may be exposed via close and long lasting contact with skin when wearing the shoes. Emissions to the environment may occur through abrasion of the shoe sole during use and additionally during the waste stage.

Case specific dilution factor

As no information on SVHC contents in shoe materials or parts was provided by the supply chain actors, no case specific dilution can be

shown. Instead, this case can illustrate how much of a SVHC that hypothetically can escape the information provisions in REACH via import of shoes that contain SVHCs in concentration below the threshold. As shown already in Table 5, import is dominating so that 4 out of 5 pairs of any kind of shoes are imported.

The total number of imported shoes and the typical average weight of 185 g per shoe gives some 900 tpa of a single SVHC that theoretically could be imported without triggering REACH information requirements if the 0.1 % limit is applied to the entire shoe.

Legal requirements and other standards

In addition to restrictions for the use of substances in REACH Annex XVII and the General Product Safety directive, legal requirements for labelling of the upper, inner and sole parts of a shoe regarding their main constituting material are established in Directive 94/11/EC. According to this directive, producers and importers are required to label the main components of footwear for sale to the consumer as regards the materials used (e.g. textile, plastics, leather). The labelling shall convey information relating to the three parts of the footwear: the upper, the lining / sock, and the outer sole (Art. 1). Only materials covering at least 80% of the surface areas or 80% of the volume of the outer sole shall be regarded. If no one material accounts for at least 80%, information should be given on the two main materials used. The manufacturer is responsible for supplying the label and for its accuracy. If he is not established in the Community, the person who first places the footwear on the market is responsible (Art. 4).

Practical experience on substance content and information dissemination

In the shoe market there are on the one hand some few actors with full design control, giving stringent specifications on the composition of all materials included in the final article. This group has control of chemical content in the raw materials used for the final shoe. On the other hand there is also a suppliers market where the actors only choose to buy or not buy articles as offered off-the-shelf. In the latter group, specified requirements are most likely to relate to functional performance of the final article rather than to information on chemical substances. The producer specifications do not reach deeply into the supply chain.

Shoe producers can usually get information on the composition and SVHC (and/or hazardous substance) content in materials on request. With suppliers outside EU it is, however, very difficult to obtain information. The interviewed shoe producer and shoe retailer both stated that they communicate lists of banned or undesired substances to their direct suppliers, prescribing which substances must not occur in the supplied mate-

rials or parts. This includes the legally required bans and restrictions, as well as company internal standards.

Compliance with the restrictions is to be proven by the material supplier through laboratory analysis and documented in certificates of conformity. In order to control the suppliers, analytical tests on materials or semi-finished goods and articles are performed by the shoe producer as well.

So, test routines for banned substances are generally performed for materials and parts as well as for whole articles as placed on the market. Actors with full design control perform testing for a number of listed substances on material samples. Only approved materials can be used for the later production steps. Therefore these actors do not foresee any problems to address future SVHC requirements at the level of materials.

However, market actors in this product group expressed that they were not inclined to deviate from the current application of the 0.1% limit to the complex article. This could indicate that the application may be of relevance at material level (and thus influence the freedom in the selection of materials) but not at the level of the final article.

Quality Management routines

Existing quality management (QM) routines are described by using the example of PUMA as a global brand producer of sports shoes. It sources materials, parts and entire shoes almost exclusively from outside the EU. PUMA demands specifications of chemicals down to the level of the manufacturer of the raw materials.

The same situation is described by one fashion & shoe retailer who stated in the interview to use lists of restricted substances and third party testing as well as audits to ensure the specification of the materials used.

Before any production of a new collection in the PUMA case, all materials have to be approved concerning the chemical composition by a third party testing institute. Otherwise the materials are not allowed to be used in production (see Figure 4).

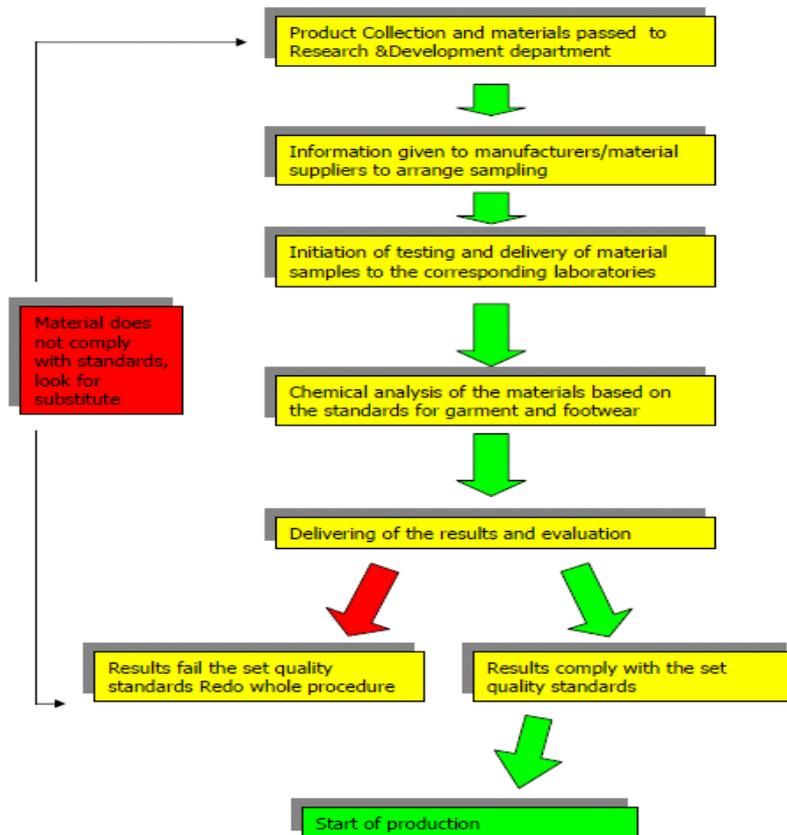


Figure 4: Flow Chart of the sampling and testing procedure (Source: PUMASafe, HANDBOOK OF ENVIRONMENTAL STANDARDS 05-2009)

Fabrication sites are only allowed to procure and store approved materials. In case the stored materials are all used and new orders have to be placed, those materials have to pass the same procedure. Thresholds for chemicals in the materials are set in a “Handbook of Environmental standards PUMASafe” (see Box 1). Other routines to guarantee workability are also described in this handbook, e.g. for testing and sampling. Testing has to be finalised prior to ordering of materials. The actor has to document whether or not a material has passed a test and provide precise data on the content of a substance.

Currently, PUMA is implementing a database to improve the capability of the test documentation. At the moment, all testing results for every product can be provided within one day.

3.1.1 Sampling materials for shoe production

Every material of the shoe, which has a direct or indirect contact with the foot, has to be analyzed. Two material sheets measuring 20x30 cm in size should be collected and labelled precisely in the way shown in Figure 2. In general one of the collected samples is sent to the corresponding lab and the other is stored at the PUMA office. The stored sample should be used as reference material to assist in interpreting results. At this point of sampling it is important to distinguish between natural fibers, manmade fibers, leathers and leather fibers, since different materials have to be analyzed via different analytical methods. The parameters to be analyzed in the field of shoe production are listed in the following chapters. All listed environmentally harmful substances are to be compared with the legal limit values required by German or European law and with the recommended limit values required by Non Governmental Organizations (NGO's).

Box 1: Material sampling procedure in shoe production (Source: PUMASafe, HANDBOOK OF ENVIRONMENTAL STANDARDS 05-2009)

Testing is done for a number of listed substances, so material samples get separated into different types of material in a very first stage, as different analytical methods will have to be used.

Relevant substances from the REACH candidate list, like phthalates or short chained chlorinated paraffines (SCCP), are blacklisted or limited by this producer, at levels far below the threshold in REACH. For example, the threshold for SCCP is 100 mg/kg shoe material (0.01 %, w/w). Furthermore, PVC is banned in all PUMA products and thus the main use of phthalates is eliminated.

PUMA does not foresee any problems to address future SVHCs and declare their content at the level of materials. PUMA states that control of SVHC in shoes does only work on the material level and that the current interpretation application of the legal text leaves freedom of choice for raw materials.

1.3 Tools (pliers/cutters)

1.3.1. Rationale of selection

The case addresses hand tools for Do-It-Yourself (DIY) and professional uses. To exemplify such articles pliers/cutters are discussed. Electric tools are not addressed in this study.

Pliers/cutters were chosen as articles of very simple composition, consisting of only a few different materials. Although they are made of a few materials, weight differences between the materials might lead to loss of information.

Generally the main part of a pliers/cutter is made of steel or a similar material. The handles are usually made of rubber or plastic. Substances in the non-metal parts are relevant for human exposure as the handle is directly touched during use. Substances of very high concern, e.g. softeners or polycyclic aromatic hydrocarbons like anthracene have been found in handle materials.

In terms of the case selection criteria, pliers are described as:

- Article may contain SVHC exceeding 0.1 % at least at material level
- Article complexity is low (< 10 materials/parts)
- Supply chain is short
- Exposure to humans may occur via skin contact during use
- Exposure to the environment occurs during the waste stage.

Short description of construction and materials of the article

Most hand tools are made of a steel component and a handle of another material. The handle can be constructed of plastic material (thermo-plastic elastomers, PVC) or rubber (in rare cases also of wood). Sometimes different materials are combined for the handle.

An example of the article as communicated by a manufacturer is shown in Figure 5.



Figure 5: Examples of two types of cutters and their components

As shown in the overview of parts and materials in Table 7, a typical pliers/cutter may weigh 400g, ranging between 100 – 700 g and weight shares of the materials may be:

- Metals 50 - 95 %
- Plastics (or rubber or other handle material) 5 - 50 %

Table 7: Typical composition of parts and materials in a pliers/cutter

Parts (weight)	Materials	Total weight
Corpus (360 – 380g)	Steel	360 – 380g
Handle (2 – 20g)	Thermoplastic elastomer or rubber	4 – 40g

1.3.2. Supply chain characterisation

The largest share of tools of the described kind are sold by large building centre companies for the DIY sector in Europe. A minor part of hand tools is sold by specialist shops. Often craftsmen and other professional users purchase the same tools as consumers and there is no differentiation between tools for professional users and for consumers.

In general, the supply chain is short and consists of just a few stages, due to the few materials and parts constituting the article. All stages of the supply chain may be present inside or outside the EU (from raw materials to finished articles).

The producer market is fragmented into many actors of small and medium size. Some produce as third parties “no name products”, others run own brands. The European Tool Committee has 237 members according to its website¹⁵. In 2008 an international hardware fair had 3360 exhibitors, of which 1467 were from EU/EFTA states and 1893 from non-EU countries (1680 from Asia)¹⁶.

Building centres sell producer-branded tools as well as own brand tools. In both cases, the building centres can influence the product design and composition, either directly if they are producers themselves or indirectly by posing respective demands to the supply chain. As stated by B&Q in an interview almost every building centre company in this sector has these two roles.

In other cases the building centre functions as a retailer only. A retailer buys products as available on the market. His influence on the production process is limited to some basic specifications on the product (e.g. colour, size).

Normally there is no influence on the product design at all in the latter case. So basically two different situations can be observed in this sector:

- Full design control (by EU actor – producer or retailer) and
- Suppliers offer articles mostly from non-EU countries.

Production volume and share of import

In the first half of 2008, the internal trade with pliers¹⁷ within the EU27 countries had the value of ~ €120 million. The import from outside EU had a value of €61 million (see Figure 6).

It is not possible to extrapolate directly from the reported values to numbers of pliers placed on the EU market due to a wide range of prices. Additionally, all metal pliers and semi finished metal parts are included in this statistics.

It can still be estimated that there is a relevant share of pliers imported from non-EU countries, clearly exceeding 50%, as the imported products from Asia¹⁸ often range in a low price segment.

Based on a median value of 17 €/kg pliers from PRODCOM¹⁹, a rough estimation shows that more than 26 million pliers are placed on the EU market per year.

¹⁵ <http://en.ceo-tools.com/>

¹⁶

http://www.eisenwarenmesse.de/global/dokumente/eisenwarenmesse/IEPW_Messereport_2008.pdf

¹⁷ in the reported statistics pliers include slugs as well as pliers without handles

¹⁸ Information received show e.g. that the share of Chinese imports is nearly 50 % of the total import

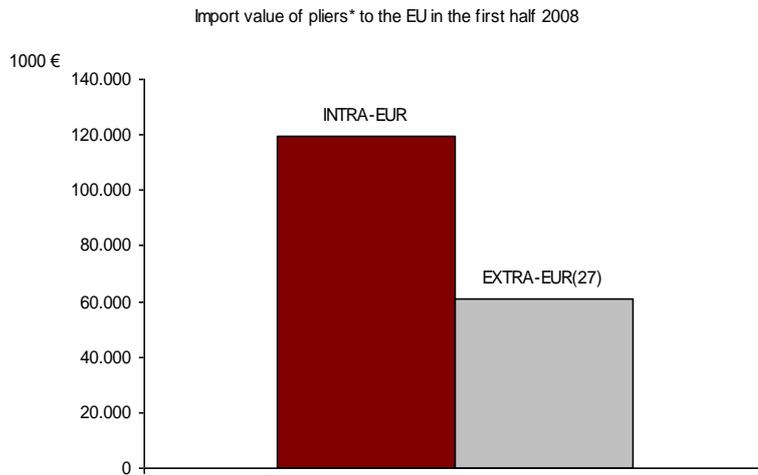


Figure 6: Value of traded pliers within the EU 27 and imported from outside EU (in 1000 €) Source: European import statistics, Fachverband Werkzeugindustrie e. V. NB the statistics for pliers include slugs as well as pliers without handles.

1.3.4 Information on hazardous substances

SVHCs are known to be a problem in tools²⁰. Softeners and anthracene (a polycyclic aromatic hydrocarbon (PAH) substance)²¹ can be found in materials in the tool handle. Softeners like dibutyl phthalate (DBP) and bis(2-ethyl(hexyl) phthalate) (DEHP) may be present in handles in concentrations above²² 20 % (w/w). DEHP is one of the most commonly found softener in components of imported tools.

Exposure relevance

Human exposure is relevant via direct skin contact, often combined with mechanical stress during use of the tool. This is relevant because of increased sweat dispensary in the palm which may lead to increased migration from the handle material.

¹⁹ EUROSTAT PRODCOM 2007

http://epp.eurostat.ec.europa.eu/portal/page/portal/prodcom/data/tables_excel

²⁰ Study of the German “Stiftung Warentest” 2005, where PAH substances and softeners were found in tools <http://www.test.de/themen/haus-garten/meldung/-/1269956/1269956/>

²¹ investigated 2008 by Federal Office of Consumer Protection and Food Safety (BVL, DE), high amounts of PAH have been found, Data will be published mid 2009

²² other reported values for soft PVC are in the range of 30 – 45 % (w/w)

Exposure to PAH substances²³ has been estimated by the German Bundesanstalt für Risikobewertung (BfR)²⁴. Based on the findings in the Stiftung Warentest study, where maximum concentrations of 2 g/kg (0.2% w/w) were measured in the handle material, the BfR derived a worst case assumption for the lead PAH substance benzo[a]pyren and found that the daily exposure from migration is significantly higher than the background intake via various other pathways.

Case specific dilution factor

The weight differences between corpus and handle described in section 1.3.1 leads to a dilution factor up to 100 for a cutter or a pliers. Hence, a tool weighing 400 g may contain up to 0.4 g of a SVHC without triggering any information obligations, as shown in Figure 7.

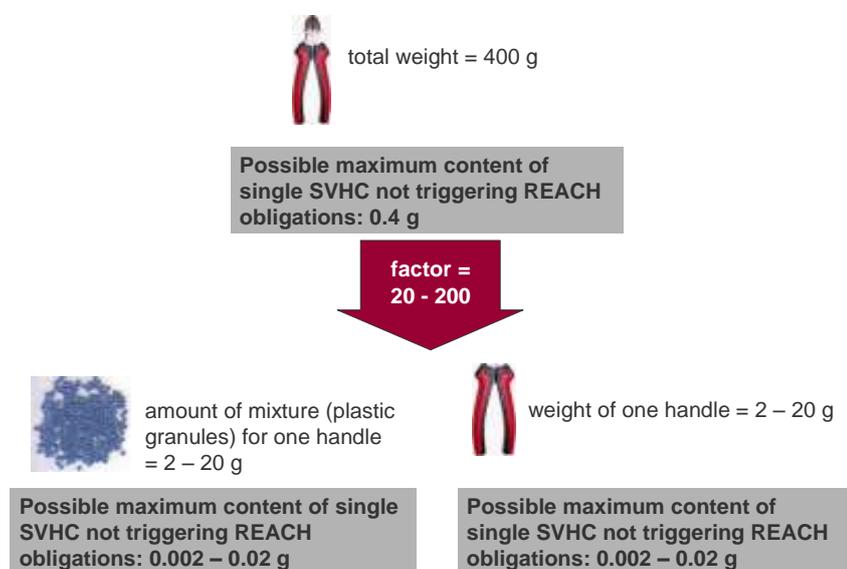


Figure 7: Possible SVHC content for a pliers/cutter with different threshold basis

Fel! Hittar inte referenskölla. Table 8 gives an overview of the amounts of SVHCs in hand tools that may theoretically be imported each year and anyhow escape the information provisions in REACH, if the threshold applies to the entire tool.

²³ according to the EPA list: naphthalin; acenaphthene; fluoren; phenanthrene; anthracene; fluoranthen; pyren; benzo(a)anthracen; chrysen; methylchrysen-6; benzo(b)fluoranthen; benzo(k)fluoranthen; benzo(a)pyrene; dibenz(a,h)anthracen; benzo(g,h,i)perylene; indeno(1,2,3-c,d)pyrene

²⁴ Statement of the Federal Institute for Risk Assessment (BfR)
http://www.bfr.bund.de/cm/216/pak_in_verbrauchernahen_produkten_sollten_so_weit_wie_moeglich_minimiert_werden.pdf

Table 8: Possible SVHC amounts in imported pliers/cutters without information

Article	Weight	SVHC content without information	Amount of tools imported	Total yearly amount of SVHC without information trigger
Entire tool	400 g	0.4 g	8.8 million	3.5 tpa
Handle	20 g	0.02 g	17.6 million (2 handles per tool)	0.35 tpa

This estimation of the import of a SVHC is based on a median value of 17 €/kg tools in PRODCOM. The value of EU import €60 million corresponds to about 8.8 million pliers. For each pliers a typical weight of 400 g and hypothetical content of 0.4 g SVHC (below the threshold) can be assumed. Thereby, a theoretical yearly import of 3.5 tonnes of a SVHC is possible, without any information requirements, if the 0.1% threshold concentration applies to the entire tool. Should the threshold apply to the handle part instead, the maximum amount would be 0.35 tonnes (here it is only a factor of ten, as two handles are needed for one pliers).

The case specific dilution will in practice, as shown in Table 9, lead to a loss of SVHC information in the supply chain if the concentration limit applies to the entire tool and not to the handle part.

Table 9: Influence of weight difference as dilution factor and of SVHC concentrations when the threshold applies to final article or parts of the article

SVHC	Material	Typical SVHC content in final article	Concentration of SVHC in final article (total weight 360 -396g)	Weight difference as dilution factor	Information obligation
	Typical SVHC concentration in material				
	Weight of material				
Phthalate (e.g. DEHP)	Plastic handle	0.8 – 8 g	0.2% - 2.2%	9-100	At all stages
	20%				
	4 – 40 g				
Anthracene (PAH)	Plastic handle	0.008 – 0.08 g	0.002% - 0.02%	10-100	- not for the final article - only for the handle part
	0.2%				
	4 - 40 g				

Legal requirements and other standards

Restrictions on relevant substances are addressed in Annex XVII of REACH and in the General Product Safety Directive 2001/95/EC.

Practical experience on substance content and information dissemination

The article is traded by market leading companies that pose strict demands on respective specifications for the tools to the supply chain. These leading companies are not identical with the manufacturers of the article but large DIY retailers with own brands, with brands of other producers, or no name products.

It was described by one producer that there are ongoing activities from some resellers to obtain more control over the supply chains. One way of doing this is by ensuring knowledge about all production sites in the supply chain from the trader to the initial producer of the article. This means that all production sites are known to the reseller and can be approached. It also means that restrictions can be communicated directly to the producers and checked. In this case, a system of audit activities can be set up, based on the principle of sharing audit results with other organisations to achieve a close net of audit control.

Laboratory analysis is the least preferred way to ensure compliance with legal requirements, as it is the most expensive option. Analysis is applied in case of supply from sources that are not part of the quality management system (e.g. when a regular supplier fails to deliver and a “stand-in” takes over). Based on an IT system, suppliers are asked to provide a material declaration for the article (not on substance level). The systems are not harmonised among the competitors in the market.

For distributor’s/retailer’s/importer’s the access to SVHC information is based on activities that are part of the “product listing procedure”:

- Asking the supplier about SVHC of the candidate list present in the article
- Asking his supplier more specifically about SVHC in specific parts, materials
- Usage of an own list of banned or undesired substances
- Contractual agreement with the suppliers with regard to substances in the article or general product conformity.

So it is most efficient from the company perspective to take these steps when new products are listed for the first time.

As one retailer mentioned, documented information from the suppliers is only received in some cases. When the article already is regulated in other, more specific legislation, it is easier to obtain information on chemicals (e.g. electric tools). Retailers and a laboratory told in the interview that the verification of received information depends on the supplier and is performed by third party institutions. If such analysis certificates

are received from suppliers it is considered sufficient to show compliance with Article 33 and 7 of REACH.

It is known that SVHCs are present in rubber grips and some phthalates are regulated by a list of banned or undesired substances²⁵ above the concentration of the REACH regulation. Importers and laboratories are of the opinion that in future efforts and IT systems will increase the knowledge. The suppliers will be asked to provide information directly into the system and the information provided will be at material level. If for example certain substances in materials are reported, B&Q will become active (e.g. send questionnaires on candidate substances). All following actions will apply at the level of the material, never on the level of the article.

According to the interviewed actors, no differences will be made between professional users and private consumers in downstream communication, as the only way to provide information according to REACH Article 33 is to include the information with the product as it is bought by both groups.

On the producer level, SVHC information is obtained through the use of standard questionnaires. In the specific example the supply chain actors are located all over Europe but no materials or parts originate from countries where REACH does not apply. The responses to the questionnaire showed that no candidate list substances are in use or that formulations have changed to a small extent only to ensure that SVHCs are absent from tools and their parts. Therefore it can be concluded, that the most relevant effect of the candidate list is a substitution drive for those substances. This is important for the producer of the article because a technological change in his production process in case of a sudden loss of a material (substance) would outweigh the costs of substitution. A sudden change in working procedures would take about six months.

Article 33 is addressed to the supplier of an article (e.g. the handle of a tool), who has to deliver the information on candidate substances above 0.1 % (w/w). Since many small and medium sized companies are active in the supply chain of the article producer, there is a need to turn around the initiative and to send questionnaires concerning the candidate list, as the knowledge of REACH obligations is very limited at the moment.

²⁵ e.g. B&Q DIY Detox - Chemical Reference Lists, a maximum permitted limit for residues in products for DEHP of 0.01 % (w/w) is defined.
http://www.diy.com/diy/jsp/aboutbandq/social_responsibility_2007/pdfs/detox_policy.pdf

1.4 Toys (cuddly bear)

1.4.1 Rationale of selection

Toys represent an article with a significant retail market in the EU of €14.234 billion (video games excluded). Due to the vulnerable user group (children) that may be in close contact with the article, toys are subject to product specific legislation concerning hazardous substances and the market is extensively surveyed. Surveillance results show that multiple hazardous substances are abundant in toys and their materials. There is a large number of readily available studies and other information²⁶.

This case study addresses only cuddly/plush toys and a teddy bear was chosen as example. In terms of the case selection criteria, the following aspects are fulfilled by a “cuddly bear”:

- Article may contain potential SVHCs²⁷ exceeding 0.1% limit at least on material level
- Article complexity is low (< 10 materials/parts)
- Supply chain is characterized by a large share of import into Europe
- Exposure to sensitive humans during use (skin, oral)
- Exposure to environment during the waste stage
- Interesting situation with possibly overlapping and complementing regulatory requirements from REACH and the new Toys Safety Directive.

Short description of construction and materials

Toys vary widely in complexity. The chosen case is made of more than just one material, mainly:

- covering textile (natural or synthetic fibres)

²⁶ FoBiG: UBA-Projekt 3707 61 300 Kanzerogene, mutagene, reproduktionstoxische (CMR) und andere problematische Stoffe in Produkten - Identifikation relevanter Stoffe und Erzeugnisse, Überprüfung durch Messungen, Regelungsbedarf im Chemikalienrecht - TEIL IV: Problematische Stoffe in Spielzeugen, Feiburg 2008 – not published yet.

RPA: Study on the impact of the revision of the council directive 88/378/EEC on the safety of toys, Final report prepared for the European Commission, 2004

RIVM: Chemicals in Toys: A general methodology for assessment of chemical safety of toys with a focus on elements, RIVM/SIR Revised Advisory Report 0010278A02 Revised Final Version, October 12, 2006

Europe Economics Chancery House: REVISION OF THE CHEMICAL REQUIREMENTS OF DIRECTIVE 88/378/EEC ON THE SAFETY OF TOYS Final Report by Europe Economics, 2007

Keeping European Consumers safe – 2008 Annual Report on the operation of the Rapid Alert System for non-food consumer products – RAPEX, European Community – Directorate-General for Health & Consumers, Brussels 2009 http://ec.europa.eu/consumers/reports/reports_en.htm

²⁷ here not only SVHC of the current candidate list are meant but also those that fulfil the criteria of Article 57

- filling material (polyester or natural fibres)
- plastic material for e.g. eyes

For cuddly toys often additional equipment is available e.g. clothing. It is not customary to have any spare parts. Figure 8 gives a description of the article, based on information from a producer of high quality toys. Table 10 shows weights and composition of the parts and materials.

Example teddy bear

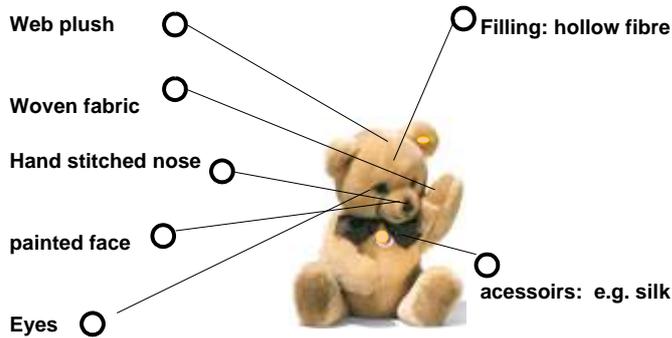


Figure 8: Main parts and materials of a cuddly bear

Table 10: Composition of parts and materials in teddy bear

Article (weight)	Part	Component (weight)	Material
Teddy bear (170 g)	Corpus	Filling (48 g)	Hollow fibre
		Covering (65 g)	Web plush Woven fabric of natural raw material like mohair, alpaca Paint for face or covering
		Yarn	Hand stitched nose Stitching of covering
	Eyes	Eyes	Polycarbonate copolymer
	Accessories, clothing	e.g. slip knot	Textile of natural material like silk

1.4.2 Supply chain characterisation

Import of toys has a clear preponderance compared to EU production in the toy sector. Most producers of toys operate parts of their production inside the EU, usually the final assembly. A production of the entire toy in EU is the exemption.

A special characteristic of the case is that product specific legislation, Council Directive 2009/48/EC on the safety of toys, defines rules for how safety of an article shall be ensured by the placers on the market, hence the producers and importers of toys.

The different roles defined in Article 3 of the Toys Safety Directive are:

- *‘manufacturer’ means any natural or legal person who manufactures a toy or has a toy designed or manufactured, and markets that toy under his name or trademark;*
- *‘authorised representative’ means any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;*
- *‘importer’ means any natural or legal person established within the Community who places a toy from a third country on the Community market;*
- *‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a toy available on the market;*
- *‘economic operators’ means the manufacturer, the authorised representative, the importer and the distributor;*

As the article manufacturer is defined as “producer” under REACH, this term will be used here instead.

The actors can also be characterised by their influence on the supply chain:

- Original Equipment Manufacturers (OEMs) in the toys industry are brand companies (like LEGO or Mattel) who produce in their own toy production sites or order toys according to specific demands from producers. They aim to have a high influence on the supply chain in order to prevent loss of brand reputation. Bigger OEMs have almost full control over product design and development, production and distribution.
- Toy retailers buy from the OEMs or from traders / importers and sell brand toys, own-brand toys and no-name toys directly to consumers. They can be specialists (like Toys-R-Us) or general stores that, among other things, sell a wide variety of toys.
 - Brand retailers such as IKEA and Otto group also act with view to maintain their brand reputation. Hence, they either design own brand toys, with defined specifications, and subcontract the production to other companies (some influence on the supply

chain) or purchase products with quality in accordance with their demands.

- Non-brand retailers buy “off the shelf” and the majority has no influence on the product design. Their demands mainly refer to properties like size or colour and product quality may be only randomly assessed.
- Importers and distributors (only Business to Business activities) are mostly small and medium sized companies. Many of them import a lot of different products, apart from toys, and are not aware of all product specific requirements. In addition, they do not have the capacity to control product safety in a meaningful way. They totally lack influence on the supply chain, so concerning conformity they rely on information from their suppliers.

EU producer of toys

Some EU producers of brand toys²⁸ exist who either assemble imported components or have the entire toy production inside EU. The detailed information regarding entirely EU-produced toys is from a personal interview with one company representative, which has been confirmed by other trading companies.

The production of very high quality cuddly toys in the higher price segment is generally sold to wholesalers and retailers within Europe. Very high quality then refers to the quality of materials e.g. safety, resilience and materials that are free from toxic substances.

Hence, these toys do not only fulfil the legal requirements but also much stricter demands e.g. they do not contain any substances for which concentration limits exist.

Public scandals and publication of test results that show contents of hazardous substances in toys have led to increased awareness of the topic.

All in all, the interviewed EU producer has a high influence on product design and therefore on substances contained in the materials of the article. It is assumed that the situation described is valid for other EU producers of high quality toys as well.

Producers located in China

Most toy producers are stated to be located in China, therefore their role is briefly described here. This part is a summary of information in a study for the European Commission in 2008²⁹.

²⁸ E.g. Steiff, Fischer Technik, Schleich, Sigikid, HABA

²⁹ Evaluating Business Safety Measures in the Toy Supply Chain – Final report – European Commission, May 2008, Brussels

The toy producing sector in China consists of about 2700 companies with the necessary licence for export. Chinese government increasingly operates inspection and export control for toys, that includes export licensing, producer auditing and classification, first item registration, video surveillance, batch testing and training.

The Chinese toy producing sector can be divided into:

- Big companies working for big OEMs, with in-house capacity to deal also with EU safety issues,
- Medium sized suppliers for bigger traders, with less developed systems for control of quality and safety of their products,
- Small suppliers for smaller traders, that often struggle to guarantee safety requirements.

For the Chinese companies it is often difficult to fully understand the legal requirements in the EU. Therefore, documented conformity with standards like the toy directive, does not necessarily ensure that the product is in compliance with all relevant safety requirements. For example a supplier can confirm the conformity with the toy directive but he is not aware that certain phthalates and azo dyes are regulated in another, non-specific piece of legislation (REACH Annex XVII).

Production volumes and share of import³⁰

Market data on toys exist in official statistics and in international and national associations. The total value of the retail market for toys (excluding video games) in the EU is quite stable at €14.234 billion.

Data exist also for different toy categories and cuddly toys are covered by the “infant/preschool” and “plush” categories, which together make up about 25 % of the total toy market (see Figure 9).

About 6% of toys marketed are plush toys. This makes a turnover of more than €100 million. All in all, cuddly plush toys generate a value of about €200 Mio in the European market.

³⁰

Toy Industries of Europe: Facts and Figures July 2008, <http://www.tietoy.org>

Share of main toy categories¹³

TOY CATEGORY	MARKET SHARE (%)	
	2006	2007
Infant/Preschool	20.6	20.9
Games / Puzzles	14.1	13.9
Dolls	12.6	12.5
Vehicles	9.5	10.0
Outdoor and Sport Toys	10.7	9.8
Building Sets	7.0	7.2
Arts & Crafts	5.4	5.4
Plush	5.2	5.0
Action Figures & Accessories	4.5	5.3
Youth Electronics	3.9	3.9
Others	6.5	6.1
TOTAL	100.0	100.0

Figure 9: Market share of main toy categories in 2008,

EU production

- Total production value of toys and games in the EU is nearly €5 billion.
- The EU has nearly 2,000 producing companies in the toy and games sector. About 80% of the EU producers have less than 50 employees; only 5% are large companies.³¹
- The toy industry directly employs nearly 100,000 people in the European Union, half of them in production and half in research and development, marketing, sales, distribution and other services.

Import into EU

- Toys are manufactured globally and Asia is the leading supplier of toys to EU with 97.6% of the total import; over 90% of all toys on the European market originated from China in 2007.
- The value of imports from other countries was €6.983 billion for traditional toys while video games account for €4.617 billion out of a total import value of €11.600 billion.

1.4.3. Information on hazardous substances

Hazardous and possible SVHC substances likely to be found in cuddly toys are heavy metals (in paints), antimony (in polyester padding), azo dyes, formaldehyde and flame retardants. Phthalates might occur in parts

³¹ Evaluating Business Safety Measures in the Toy Supply Chain – Final report – European Commission, May 2008, Brussels

of cuddly toys. In September 2008, the Finnish Consumer Agency recalled 6 toys (dolls, soccer set, and children's bib) because they contained up to 36% DEHP and up to 35% DINP.

Compared to plastic toys, cuddly or plush toys are rarely tested. Therefore there is little information publicly available. In the RAPEX System one cuddly toy imported from China was recalled in 2008 because it contained 310 mg/kg of an antimony component. This equals 0.01%, which is much lower than the 0.1% limit under REACH.

Exposure relevance

Exposure to hazardous and potential SVHC substances can occur through inhalation, sucking (oral) and dermal contact during use of the toy. It should be noted that many toys have a relatively short life span, from a month to a few years, so concentrations may remain high during the entire use phase (no relevant decrease over the lifetime of the article) as well as during the waste stage.

Case specific dilution factor

Table 11 shows the possible SVHC amount in a cuddly bear, which is below the trigger for REACH obligations, in case the 0.1% threshold is applied to the whole article or to the different parts of the toy.

Table 11: Possible SVHC amount in an imported cuddly bear, without information obligations

Article (material)	Weight	SVHC content without information trigger
Cuddly bear	170g	0.17g
Filling (hollow fibre)	48g	0.048g
Covering (web plush / woven fabric)	65g	0.065g

Legal requirements and other standards

The use of hazardous substances in toys is subject to the general restrictions in Annex XVII to REACH. For instance, item 51 states for certain plasticizers (phthalates on the candidate list) that they “shall not be used as substances or in mixtures, in concentrations greater than 0.1 % by weight of the plasticised material in toys and childcare articles“.

Also, the use of azo-dyes is restricted in item 43: Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8, in detectable concentrations, i.e. above 30 ppm in the finished articles or in the dyed parts thereof, according to the testing methods listed in Appendix 10, shall not be used in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as: – ; – textile or leather toys and toys which include textile or leather garments”

In addition, the Council Directive 2009/48/EC on the Safety of Toys defines rules how safety of a toy shall be ensured by the placers on the market, hence the producers and importers. A safety assessment is to be conducted concerning the content of hazardous substances. Compliance with the requirements is to be documented, either through chemical analysis or through keeping harmonized standards during all production processes.

This directive prohibits the use of CMRs in toys while the use is restricted for some other hazardous and potential SVHC substances, such as metals.

So all substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR), in category 1A, 1B or 2³² may not be used “*in toys, in components of toys or in micro-structurally distinct parts of toys*”. This expression has so far not been defined but the general perception seems to be close to an interpretation as homogenous material (as used in standards, e.g. EN 71/3 on heavy metals).

Limits for the migration of a number of metals are established, depending on the quality of the material (e.g. separate limits for dry, brittle, powder-like or pliable toy material, for liquid or sticky toy material and for scraped off material).

EU producers that incorporate or attach imported article parts or mixtures to their toys, should obtain information according to the Toy Safety Directive or should be able to rely on the absence of prohibited substances. Consequently importers of toys have to accomplish the same tasks as manufacturers/producers do.

Furthermore, requirements on the declaration of conformity and CE marking are also laid down in the Toy Safety Directive. In this system there are two ways to declare conformity according to Article 19 and 20 (see graphical description in Figure 10).

The first way is chosen when all applicable safety requirements are covered by harmonised standards for production. In this case the producer, importer or distributor shall use the procedure set up in module A of Annex II of the decision 768/2008 of the European Commission on a common framework for the marketing of products. If harmonized standards were not or only partially applied, do not exist or if the producer / importer / distributor “*considers that the nature, design, construction or purpose of the toy necessitate third party verification*”, the second path shall be chosen.

Concerning the sampling and testing of the toy or the toy material, the European Committee for Standardization (CEN) provides a European Standard for the safety of toys (EN 71). Testing is limited to health effects, environmental effects are not assessed.

³² Categories referring to the new regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP)

The test conditions are described and refer to samples of homogenous materials. In Part 3 of EN 71, toys are categorized according to the material they consist of, to determine the migration of certain elements. If heavy metals e.g. in coatings are investigated, the toy directive sets thresholds for the scraped off toy material. The reference to parts or material is also adopted in the respective test standards (European Committee for Standardization, CEN, 1994).

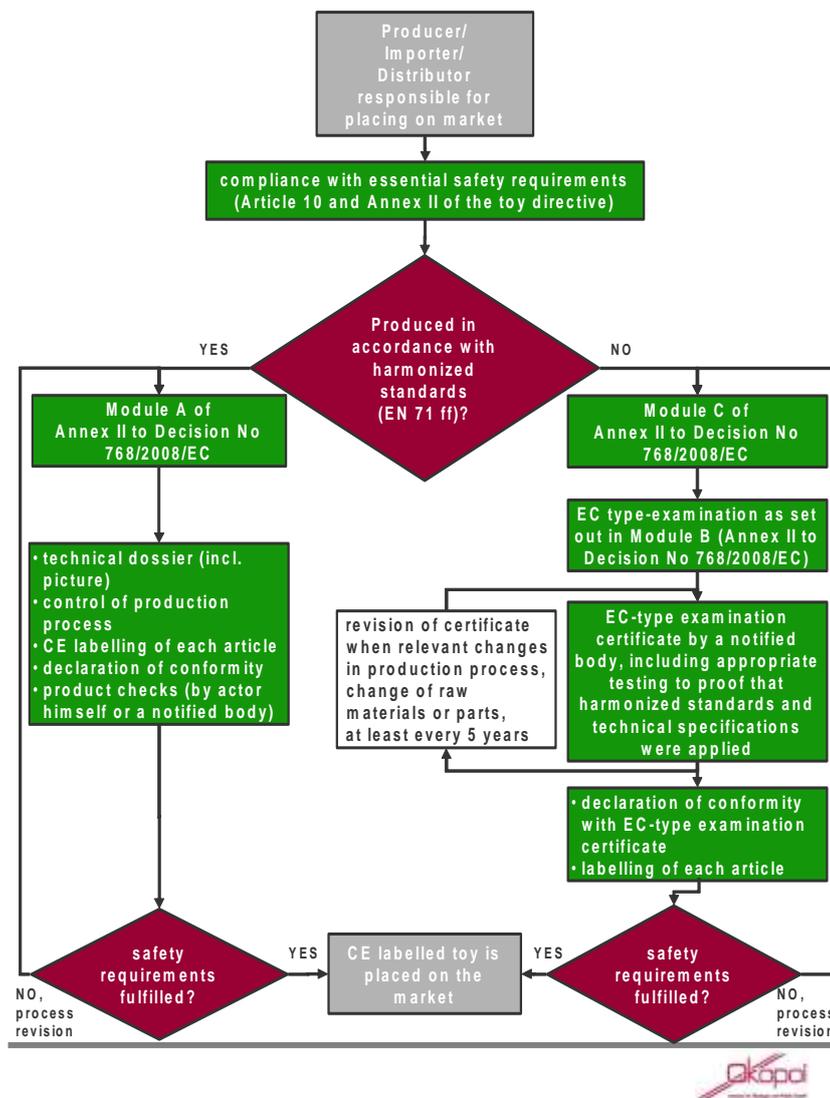


Figure 10: Graphical description of CE marking of toys

With regard to enforcement, the general Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, are relevant for toys with regard to market surveillance and rules of conformity.

A voluntary labelling scheme that is often used in the clothing sector is also applicable to textiles for cuddly toys. In this scheme, the Öko-Tex Standard 100, 100+ lists requirements regarding the content of hazardous substances in textiles according to their use. Concentration limits always refer to the material. A Blue Angel is in preparation for textile toys. Currently the standard differentiates between textiles used:

- for babies
- for direct contact with skin
- with no direct contact with skin and
- for decoration.

Practical experience on substance content and information dissemination

In the following, some experiences and challenges to illustrate quality control are given, based on an interview with an EU producer of toys.

Complete control over the production of toys or their parts in non-EU countries was said to be impossible, as has become obvious by the fact that prohibited substances are repeatedly found in imported materials. One problem is seen in the growing extent of sub-contracting, so, even if contracts exist with the non-EU supplier, they frequently sub-contract further companies which are then out of reach for the EU producer.

Producing in the EU was stated to enable quicker and more flexible reactions to customer demands. Consequently, only a complete production in the EU would ensure that materials and components fulfil company specific requirements. One of the means to control the supply chain fully is to take over former supplier companies.

The interviewed EU toy producer has implemented a quality management system according to ISO 9001:2008 in order to ensure compliance with all legal and company internal requirements. All persons involved in product design and production process are trained respectively. This includes detailed process descriptions with regard to quality and safety.

Testing organisations / laboratories play an important role in product safety in the toy sector. They are commissioned with

- Testing of products
- Conducting risk assessments
- Giving advice on quality management procedures
- Doing factory audits
- Controlling products before shipping.

Some of these organisations are also notified bodies³³ under the Toy Safety Directive.

³³ notified bodies are testing organisations that are authorised by MS authorities to carry out third-party conformity assessments, the so-called EC type-examination procedure

There are notable concerns on their role, which result from different interpretations of the European harmonised safety standards and test methods by different laboratories. Furthermore, difficulties have been observed in communication within the testing organisations / laboratories, as well as a perception of a lack of competence by the commissioning companies.

It is summarised in the 2008 study for the European Commission³⁴ that:

- product safety cannot be guaranteed only by final product testing as it is too complex and too costly because of the large variety and amount of products
- product safety has to be embedded in the entire product development and production process
- adopting and maintaining a strong quality and safety culture in the company is critical to ensure product safety
- larger and brand toy companies are in the best position to guarantee a reliable approach on product safety issues
- for many smaller operators in China, the Chinese government's export controls are the only independent product controls before the toys are placed on the European market
- problems of Chinese producers are related to understanding and therefore also fulfilling the complex European harmonised toy safety standards
- the findings in the toy sector are likely to be pertinent to other product sectors as well.

³⁴ Evaluating Business Safety Measures in the Toy Supply Chain – Final report – European Commission, May 2008, Brussels

1.5 Electric installation (power distribution units)

1.5.1 Rationale of selection

Electric installations are available at all stages of complexity. They may contain harmful substances similar to computers (heavy metals, softeners, flame retardants). This case addresses a power distribution unit as an example. In terms of the selection criteria it is described as:

- Article may contain SVHC exceeding 0.1 % at least on material level
- Article complexity varies widely (10 - 100 materials/parts)
- Supply chain with market actors on each level inside and outside EU
- Exposure to humans may occur via skin during assembly and use
- Exposure to environment occurs during the waste stage.

Short description of construction and materials of the article

A power distribution unit is a standard article used in many industrial applications. Consumer use is unusual, installation in private households is rather an exception. The article is assembled from modular components that can be combined or adapted according to the customer specification. A standard model is shown in Figure 11. The chosen article has a level of complexity 10 - 100 parts. Each part can on the next level contain some 10 components in average. All standard parts may be combined into ~ 6,000 variations, but consist mainly of some 50 different materials.



Figure 11: Example of a power distribution unit with standard equipment

The article has a total weight of 6000 g. Table 12 exemplifies the share of the main components and the used materials of the complete article, however, not all levels of parts, components and materials are shown.

Table 12: Construction³⁵ and weight distribution of components and materials in a Power distribution unit (several levels of parts, components and materials exist)

Part (weight)	Component (weight)	Material (weight)
1 Plastic enclosure (2109 g)	base (1013 g)	Polybutylene terephthalate / Polycarbonate (PBT/PC) plastic (1013 g)
	Hinged cover (995 g)	PBT/PC plastic (995 g)
	transparent window (59 g)	PC plastic (59 g)
	6 double thread cover screws	Polyamid (PA6) (42 g)
3 SCHUKO receptacles (77 g/unit = 231 g)	Housing	PA6 (51.0 g)
	contact holder	n.a.
	cover Schuko	PA6 (25.5 g)
	Spring	steel (ca. 0.6 g)
	tubular rivet	n.a.
1 CEE receptacle 32 A, 5p, 400 V (99.6 g)	Housing	PA6 (69.0 g)
	Cover	PC (28.6)
	spring	steel (ca. 0.6 g)
	cover axis	PBT/PC (1.4 g)
	label	n.a.
1 CEE receptacle 16 A, 5p, 400 V (99.6 g)	housing	PA6 (69.0 g)
	cover	PC (28.6)
	spring	steel (ca. 0.6 g)
	cover axis	PBT/PC (1.4 g)
	label	n.a.
Wires (528.44 g)	conductor wires	Copper (336.96 g)
		PVC (191.48 g)

³⁵ Composition of the article and the components is only shown as an extract. More parts / components / materials contribute to the article at different levels.

1.5.2 Supply chain characterisation

The supply chain differs in complexity depending on the specific electric installation selected. Producers of this supply chain source raw materials and semi finished article parts inside or outside the EU. Afterwards there are different ways how the articles are distributed.

- The first way of distribution is B to B. The articles are sold to other producers of articles. Sometimes RoHS conformity from the producer of the electrical installation part is demanded by the customer.
- The articles are distributed by wholesale companies either to large retailers or directly to industrial customers, which assemble larger and more complex articles from them.

Wholesale traders may purchase directly from producers (EU) or from importers. Direct procurement of industrial installations from non-EU suppliers is not common but may also occur.

The supply chain is comparably short due to the limited amount of different parts and materials assembled in this article, between 100 - 1000 suppliers from raw material to final product. For many components and materials more than one supplier may exist, which explains the high number of suppliers as compared to the number of parts.

The development cycle of the final product is rather short (about four weeks) as it is assembled from modular parts. This corresponds to the time needed to obtain components from suppliers. Longer development cycles occur when single modules are developed (e.g. about one year for an enclosure). The latter development is the key step for the selection of components and materials that are used.

Some parts like enclosures are produced directly from substance mixtures or preparations; other parts are preassembled components (e.g. switches) and installed into more complex assemblies (e.g. a receptacle) that are part of the final article. All components and materials are procured by the assemblers of complex electric installations within the EU. However, this does not mean that they have been manufactured within the EU, as they could also be imported by a supplier, or in case of more complex parts could have been produced outside the EU. Therefore it is uncertain if a part was produced inside or outside the EU. The preassembled parts of the article can also be bought as spare parts (Figure 12).

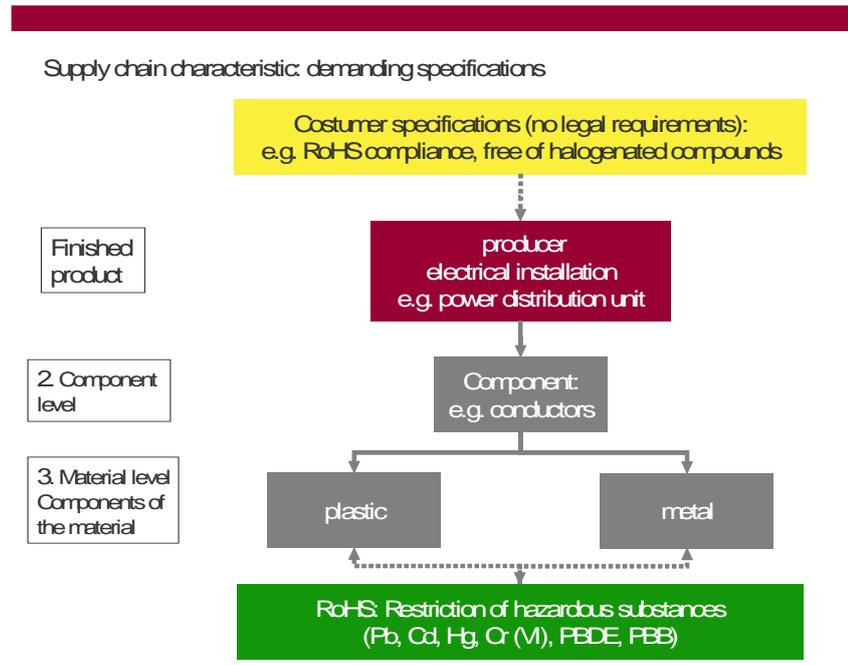


Figure 12: Supply chain and specification demands for power distribution unit. Although no legal requirements apply, costumers sometimes demand certain specifications. As standard components and materials are used, they often fulfil legal requirements for the electronics sector (RoHS).

Time is an important aspect for customers, since the article is needed to supply machines and buildings with electricity. They are installed in the building phase of industrial plants or to replace older power distribution units. In both cases long delivery times would generate high expenses for the costumers because processes can not proceed.

Electric installations are usually bought in low numbers, frequently just “one at a time” so that no spares are stored. They are produced on demand and frequently the standard installation has to be modified to fit the specific needs. The time period from placing an order to delivery of the product is shorter inside EU than if produced outside the EU. This advantage outweighs the higher production costs inside EU.

No detailed market data is available, but according to one producer, there are about one hundred competitors on the EU market. The typical market value of a power distribution unit is ~ €300 per piece. The main drivers influencing the market are performance followed by high quality. Price is not a main driver.

1.5.3. Information on hazardous substances

Up to now, suppliers have not reported that SVHC from the candidate list are present in power distribution units. Nevertheless it can be ex-

pected that DEHP is contained in the PVC cover of conductor wires. A general tendency can be observed that suppliers of parts declare to substitute all SVHC on the candidate list. However, some substitutes of DEHP, like DIHP, may become candidate substances in the future. Sometimes customers demand to get the article free of halogenated substances and PVC material gets replaced. By this, not only potentially contained phthalates but also flame retardants, some of which are also on the candidate list, can be excluded from the article.

It is known that brominated flame retardants are present in the PBT/PC materials of electric installations in concentrations of about 20 %. It was stated by a manufacturer that these substances are not on the candidate list as declared by the supplier. The complete substitution of brominated flame retardants from plastic materials in electrical installations may be possible for some, but not all applications, since their substitutes have important disadvantages (technical difficulties in the production processes and poorer technical performance).

In general it can be concluded that potential SVHCs are expected to be found in the plastic parts of the article. In this industry sector, heavy metals are normally eliminated due to the application of the RoHS directive.

Case specific dilution factor

It can be expected that information according to REACH Article 33 on SVHC will have to be provided, independent of the way of applying the 0.1% trigger (to the power distribution unit as a whole or to its parts and components). The SVHC concentrations in plastic parts of the article will, although being diluted by the total article weight, remain above the threshold.

This is shown in table 13, where softeners like DEHP, DBP and BBP were assumed for PVC material in wires and HBCDD as flame retardant for the PBT / PC material.

Table 13: Influence of weight difference as dilution factor and of SVHC concentrations on information obligations

SVHC	Material	Typical SVHC content in final article	Concentration of SVHC in final article (total weight 6000g)	Weight difference as dilution factor	Information obligation
	Typical SVHC concentration in material				
	Weight of material				
DEHP / DBP / BBP	soft plastic material (e.g. PVC)	38 g	0.6%	33	At all stages
	20 %				
	191.48 g				

SVHC	Material	Typical SVHC content in final article	Concentration of SVHC in final article (total weight 6000g)	Weight difference as dilution factor	Information obligation
	Typical SVHC concentration in material				
	Weight of material				
HBCDD	PBT / PC material	500 g	8.3%	2.4	At all stages
	20 %				
	2500 g				

Legal requirements and other standards

Restrictions on relevant substances are addressed in Annex XVII of REACH and in the General Product Safety Directive 2001/95/EC.

The article, although sometimes installed in buildings, is not in focus for the Construction Products Directive (89/106/EEC) and its ongoing revision.

Although the requirements in RoHS (2002/95/EC) do not apply, they have a certain relevance for the article, since many standard components comply with these regulations because they are also used for articles that are covered by RoHS. Producers use the information on the content of substances regulated by RoHS if there are specific customer specifications.³⁶

Specific standards that are of relevance for a power distribution unit: DIN EN 60309 - testing routine for flammability of electrical installations, UL 94 - requirement in the US (transferred into IEC/DIN EN 60695-11, -10 and -20; not harmonized) testing routine for flammability of electrical installations, that indirectly defines the need for flame retardants in plastic components.

Practical experience on substance content and information dissemination

Since performance is the most important characteristic of the article, the first step in quality management described by an interviewed EU producer of electrical installations is the careful selection of suppliers. The core selection criterion is that products meet the technical specifications. When new suppliers are listed, one time audits are conducted at the supplier's production site. Later on, audits are conducted repeatedly to evaluate the performance of the supplier. For liability reasons, it is a pre-

³⁶ Öko-Institut (2008): Study on hazardous substances in electrical and electronic equipment, not regulated by RoHS http://hse-rohs.oeko.info/fileadmin/user_upload/Documents/RoHS_Hazardous_Substances_Final_Report.pdf

condition for suppliers that they are a legal entity inside the EU. The quality of purchased materials is sporadically checked by the purchasing company: Some tests are realised on the delivered materials (e.g. on water content of plastic granules, no focus on SVHCs)

Information on the SVHC content in the entire, complex article, could easily reach the professional end user, e.g. in the form of a technical data sheet. These technical data sheets are always supplied together with the complex article.

Producers of the power supply unit doubt that identification of SVHC in articles with less complexity (e.g. a switch) will work. Parts are usually provided to wholesale traders in units of more than one part. If the parts are passed on individually or in smaller packages, the information would have to be multiplied and again attached to the products. Another idea could be to transport relevant SVHC information on the bill of the articles. Both ways, the wholesalers would have to prepare and document the transported information. There is up to now no technical solution (e.g. IT system) planned.

Information for the producer of the complex article is partially available just one step down the supply chain at his direct supplier. If he produces parts himself from chemicals, he has got the material safety data sheets indicating the content of all hazardous substances and SVHCs in concentrations above 0.1 %. For parts and components the producer purchases as articles, he has to rely on the information provided by the suppliers. Producers in this supply chain have started to ask the suppliers only for plastic materials, up to now.

If a supplier of a certain part or component reports the presence of a SVHC to the producer, he will ask all other suppliers of the same part or component to ensure awareness of this fact.

Therefore the intended solution in the sector is to attempt to exclude SVHC from parts and components, knowing that this might be a limited solution if there will be a growing candidate list.

Blacklists of substances or additional REACH contract conditions are not normally used. There is no coordinated approach among the market actors to start a concerted action to obtain information from the suppliers in the sector.

As there currently are no legal requirements addressing chemicals specifically for this sector, no documentation exists on legal compliance of the article. The most striking business effect of the new obligations might be a call-back of the final product, so the final efforts all lead to effective substitution as a precautionary measure to avoid such a scenario.

1.6 Desktop computers

1.6.1 Rationale of selection

Computers represent an article with broad professional and private use. The case study addresses as example the desktop computers, which are computers with the main unit intended for a permanent location, often on a desk or on the floor. They are not designed for portability and normally external monitor, keyboard and mouse are connected via cables.

It is known that multiple hazardous substances may be contained in computers. Exposure could occur at different stages of the life cycle. The supply chain is familiar with the declaration of substances, where the thresholds refer to homogenous materials in the article.

In terms of the selection criteria, the following aspects are fulfilled by a desktop computer:

- Article contains SVHC exceeding 0.1 % w/w
- Article complexity is high (> 1000 parts)
- Supply chain is complex, with market actors at each level inside and outside EU. Spare parts and upgrade kits can be bought separately for repair, upgrading and “home” assembly and the second hand market is considerable
- Exposure of humans during production and use (via air and skin)
- Exposure of the environment mainly during waste stage (but separate collection)

Short description of construction and materials

A desktop computer is an article of high complexity. A typical product development cycle is 18 - 24 months. The hierarchy of the constituents in electronics in general is:

- Final article e.g. desktop computer
- Sub-assembly or sub-part or module e.g. motherboard
- Component e.g. resistor
- Material, often defined homogenous material according to RoHS Directive e.g. copper wire (it has to be kept in mind that objects on the material level can fulfil the definition of article under REACH also; according to the Guidance on substances in article a wire is to be considered as an article).

The computer can be divided into parts like hard disk drive (HDD), optical drive, power supply unit (PSU), motherboard, etc. The computer contains more than 100 components like casing, cables, screws, printed wiring boards (PWB), that in turn are composed of more than 1000 mate-

rials³⁷ like steel sheets, copper wires, ABS plastics etc. The typical break down of a desktop computer into parts, components and materials is shown in table 14.

Table 14: Typical composition of parts, components and materials in a desktop computer

Parts	Components	Materials
Optical Drive	Cable Screw Casing PWB Switch Plastic arm Disc tray	Cu-wire Steel tube Steel sheet PBW/Solder Steel Sheet ABS ABS
Hard disk drive (HDD)	PWB Screws Magnet arm Plate Motor Body	PWB, slots, solder steel tube steel tube Cu winding wire, steel tube cast iron
Power supply unit (PSU)	Casing Screws Power supply Transformer Cables Fan	Steel sheet Steel tube PET Cast iron/Cu winding wire Cu wire PET/solder
Motherboard	Rubber pins CPU heatpipe Screws Lens Battery Plugs	PVC PC Steel tube PC PET, steel tube
Housing	Metal Bezel HDD trays Screws Chassis	Steel sheet ABS PC/ABS Steel tube Steel sheet, ABS
Cable	-	Cu wire
Mouse	Cables Plastic part Ball steel	PVC, Cu wire ABS Cast iron
Keyboard	Cables PWB Housing	PVC, Cu wire ABS Steel sheet, HIPS, PS, ABS

³⁷ In fact these products may themselves be articles under REACH but the sector treats them as materials because they are typically formed directly from substances or preparations. It is assumed that at this level of production the knowledge about substance content in the raw material may be highest.

The weight of a typical desktop computer is about 10 kg on average. The weight share of the different materials of the article is presented in table 15. A detailed description of materials and weight shares of a desktop computer for office use is given in Table 16.

Table 15: Typical share of materials

Materials	Desktop computer	Keyboard	Mouse
Metals (ferrous and non-ferrous)	ca. 75%	ca. 63%	ca. 57%
Plastic	ca. 10%	ca. 36%	ca. 43%
Others (e.g. electronics)	ca. 15%	ca. 0.5%	-

Table 16: Bill of materials and their weights in a desktop computer (EuP preparatory study, TREN/D1/40-2005, Lot 3)

EuP Lot 3 prep study: Office desktop PC		MZ	
Pos. nr.	MATERIALS Extraction & Production Description of component	Weight in g	Category Click & select Material or Process select Category first!
1	LDPE	246	1-BlkPlastics 1-LDPE
2	ABS	381	1-BlkPlastics 10-ABS
3	PA 6	138	2-TecPlastics 11-PA 6
4	PC	264	2-TecPlastics 12-PC
5	Epoxy	98	2-TecPlastics 14-Epoxy
6	Flex PUR	2	2-TecPlastics 16-Flex PUR
7	Steel sheet galvanized	6312	3-Ferro 21-St sheet galv.
8	Steel tube/ profile	107	3-Ferro 22-St tube/profile
9	Cast iron	483	3-Ferro 23-Cast iron
10	Ferrite	0	3-Ferro 24-Ferrite
11	Stainless 18/8 coil	10	3-Ferro 25-Stainless 18/8 coil
12	Al sheet/ extrusion	315	4-Non-ferro 26-Al sheet/extrusion
13	Al diecast	15	4-Non-ferro 27-Al diecast
14	Cu winding wire	257	4-Non-ferro 28-Cu winding wire
15	Cu wire	334	4-Non-ferro 29-Cu wire
16	Cu tube/sheet	67	4-Non-ferro 30-Cu tube/sheet
17	Powder coating	2	5-Coating 39-powder coating
18	Big caps & coils	483	6-Electronics 44-big caps & coils
19	Slots /ext. Ports	310	6-Electronics 45-slots / ext. ports
20	Integrated Circuits, 5% Silicon, Au	69	6-Electronics 46-IC's avg., 5% Si, Au
21	Integrated Circuits, 1% Silicon	96	6-Electronics 47-IC's avg., 1% Si
22	SMD & LEDs avg	194	6-Electronics 48-SMD/ LED's avg.
23	PWB 1/2 lay 3.75 kg/m2	78	6-Electronics 49-PWB 1/2 lay 3.75kg/m2
24	PWB 6 lay 4.5 kg/m2	163	6-Electronics 50-PWB 6 lay 4.5 kg/m2
25	Solder SnAg4Cu0.5	48	6-Electronics 52-Solder SnAg4Cu0.5
26	Cardboard	2287	7-Misc. 56-Cardboard

1.6.2. Supply chain characterisation

Computers are brought onto the market and bought as a whole. The economic lifetime of a desktop computer is approximately 6 years on average (Study for the European Commission DG TREN, 2007)³⁸. However, modifications, upgrades and repairs get supported by imported spare parts, replacement items and upgrade kits. Particularly for the more expensive business equipment it is common practice to provide repair components within the EU rather than shipping the whole computer back to the country of production for repair. The resulting second hand market from modifications and upgrades can be important for some parts (e.g. graphic cards).

All these spare parts and components are available as separate articles on the market. This includes for example central processing units (CPU), memories, hard disk drives (HDD), optical drives or motherboards. Also accessories like mouse, keyboard or monitor are sold either in combination with desktop computers or separately.

The supply chain is very complex with 100 – 1,000 suppliers from the raw materials to the final product. Supply chain actors are present both inside and outside the EU on all levels.

A few general characteristics for the supply chain have been described in another study from 2008³⁹ and the patterns seem to be similar for many producers: integrated circuits and other components for desktop computers are produced mainly in South East Asia. For laptops and displays (LCD), the entire production is located in South East Asia, while desktop computers often are assembled from parts produced in South East Asia at sites closer to the market in Europe, due to the more modular design.

The number of international producers of desktop computers is limited. Some relevant examples are Hewlett Packard, Dell, Acer, Lenovo, Fujitsu Siemens, Apple, and Toshiba⁴⁰. The companies that are dominating the market for office desktops seem to be Dell and Hewlett Packard while for desktop computers in home use, Packard Bell has a similar market share as Hewlett Packard and Dell. Apple, Lenovo (former IBM), Acer and NEC are also present.

Industry points to the fact that around 10% - 35% of the market is held by more or less temporary suppliers operating without a brand, so called “white boxes”. They buy desktop computers and spare parts in surplus on the global market and compete in the lower price segments. These actors are by nature hard to reach for voluntary agreements concerning the environmental performance or product quality standards. The number of

³⁸ European Commission DG TREN (2007): Preparatory studies for Eco-design Requirements of EuPs; Lot 3: Personal Computers (desktops and laptops) and Computer Monitors; Final Report (Task 1-8); Contract TREN/D1/40-2005/LOT3/S07.56313

³⁹ Turnbull, A. (2008): REACH requirements for component suppliers and equipment manufacturers; ENVIRON; available from www.BOMcheck.net

⁴⁰ The list of computer manufacturers is not exhaustive.

competitors on the EU market is estimated to be more than a hundred. The “white boxes” are more common on the consumer market.

Dell states to have approximately 75 direct suppliers of sub-parts or sub-assemblies located in 153 different sites in the 2007 Sustainability Report⁴¹. Dell suppliers worldwide (expressed in supplier spend) were 71% from Asia (China, Japan, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand); 27% from U.S. & South America (U.S., Mexico, Costa Rica and Brazil) and 2% from Europe (Germany, Italy, Ireland and Spain) in 2006.

Hewlett Packard has over 400 contracted suppliers with own production facilities and a published list of 98 top tier suppliers⁴².

Thus, the supply chain involves several tiers of suppliers who each place articles on the market for assembly into more complicated articles by the next producer in the supply chain.

A graphical overview of the main characteristics for the electronics industry supply chain is given by Turnbull (2008): the production of a power supply unit by a contract producer located inside the EU as shown in Figure 13. It starts with the manufacturing of a circuit board based on epoxy resin (a preparation) and copper foil. The resulting circuit board (an article) is supplied to a circuit board assembler. The circuit board assembler purchases commodity components (articles) from importers. He produces the populated circuit board, PCB (an article), which he supplies to a contract manufacturer. The contract manufacturer then assembles the PCB into the housing (another article) together with cables (more articles) to form the final power supply unit (another article).

⁴¹ Dell Sustainability Report & Fiscal Year 2007 in Review: Dell Sustainability Report & Fiscal Year 2007 in Review; <http://i.dell.com/sites/content/corporate/environment/en/Documents/cr-report-2007.pdf> The information given is for all Dell products and therefore not accurate for desk-top computers.

⁴² Hewlett Packard HP Global Citizenship Report 2007: <http://www.hp.com/hpinfo/globalcitizenship/gcreport/supplychain.html>

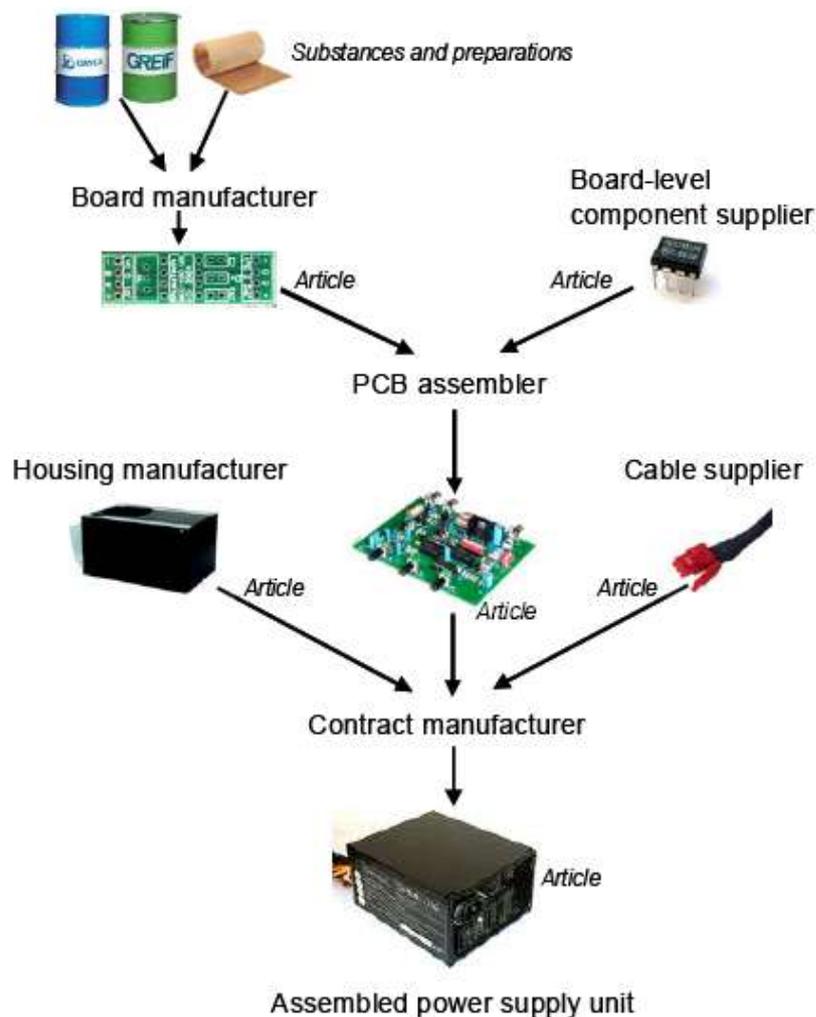


Figure 13: Production of a power supply unit (Turnbull 2008)

Production volume and share of import

Some data on EU production and import volumes are given in Lot 3 of the study from 2007 mentioned above, but it is also stated in the report that the data on domestic production seems unreliable and incomplete. No other data e.g. from producers is available. Therefore, only totals for the production and trade 2003-2005 within EU-25 can be shown, see Table 17.

Among other things, the table shows that about twice as many desktop computers were imported as exported. Anyhow, the value of exports from the EU was higher than the import value in 2005.

Table 17: EU-25 Total trade (import / export) (PRODCOM Statistics; Source: EuP preparatory study, TREN/D1/40-2005, Lot 3)

Period	Volumes (1000 units)		Value (M Euro)	
	Exports	Imports	Exports	Imports
2003	1084	2255	574	820
2004	1995	3373	730	823
2005	2125	4181	957	657

The average unit prices (when passing customs) for desktop computers 1995 – 2005 are presented in table 18. The weighted mean value of retail prices in 2005 was approximately €620 per unit for desktop computers used in offices and approximately €520 per unit for desktop computers used in private homes.

Table 18: Average unit price of desktop computer when passing the EU customs (calculated from PRODCOM import data; Source: EuP preparatory study, TREN/D1/40-2005, Lot 3)

Period	Average unit price (Euro)
1995	585
2000	346
2003	364
2004	244
2005	157

1.6.3. Information on hazardous substances

Turnbull (2008) analysed the substances on the first Candidate List and found that several of them are likely to be found in electrical and electronic equipment (see Table 19).

Table 19: Substances of very high concern on the first Candidate List that may be found in electrical and electronic equipment (Turnbull, 2008)

Substance (classification)	Likely to be found in electrical and electronic equipment
DBP (dibutyl phthalate) (Reprotox cat. 2)	Yes. DBP is often used, in combination with other phthalates, in flexible PVC. Typical phthalate contents in PVC range from 30 to 45% w/w, of which DBP is a major component at up to 15%. DBP is also used in neoprene and nitrile rubber, PVA adhesives, nitrocellulose lacquers, printing inks, sealants and coatings
Cobalt dichloride (Carcinogenic cat. 2)	Very unlikely. Used as a humidity indicator in hygrometers, barometers and self-indicating silica gels and also as an absorbent agent for ammonia gas (e.g. gas masks).
Diarsenic pentoxide (Carcinogenic cat. 1)	Very unlikely. The nearest application to the electrical and electronics industry is for the manufacturing of certain types of glass.

Substance (classification)	Likely to be found in electrical and electronic equipment
Diarsenic trioxide (Carcinogenic cat. 1)	Very unlikely. Although diarsenic trioxide is used in the manufacturing process for arsenide semiconductors, diarsenic trioxide is not found in the manufactured semiconductor components. The nearest application to the electrical and electronics industry is for the manufacturing of certain types of glass.
DEHP (Reprotox cat. 2)	Yes. DEHP is widely used as a plasticiser in polymer products, mainly PVC. In flexible PVC the typical phthalate content ranges from 30 to 45% w/w. DEHP is also used in other vinyl resins, cellulose ester plastics, dielectric fluid in capacitors, adhesives, sealants, lacquers and paints.
HBCDD (hexabromocyclododecane) (PBT)	Yes. HBCDD is used as an additive flame retardant in high impact polystyrene (HIPS) which is found in electrical equipment including housings and distribution boxes. Typical content range is 5% to 7%. HBCDD is also used in expandable polystyrene (EPS) and extrudable polystyrene (XPS).
SCCP (short-chain chlorinated paraffins) (PBT, vPvB)	Possible. SCCP are currently used as a flame retardant in textiles and rubber, in paint and in sealants and adhesives.
TBTO (tributyltin oxide) (PBT)	Possible. TBTO is used at concentrations at about 1% in biocides used in several manufacturing applications including polyurethane foam, where it is added during the 'blowing process' and is subsequently incorporated into the polymer matrix.
BBP (benzylbutyl phthalate) (Reprotox cat. 2)	Yes. BBP is one of the most expensive phthalates and so other phthalates are generally used when possible. However, BBP is used as a plasticiser in polymer products, mainly PVC. In flexible PVC the typical phthalate content ranges from 30 to 45% w/w. BBP is also used in certain sealants, adhesives, paints, inks and lacquers

Exposure relevance

Workers may be exposed to SVHC during the assembly of sub-parts and final products. Exposure may occur via inhalation or and dermal contact. Workers and consumers may be exposed through "leaching" and volatilisation of SVHC during use of the desktop computers.

Exposure of the environment may occur during recycling and final disposal in the waste phase of electronic equipment.

Case specific dilution factor

One producer of desktop computers stated that individual SVHC concentrations are below 0.1% in the entire computer, however, they may be above the 0.1% limit in certain parts, as shown in table 20. The producer stated that for DEHP even the tonnage threshold for the notification requirement might be exceeded.

Table 20: Desktop computer parts with SVHC concentration above 0.1 %

Parts	SVHC
Wired keyboard; wired mouse (accessory)	DEHP (Bis (2-ethyl(hexyl)phthalate))
External Rotating media storage device – RMSD (including HDD, Floppy, Optical Drives, Card Readers, Tape, etc.)	
External Power Supply / Power Adapter	
External Cables (DVI, HDMI, PC, USB...)	
Power Cord	

A desktop computer assembled outside the EU and then imported is treated as an article and the information obligations apply when candidate list substances are present in concentrations above 0.1%. For computers, sub-assemblies and parts assembled inside EU, the requirements are currently interpreted to apply to the placer of components on the market. It was confirmed by one actor that each object that can be shipped as such is treated as an article.

Based on the weight of a desktop computer (approximately 10 kg), it can be estimated that up to 10 g of an individual SVHC may be present without triggering the requirement if the 0.1% w/w limit relates to the whole article. Extrapolated to the total number of desktop computers imported into the EU-25 in 2005 (4,181,000 units), up to 41.8 tonnes of SVHC could be imported through desktop computers without information requirements.

Legal requirements and other standards

In addition to restrictions in REACH Annex XVII, restrictions for use in electronics are addressed in Directive 2002/95/EC on the restriction of the use of certain hazardous substances (RoHS). New electrical and electronic equipment put on the market is not allowed to contain lead, mer-

cury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE). A maximum concentration of 0.1% by weight in homogeneous materials⁴³ is allowed for lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) whereas for cadmium the maximum concentration is 0.01% by weight in the homogeneous materials.

Thus, a company placing a computer on the market has to be able to prove that the six substances resp. substance groups do not exceed the established limit values. Consequently, information is required on every single material in every part or component in the article.

A producer stated that due to this product related legislation, it has become easier to get information from suppliers because they have become aware of issues around substance use. In some EU countries these regulations are already subject to national market surveillance like for example RoHS in the UK.

Declarations of conformity with RoHS are controlled by authorities, but some of the interviewed actors stated that these documents are not suited to show REACH compliance to Articles 7 and 33 as they only show the absence of certain substances in the materials, products and articles.

Practical experience on substance content and information dissemination

According to a producer of computers (within the sector termed Original Equipment Manufacturer = OEM) the transfer of knowledge within the supply chain is limited. A material data system comparable to the automotive industry IMDS⁴⁴ is not available within the electronics industry. Information on hazardous substances in materials is only available if collected for RoHS compliance and/or compliance with company specific substance restrictions (e.g. black lists).

The Electrical and Electronic Equipment (EEE) industry tracks and discloses specific information about the composition of its products due to legal and market requirements. In order to obtain this information, the industry must gather information about the composition of products and subparts from suppliers. This affects the entire supply chain worldwide.

The information on the composition of materials can help producers to satisfy legal requirements and to respond to inquiries from customers, product recyclers and other stakeholders.

The producer influence on details in the design and performance of (components of) desktop computers depends on the article in question.

⁴³ Homogeneous material means a material that can not be mechanically disjointed into different materials. The term "homogeneous" means "of uniform composition throughout". The term "mechanically disjointed" means that the materials can, in principle, be separated by mechanical actions such as: unscrewing, cutting, crushing, grinding and abrasive processes.

⁴⁴ The International Material Data System (IMDS) is a computer-based material data system used by automotive OEMs to manage environmentally relevant aspects of the different parts used in vehicles. Through this system, the automotive industry is able to reconstruct the complete material flow within the supply chain.

For commodity articles like wires, screws and printed circuit boards the producers have low or no influence on design or chemical composition.. Nevertheless, most producers have developed material questionnaires (also known as green procurement surveys) that require suppliers to disclose information about their products. These questionnaires usually take the form of a list of banned or restricted materials and substances that the supplier must certify are not present in the product or subpart. In addition, they often include a separate list of materials and substances that need to be reported when present. The lists are communicated along the supply chain. Due to the diversity of information requests and formats, it is difficult for suppliers to manage material declaration requests.

Producers stress that they only receive information about the presence or absence of SVHC and other banned or restricted substances in their products, however they do not receive information on further ingredients in form of a complete material declaration.

Furthermore the point was made by interview partners that due to the wide spread structure of the supply chain and the limited market share of EU producers it is difficult to get the relevant information from suppliers in the global market. it was mentioned that in the last months about 50% of the suppliers (mainly located in Asia) responded to the requests on SVHC of the first candidate list.⁴⁵

Existing quality management systems include product tests performed in in-house laboratories, supplier audits and third party certifications. The quality management focus up to now lies on function and performance as well as on electrical or mechanical safety of the components. Chemical composition and safety is also quality-proved but is considered less relevant than the aforementioned aspects.

The dissemination of information about SVHC and other substances in desktop computers along the supply chain is illustrated in Figure 14.

⁴⁵ This leads to the situation, that currently some producers of electronic devices simply provide the general information that phthalates from the first candidate list may be included in concentration more than 0.1%

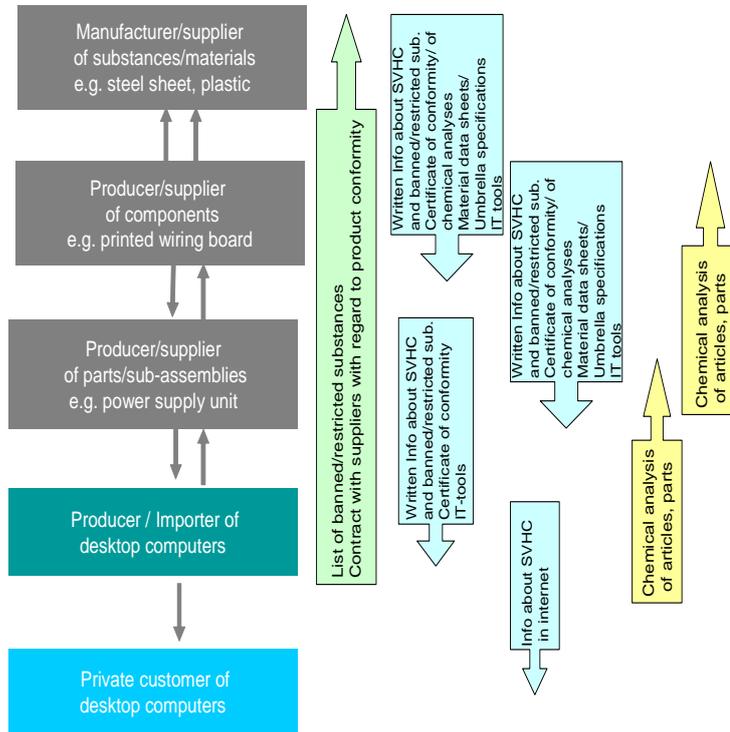


Figure 14: Information dissemination within the supply chain

A working group composed of industry representatives developed a Joint Industry Guide on Material Composition Declaration for Electronic Products⁴⁶ (JIG 2008).

This is an instrument to harmonise declarations with respect to substances and threshold levels in specific materials, components and products. The guide applies to products and parts that are supplied to producers of electrical and electronic equipment. It represents industry-wide consensus and is designed to promote consistent and standardised material declaration requests across the global supply chain.

The JIG Declarable Substance List specifies threshold or reporting levels. The threshold levels are set by legal requirements and if a new threshold is established for banning or restriction purposes, the list will be revised accordingly. Due to the diverse requirements underlying the JIG Declarable Substance List the threshold levels may apply to the article as

⁴⁶ Joint Industry Guide – JIG (2008): Material Composition Declaration for Electronic Products; JIG-101. Ed 2.0 (Revision of JIG-101A); Draft version November 24, 2008

such, the homogeneous material⁴⁷, the product⁴⁸, the surface coating or to the battery.

⁴⁷ Homogeneous material: a material that cannot be mechanically disjointed into different materials. The term “homogeneous” means “of uniform composition throughout.”

⁴⁸ Product: The item that the respondent is supplying (e.g., assembly, subassembly, component, raw material). A product may include product families if the products within those families perform the same function and have consistent material declarations.

2. Appendix: Questionnaire

Preliminary remarks

With the following list of questions the consultant team intends to collect information in selected supply chains how the implementation of the REACH requirements triggered by the 0.1% threshold for SVHC content in article according to Article 7 and 33 influence communication, quality assessment and other activities.

In order to focused and meaningful information the questions address the situation regarding one single kind of product (article⁴⁹ in REACH definition). If the information asked for are not available on the necessary level of detail for that single product information for the respective product group might be included but please indicate respectively in such cases.

The information will only be used for the ongoing study process. In case no other agreements are made the information will only be made public in an aggregated and anonymous form.

Characterisation of actor and supply chain

Role of actor and supply chain characterisation

1. Are you

Producer	
Importer	
Distributor/Retailer	

of an article?

⁴⁹ In this context "article" always means article fulfilling the definition of REACH Article 3(3). Therefore a part or a component on a complex article can itself be an article.

2. Do you sell the article

To other professional user (B2B), like	
Producer of article	
Wholesaler of article	
Retailer of article	
To private consumers (B2C)	

3. If you are the producer of the final article: How many suppliers of

Articles (parts, components, materials) do you have?	
Substances / mixtures	

do you have?

4. Where are the different suppliers located*?

	Non-EU	EU
Producer of the final articles		
Producer of parts/ sub parts, sub assemblies		
Producer of components		
Producer of semi finished goods		
Producer of raw material		
Other		

* Double answers possible

5. How much can you influence the details of the design and/or performance of the article?

No influence	
Low influence	
Medium	
High influence	

*Market data on article***6. Description of market related information**

1	Which size has the total EU market of the article?	In Euro:			In numbers:		
2	To which extend is the final article imported into the EU?	Major share imported		About 50:50		Mainly EU production	
3	What is a typical market value/prize of the article(s)?						
4	How long is a typical product development cycle?						
5	What are major market drivers?	price		Performance		Quality/brand	
6	How many competitors are on the EU market?	< 10		10 -100		> 100	
7	How long in advance do you need order from your suppliers?						

7. Description of existing quality management and related information

How do you check quality requirements today?	Product tests		Supplier audits		Third party certification
What is the major focus of QM up to now?	Function performance		Electr./-mechanic safety		Chemical safety
What is the biggest challenge for your QM?					
Which share of profit margin do you spend for QM?					

8. Description of the article, overview

Product name			
Total weight			
Number of parts / components (order of magnitude of different parts/materials included)	> 1000		
	> 100		
	> 10		
	< 10		
Are there spare parts available for the article? Which?			
Is there further equipment available? Which?			
How many and which materials are included in the article?			

For more detailed information on parts, components and materials of the article please complete tables at the end of the questionnaire.

Information on SVHC in the article - General questions on information on SVHC**9. Description of SVHC in the article**

	Are SVHCs of the candidate list (possibly) contained in the article? Which?	
	Are SVHC that fulfil the criteria according to REACH Article 57 (CMR cat. 1 +2, PBT, vPvB or similar substances) and can be expected to be included later in the list contained in the article?	
	In which part or material is the SVHC contained in the article (make reference to table in Annex)?	
	In which amount is the SVHC contained in	Whole article?
		In part or component?
		In material?
	For which SVHC do you exceed the threshold of >1t/a?	
	Which function does the SVHC have in the article (material)?	
	Are there known exposure pathways for a certain SVHC?	
	Do actors within in your sector co-operate to get information on SVHC from suppliers?	
	Will the information on SVHC pass along the whole supply chain to the recipient of the final complex article or to the private consumer? Or will it stop on the way and if so, where and why?	

What knowledge on substances from the supply chain is available at the different stages? Knowledge is available at the level of:	1 step down (e.g. pre-product level – requirements for functional units e.g. supply unit)	
	2 steps down (e.g. component level – design of circuit board)	
	3 steps down (e.g. material level - components of plastics)	
How will the implications with regard to articles be influenced by the number of SVHCs to ask and inform about? ⁵⁰		
Is there a need for more help from ECHA with this, and if so, in what way?		
What mechanisms for quality management are established by the market actors (lists of banned substances to suppliers, chemical analysis)?		
Which IT-tools do you use for gaining information and documentation about substances in the article?		
Is there a need for developing new tools?		

⁵⁰ At present there are 14 SVHCs on the Candidate List, and some of them are used in articles. In a few years there may possibly be a couple of hundred SVHCs on the list, out of which maybe one hundred is used in articles. Probably only a few of these are used in articles within a certain sector/a certain category of articles. An absolute majority of the so far about 1000 substances classified as CMRs have no use in/cannot be used in articles.

Getting information from supplier Please answer these questions if you buy articles from suppliers.

10. How do you get information about the SVHC from your supplier?

	By asking supplier of article (EU/non-EU) about SVHC of candidate list	
	By asking supplier on part, raw material (or substance, material, article) about SVHC of candidate list	
	By using lists of banned or undesired substances	
	By making a contract with your suppliers with regard to substances in the article or general product conformity	
	Other, comments	

11. What kind of information do you get?

	Written information?	
	Certificate of conformity?	
	Certificate of chemical analysis?	
	Filled in existing information system (IT-tool)	
	other	

12. Do you verify the information received from supplier by own analysis? If yes, what do you analyse

	whole article?	
	specific part, component?	
	material?	
	Other, comments	

13. Product related regulations concerning chemicals

	Is it easier to get information from your supplier because of existing product related regulation?	
	Are these regulations already subject to national market surveillance?	
	Which documents on conformity are controlled by the authorities?	
	Are these documents also suited for showing REACH compliance according to Articles 7 and 33?	
	Will information on SVHC in articles help/allow fulfilling responsibilities in relation to other legislation beside REACH e.g. occupational safety and health, waste, general product safety?	

14. What business importance has the information on SVHC in relation to possibilities for

	early substitution of SVHC to avoid potentially higher costs from late action	
	avoiding potential “bad press”	
	other	

Giving information to customers

If you are in the role of a supplier please answer these questions

15. Which information about SVHC do you give to your customer?

	Why do you give information about the SVHC to your customer?	
	Does your customer require a contract with regard to substances in the article or conformity?	
	Does your customer use lists of banned or undesired substances?	

16. Do you give information about SVHC in relation to

	whole article	
	part, component	
	raw material (substance, article)	
	material	

17. What kind of information do you give?

	Written information	
	Certificate of conformity	
	Certificate of chemical analysis	
	Filled in existing information system (IT-tool)	
	other	

18. Product related regulations concerning chemicals

	Is it easier to give information to you customer because the requirements are inline or complement to other existing product related regulation? Which?	
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	Are these regulations already subject to national market surveillance?	
	Which documents on conformity are controlled by the authorities?	
	Are these documents also suited for showing REACH compliance according to Articles 7 and 33?	
	Will information on SVHC in articles help/allow fulfilling responsibilities in relation to other legislation beside REACH e.g. occupational safety and health, waste, general product safety?	

19. What business importance has the information on SVHC in relation to possibilities for

	early substitution of SVHC to avoid potentially higher costs from late action	
	avoiding potential “bad press”	
	other	

Giving information to private consumers If you sell products to private consumers please answer these questions.

20. Are you able to respond questions from consumers or NGOs according to REACH Article 33 within 45 days?

	Yes – Why?	
	No – Why not?	
	How can you ensure the validity of the information?	

21. What kind of information about SVHC do you give to private consumers?

	Written information	
	Internet information	
	Product information	
	Other (please describe)	

22. What business effects on e.g. credibility, press, brand name, and future sales do you expect if

	No response to consumers/NGOs is given at all	
	No factual response can be given because shortage of information (e.g. the supplier don't give any information)	
	Response “no SVHC of candidate list above threshold” is given but then e.g. consumer organisation find out that there are SVHCs above the limit in parts of the article	
	The respond “SVHC XY is above the limit in part XX but we work to substi-	

	tute it” is given	
	The respond “no SVHC above the limit even in parts of the article” is given and can be also verified (e.g. by a certificate, analysis)	

23. Effort to avoid expected negative effects

	What kind of efforts do you make to avoid disadvantages or negative business effects (bad press because of dangerous substances in the article, effect on brand name, future sales and so on) because of low product quality?	
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General comments

If you have any comments not yet incorporated in the questions, please write down here (e.g. on general difficulties or benefits)

Annex**24. Exemplary description of the article: parts, components:**

Article	Parts/ Sub-parts/modules (weight)	Component (weight)	Material(s) (weight)	Total weight
Desktop	Optical Drive (weight)	Cable Screw Casing PWB Switch Plastic arm Disc tray etc.	Cu-wire Steel tube Steel sheet PBW/Solder Steel Sheet ABS ABS etc.	
	Hard disk drive (HDD)	PWB Screws Magnet arm Plate Motor Body etc.	PWB, slots, solder steel tube steel tube Cu winding wire, steel tube cast iron etc.	
	Power supply unit (PSU)	Casing Screws Power supply Trafo Cables Fan etc.	Steel sheet Steel tube PET Cast iron/Cu winding wire Cu wire PET/solder/etc. etc.	

25. Typical share of materials (substances) in the article;

article: <i>Product name</i>	
total weight of article:kg
materials	
1. Plastic	
Which proportions of weight in the whole article consist of plastic?kg
Which plastics are used in the article?	

In which amounts? (% of whole article)	
1.	
2.	
Other:	
Which (SVHC) chemicals do the different plastics contain and in what amounts?	
1.	
2.	
other:	
2. Metals	
Which proportions of weight in the whole article consist of metal?kg
Which metals are used in the article? In which amounts? (% (w/w) of whole article)	
1.	
2.	
other:	
Which (SVHC) chemicals do the different metals contain and in what amounts?	
1.	
2.	
Andere:	
3. textile	
Which proportions of weight in the whole article consist of textile?kg
Which textiles are used in the article? In which amounts? (% (w/w) of whole article)	
1.	
2.	
other:	
Which (SVHC) chemicals do the different metals contain and in what amounts?	

1.	
2.	
other:	
4. other materials (z. B. ceramic, glass, wood, paper, leather etc.)	
Which proportions of weight in the whole article consist of other materials?kg
Which other materials are used in the article? In which amounts? (% (w/w) of whole article)	
Which (SVHC) chemicals do the different materials contain and in what amounts?	
5. Residual chemicals	
Chemicals left over from the manufacturing process sometimes remain in the finished product. Which residual chemicals could conceivably be found in this article?	