Chemical requirements for consumer products

Proposals for regulatory measures to improve chemical safety for consumers

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Summary

Introduction

This report focuses on the European legislation regarding chemicals in consumer products. The current regulatory framework in the European Union to protect consumers from chemicals contained in consumer products has been criticized for being entirely insufficient.

Annex 1 to this report contains a long list of examples of dangerous chemicals that have been found in consumer products. The content of dangerous chemicals found in the listed consumer products is not necessarily illegal as such, i.e. no specific legislation is restricting the content of these chemicals in the specific mentioned products. However, because of general safety provisions, the authorities can take action and withdraw consumer products from the European market, if the chemicals in the consumer products pose a risk. The problem is, however, that it is an expensive and laborious process to prove that the chemicals in the consumer products pose a risk.

The examples in annex 1 illustrate that dangerous chemicals in consumer products are common and an everyday occurrence, and support the critisims that the current European regulatory framework on chemicals in consumer products is insufficient.

The purpose of this study

The purpose of this study has been:

- To review the provisions of REACH with respect to chemical safety of products.
- To review chemical requirements in selected product legislation.
- To review the current regulative “coverage” of nanosubstances.
- To identify and discuss the major gaps in the current legal framework.
- To suggest a horizontal approach to cover chemical risks across all product groups.
- To establish recommendations concerning changes of the European regulatory framework as well as recommendations for further studies.

The aim of suggesting a horizontal approach is necessary, as a study by the Danish EPA has shown (by using QSAR models) that approximately 30,000 chemicals ought to be classified as hazardous, as opposed to the 7,000 that today are classified as hazardous (Niemelä et al, 2009). This huge number makes it nearly impossible to set specific limit values for all hazardous chemicals used in consumer products and underlines the need for a horizontal approach, in which general requirements would be set for groups of chemicals (e.g. carcinogenic) instead of specific requirements for each individual chemical.

Review of European legislation

A review of relevant European legislation has been performed. This review includes a discussion of REACH, the General Product Safety Directive, the Toy Safety Directive, ROHS, the Energy Related Products Directive, the Personal Protection Equipment Directive and the Construction Product Directive.

The overall conclusion from the review is that the current legal framework is insufficient because very few chemical requirements in general exist for consumer products. Chemical requirements are:

- missing entirely in the General Product Safety Directive (only "products must be safe"),
- inadequate in REACH, Toy Safety Directive and ROHS (too few substances restricted or not strict enough to protect human health),
- or just related to regulations in Member States (Construction Products Directive).

Another reason for the insuffiency of the current legal framework is that the regulations do not allow for establishing proper limit values and to adopt them quickly by using a committee procedure (comitology) – except for the proposed revised ROHS directive and the restrictions of REACH (annex XVII). The new Toy Safety Directive only includes a committee procedure for toys for children up to 3 years of age.

Other conclusions from the review are:

- Weak phrases that are difficult to act on by producers/importers are used – e.g. "products must be safe" or "human health may not be endangered". Should be replaced by either specific limit values or harmonised standards that set limit values for specific substances, so companies know what to act on.
- REACH has many good intentions but there is a long implementation period and procedures (e.g. for substance evaluation, authorisation restrictions) are rather slow.
- The data requirements of REACH depend primarily on the amount of substance sold and not on the hazardness of the substances.
- REACH implements almost no requirements towards content of chemicals in consumer products.
- REACH relies to a large extent on industry self-assessments.
- Market surveillance of illegal consumer products (because of hazardous chemical substances) could be much more focused and more intense to ensure that only safe products are on the market.
- The RAPEX notifications (chemical notifications) show that notifications are mainly made due to the lack of compliance with restrictions on chemical substances. Only few notifications (if any) are made due to "products must be safe". This means that loose statements do not seem to work for market surveillance either. It is much easier to handle limit values.

Furthermore, the following conclusions can be made on the present coverage of nanosubstances within REACH:

- Whilst the Commission considers the current regulatory framework sufficient to address risks relating to nanomaterials and only in need of some modifications at the implementation level, this position seems more than doubtful and is also not supported by the EU Parliament.

- REACH only requires registration for substances produced in amounts above 1 tonne per year. Not all substances and nanosubstances are therefore included. However, the parent substances of many nanosubstances have already been pre-registered – many of them in the > 1000 ton/year band.
- REACH information requirements and other provisions (e.g. preparation of a chemical safety report) rely on the tonnage philosophy, which may not be appropriate for nanosubstances that can be produced in relatively small amounts.
- A nanomaterial that has a bulk counterpart will have to comply with the information requirements applicable for the sum of the nano and bulk form. For instance, if this total amount is produced in > 1000 tonnes annually the substances would, of course, be registered with the most extensive data set. In theory, the registration dossier of the bulk form of a chemical substance should include specific consideration concerning the nanoform of the substance (or be updated when a nano form of an existing bulk substance is placed on the market). However, even if bulk and nano form exceed the relevant information triggers, it is far from clear whether the foreseen toxicity tests have to be performed for the bulk substance as well as the nano form.
- In addition to standard information requirements nano specific data may have to be defined in a flexible way e.g. by an independent scientific committee.
- Only a small fraction of registration dossiers will be evaluated by ECHA and the Member States. However, it is advisable that dossier and substance evaluations are carried out for all nanosubstances.
- Existing testing methods on nanosubstances may not be appropriate and will have to be adopted.
- The Commission takes assurance in market surveillance for compliance with legal requirements regarding nanosubstances/materials. However, in absence of clear-cut assessment rules the enforcement bodies will encounter difficulties in taking action.
- The REACH rules should be adapted taking into account the points above and need to be complemented by provisions in product regulation including approval procedures as e.g. in the Cosmetics Directive.

Suggested horizontal approach in short

A solution to cover chemical risks in a horizontal approach across all product groups has been suggested, but it is recommended that the solution should be discussed further in expert groups.

In short the horizontal approach suggested in this study includes the following elements:

- Expansion of the ERP Directive to include generic and specific chemical restrictions for all products. Thus, the ERP Directive should be expanded to cover all products rather than just energy related ones and to cover a multitude of environmental aspects mirroring the EU Eco-label Regulation at a somewhat lower level of ambition. This offers opportunities for synergies and efficient resource use.

- The approach for chemical restrictions may rely on positive lists, negative lists or a combination of both.

- The generic approach for restrictions of chemicals in consumer products should be based on the definition of SVHCs in REACH (i.e. to ban substances falling in this category such as carcinogenic, mutagenic, toxic for reproduction, etc.). However, it should be further considered (in expert groups) whether further categories of chemicals should be included (as for instance sensitising substances or substances that are toxic).

- The general concentration limit of the chemicals restricted by the generic approach should be set at 0.1% (as in REACH) for any homogenous component of the product.

- It should be further discussed whether in some cases (or in which cases) the relevant type of limit-requirements should be based on migration or emission levels instead of content or concentration.

- It should be possible to allow for exemptions for certain substance in certain consumer products.

- It should be possible to establish more specific chemical requirements in special cases (like products emitting dangerous substances to our indoor environment) or for specific groups of products (like e.g. toys addressing a certain consumer group) or specific chemical substances not covered by generic restrictions. In these cases, a risk assessment must be performed. Perhaps an extra uncertainty/safety factor could be used in order to account for the combination effects or for multiple exposures. Risk assessments including possible exemptions should be assessed by an independent scientific committee (e.g. SCHER).

- A product declaration scheme should be introduced for all consumer products. It is suggested that all chemicals classified as hazardous with a content of 100 ppm or higher should be declared. Concentration intervals should be stated.

- The legal framework should include the possibility of changing the chemical requirements by using a committee procedure.

- A systematic assessment of the occurrence of chemicals in (certain) products should be carried out.

- Establishment of an adequately funded and more efficient market surveillance system including random tests and control measurements.

- The random tests carried out by the authorities should give feedback to the process of establishing limit values for special chemical substances for special consumer products. If necessary, the special limit values could be changed or new could be adopted – again by use of a committee procedure.

1 Introduction

Already in the 1960's the first warnings were given on man-made chemicals having a deadly toll on birds and wildlife. For the last 15-20 years more and more research has been made on chemicals found in humans. Theo Colborn showed already in 1996 with the book "Our Stolen Future: Are we threatening our fertility, intelligence and survival?" that man-made chemicals are threatening the human ability to reproduce and that chemicals thereby invisibly are undermining human future (Colborn et al., 1996).

Newer research shows that even chemicals at a very low dose can have a large impact on humans, if combined with other chemical exposures (combination effects). Only relatively recently we have learned that a large number of chemicals can penetrate the womb and alter the construction and programming of a child before it is born. Through trans-generational exposure, endocrine disruptors cause adverse developmental and reproductive disorders at extremely low amounts in the womb, and often within the range of typical human exposure. (TEDX, 2010).

The Swedish movie "The submission", which premiered in April 2010, also addresses the topic of human exposure to dangerous chemicals from our everyday life. The blood of two people was examined and hundreds of different chemicals were found in their blood. The purpose of the movie was to illustrate the problem: humans are exposed to thousands of chemicals of which we do not know enough. Furthermore, there is a large gap between scientists within the area and decision-makers.[1] The American professor Theo Colborn states in this movie that the threat from man-made chemicals is more severe than climate change, which today is a hot topic[2].

This report focuses on the European legislation regarding chemicals in consumer products. The current regulatory framework in the European Union to protect consumers from chemicals contained in consumer products has been criticized for being entirely insufficient.

Annex 1 to this report contains a long list of examples of dangerous chemicals that have been found in consumer products. The content of dangerous chemicals found in the listed consumer products is not "illegal" as such, i.e. no specific legislation is restricting the content of these chemicals in the specific mentioned products. However, because of general safety provisions, the authorities can take action and withdraw consumer products from the European market if the chemicals in the consumer products pose a risk. The problem is, however, that it is an expensive and laborious process to prove that the chemicals in the consumer products pose a risk.

The examples in annex 1 illustrate that dangerous chemicals in consumer products are common and an everyday occurrence, and illustrate the point

[1] The movie is described in more details on http://www.underkastelsen.se/ and http://www.nyteknik.se/nyheter/energi_miljo/miljo/article767228.ece (in Swedish).
[2] http://www.aok.dk/film/fremtiden-er-i-fare (in Danish).

that the current European regulatory framework on chemicals in consumer products is insufficient.

1.1 Purpose

Thus, the purpose of this study has been:

- To review the provisions of REACH with respect to chemical safety of products.
- To review chemical requirements in selected product legislation.
- To review the current regulative "coverage" of nanosubstances
- To identify and discuss the major gaps in the current legal framework.
- To suggest a horizontal approach to cover chemical risks across all product groups.
- To establish recommendations concerning changes of the European regulatory framework as well as recommendations for further studies.

The purpose of the review carried out in this report is partly to illustrate the problem – that the risk of developing health problems related to the content of chemicals in consumer products is not hindered effectively by the European legislation, and partly to give input to how chemicals ideally should be handled in European legislation.

2 Review of chemical requirements in existing legislation

In order to illustrate the gaps in the legal chemical requirements for consumer products in existing EU legislation, selected product and chemical legislation are reviewed in this chapter.

Two types of legislation are reviewed: product legislation and chemical legislation. REACH is chemical legislation. In REACH, chemical substances and preparations are the focus point, but implementation of REACH will also have an impact on consumer safety. Product legislation is legislation where products are in focus, like e.g. General Product Safety Directive and Toy Safety Directive.

In this chapter, the following legislation will be reviewed:

- REACH as the only chemical legislation
- And the following product legislation
    - General Product Safety Directive
    - Toy Safety Directive
    - ROHS
    - Energy Using Products Directive
    - Personal Protective Equipments Directive
    - Construction Products Directive

Other legislation, such as the Cosmetics Directive, could of course also be relevant to examine, but in collaboration with the Consumer Council at the Austrian Standards Institute the above legislation has been selected to undergo a review. The reason for this is that this legislation does not only cover a broad range of consumer products but also represents different types of regulatory approaches with respect to setting chemical requirements for consumer products. Furthermore, the products within the scope of the investigated directives are articles as defined by REACH (see below).

In this chapter, it is discussed how the selected legislation listed above actually works with respect to protecting the consumers against the exposure to chemicals.

Finally, the coverage of nanosubstances in the present legislation is described in more details, as there is a growing concern of the health impacts related to nanosubstances. In order to perform a reasonable review of chemical requirements, it is therefore necessary to look at the nanomaterials as well.

2.1 Chemical legislation

Different chemical legislation exists within the EU. This chemical legislation can be divided into horizontal legislation and sectorial legislation that is only valid for a specific sector. Examples of chemical legislation are:

Horizontal chemical legislation:

- REACH Regulation (Registration, Evaluation, Authorisation and Restriction of Chemical Substances)
- CLP Regulation on Classification, Labelling and Packaging of Substances and Mixtures
- Directive on Classification, Packaging and Labelling of Dangerous Substances (will be replaced by CLP Regulation, but not until 2017 where CLP is fully implemented)
- Directive on the control of major-accident hazards involving dangerous substances (Seveso Directive)
- Regulation on persistent organic pollutants (POPs)
- Regulation on export and import of dangerous chemicals

Sectorial chemical legislation:

- Framework Directive on Sustainable use of Pesticides (in the process of renewal)
- Regulation on Authorization of Plant Protection Products (in the process of renewal)
- Regulation concerning the Placing on the Market and Use of Biocidal Products (new proposal – change of existing directive concerning the placing of plant protection products on the market)

REACH will, as the newest and most comprehensive chemical legislation, be reviewed as the only chemical legislation. The reason being that REACH also covers articles, i.e. consumer products, to some extent whereas the other chemical legislation focuses on chemicals and chemical mixtures.

2.1.1 REACH

The REACH Regulation (EC) no 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals is a comprehensive legislation and the Regulation text in itself comprises more than 250 pages. To this should be added the many thousand pages of guidelines that have been developed in order to understand and comply with REACH.

This review will not describe and discuss every little detail about REACH as this will be a too comprehensive task within the scope of this study. The focus will be on some of the most important issues and on issues relevant for the consumers, i.e. articles (consumer products).

2.1.1.1 Description of the Regulation

In 1993, the Regulation 793/1993 on the evaluation and control of the risk of existing substances was established in order to assess potential hazards to human health and the environment arising from substances that were commonly used in the EU. Member States of the EU were responsible for prioritizing the substances to determine which would be evaluated first, and 141 chemicals were placed on a priority list. However, between 1994 and 1998, only four chemicals had went through the full assessment process, with only 38 chemicals having been discussed at all. In many cases, the risk assessment concluded that too little information was available on the properties of the chemical to adequately evaluate its safety. In 1999, a review by the European Chemicals Bureau revealed that 21 % of the high-production-volume chemicals had no assembled data at all, and 65 % had some data, but less than was required for new chemicals. Thus in 2001, the first thoughts behind REACH were proposed in order to compile more

physicochemical, toxicological and ecotoxicological data for chemicals to prevent the use of substances of very high concern (without approval) and to restrict the use of chemicals which cannot be used safely (Williams et al, 2009).

The purpose of REACH is as it is stated in the first preamble of the REACH Regulation: "this Regulation should ensure a high level of protection of human health and the environment".

REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals and operates with these terms (registration, evaluation, authorization and restriction) in the Regulation. REACH will not be fully implemented until 2018, and thereby operates with an implementation period of 12 years. This is done in order to give industry, consultants etc. a chance of compiling the necessary data for chemicals to be registered.

Registration

Previously, new substances produced in more than 10 kg per year required a comprehensive evaluation before being placed on the market. With REACH this limit is raised to 1000 kg (1 tonne). All substances manufactured or imported in quantities greater than 1 tonne per year must be registered within ECHA (European Chemicals Agency). However, several categories of substances are exempted from the registration, such as substances used in medicinal products and foodstuffs, polymers, radioactive substances and many naturally occurring substances.

Before December 2008, companies had to pre-register all substances at ECHA in order to be able to use the transition registration deadlines of December 2010, June 2013 or June 2018. When the final registration is due depends on the tonnage band (total annual production or import) of the substance and the properties of the substance. The most dangerous substances (CMR[3] substances (> 1 tonne annually) and those toxic to aquatic environments (> 100 tonnes annually)) and the substances produced or imported in the highest amounts (> 1000 tonnes annually) must be registered by the first registrations deadline December 2010.

With the registration the companies must deliver information about the physicochemical, toxicological and ecotoxicological properties of the chemicals. The information required increases with the increase of the annual production/importation. For substances produced or imported in the tonnage band from 1 to 10 tonnes annually, mostly physicochemical properties, a few toxicological properties and the biodegradability properties must be delivered as a part of the registration (see Table 2.1 for details).

For any substances registered in the tonnage band above 10 tonnes annually, a chemical safety report is required as part of the registration dossier. The goal of the chemical safety report is to assess and characterize risks arising from the varied uses of each substance, and to demonstrate that the use of risk management measures can adequately control the potential risks to human health and the environment.

It is the intention that the information derived from the chemical safety report will provide the basis for new and more informative safety data sheets –

[3] CMR = carcinogens, mutagens and reproductive toxins

thereby giving more information down the supply chain to the users of the chemicals/preparations.

Table 2.1 Information requirements for substances manufactured or imported in tonnage bands mandated by REACH (Milieau RPA, 2009; Williams et al, 2009).

Tonnage threshold (tonnes per year):	**1**	**10**	**100**	**1000**
Relevant REACH Annex:	**VII**	**VIII**	**IX**	**X**
Physicochemical properties:				
State of substance Melting/freezing point Boiling point Relative density Vapour pressure Surface tension Water solubility Partition coefficient Flash point Flammability Explosive properties Self-ignition temperature Oxidising properties Granulometry (solids only)	x	x	x	x
Stability in organic solvents and identity of relevant degradation products Dissociation constant Viscosity			x	x
Toxicological information:				
Skin irritation/corrosion Eye irritation	x	xx	xx	xx
Skin sensitisation	x	x	x	x
Mutagenicity	x	xx	xxx	xxx
Acute toxicity	x	xx	xx	xx
Repeated dose and reproductive toxicity		x	xx	xxx
Toxicokinetics		x	x	x
Carcinogenicity				x
Ecotoxicological information:				
Aquatic toxicity	x	xx	xxx	xxx
Degradation	x	xx	xxx	xxxx
Fate and behaviour in the environment		x	xx	xxx
Effects on terrestrial organisms			x	xx
Long-term toxicity to sediment organisms				x
Long-term or reproductive toxicity to birds				x

For some properties the information requirements increase with usage (i.e. tonnage). As such, "xxx" represents more detailed requirements that "xx" for the same property at a lower tonnage band. The number of "x'es" cannot be compared across properties.
The table is not taken directly from Milieu RPA, 2009, as Williams et al, 2009 presents this a bit different with respect to mutagenicity.

Evaluation

The Member States, ECHA and the European Commission are responsible for evaluating the substances under REACH. It is expected that 5% of the registration dossiers will be evaluated by ECHA with the purpose of checking for compliance with REACH information requirements (not to be confused with substance evaluations). Furthermore, it is expected that all dossiers submitted in the top two tonnage bands will be evaluated to consider testing proposals to fill data gaps. However, examination of testing proposals will be

prioritized for PBT[4], vPvB[5] and CMR[6] substances, and the uppermost tonnage band (Williams et al, 2009).

Where a compliance check is carried out first, any information obtained as a result of this evaluation process shall be taken into account by Member States Competent Authorities (MSCAs) in order to conclude whether there is concern that the substance constitutes a risk to human health or the environment. In case of a risk the MSCA shall highlight the substance to the Agency for addition to the Community rolling action plan for further evaluation (ECHA, 2007).

The substance evaluation process provides a mechanism for MSCAs to require the registrant(s) to obtain and submit additional information to address the initial concern. MSCAs carry out the substance evaluation when a substance is on the Community rolling action plan. Following substance evaluation, the MSCAs may come to the conclusion

- that action should be taken under the authorisation, restriction or classification and labelling procedures in REACH, (e.g. if substances should be identified as SVHC)
- that information should be passed to other authorities responsible for relevant legislation,
- or that no further action is needed (ECHA, 2007).

Authorization

The Member States have the responsibility of identifying and suggesting substances that should be added to the candidate list for authorization. It has been estimated that 1500-2000 substances are eligible for this candidate list (i.e. the substances are candidates for authorization) (Williams et al, 2009; Chemical Watch, 2009).

According to article 57 of REACH, the substances that are subject to authorisation, i.e. substances that at the moment are put on the candidate list for authorization – also called the SVHC list (Substances of Very High Concern) – are defined as follows:

- Carcinogenic substances category 1A and 1B (C substances)
- Mutagenic substances category 1A and 1B (M substances)
- Substances toxic to reproduction category 1A and 1B (R substances)
- Persistent, bioaccumulative and toxic substances (PBT substances)
- Very persistent and very bioaccumulative substances (vPvB substances)
- Substances that do not fulfil the above PBT or vPvB criteria, such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties, but for
    - which there is scientific evidence of probable serious effects to human health or the environment,
    - which give rise to an equivalent level of concern as CMR substances

The CMR substances of category 1A and 1B are as defined in 3.5 to 3.7 of Annex 1 of the CLP Regulation No. 1272/2008. Category 1A and 1B cover CMR substances that are known to give CMR effects in humans. Category 2

[4] PBT = Persistent Bioaccumulative and Toxic substances
[5] vPvB = very Persistent and very Bioaccumulative substances
[6] CMR = carcinogens, mutagens and reproductive toxins

substances being substances that cause concern for humans because they may give CMR effects in humans - i.e. suspected CMRs, are hence left out from the SHVC definition.

The Member States have as a result of their substance evaluation come to the conclusion that 38 substances (August 2010) are too hazardous for industry to use, for which reason these substances are put on the candidate list for authorization (the SVHC list). At the moment (August 2010) four phthalates are on the SVHC list and three of these phthalates plus four other of the 38 substances have been recommended for inclusion in Annex XIV of REACH (substances subject to authorization), i.e. in total seven substances. In other words, substances are initially included on the SVHC list/candidate list, when identified as substances of very high concern, and then later on perhaps recommended for inclusion on Annex XIV – substances, which are subject to authorization. This first recommendation of substances to be included in Annex XIV was submitted by ECHA to the Commission on June 1st 2009. The European Commission finally decides, by "comitology" procedure (with scrutiny), which substances will be included in Annex XIV and with which exceptions. Recommendation of substances to be included in Annex XIV will be made at least every second year (ECHA, 2010).

Authorization means that for certain very dangerous substances it is necessary to apply for permission to use the substances. The purpose of the authorization requirement is to ensure that risks from the use of such substances are either adequately controlled or justified by socio-economic grounds, having taken into account the available information on alternative substances or processes.

The purpose of the SVHC list is partly to identify substances that later may be subject to authorization, and partly to ensure the knowledge about the use of SVHCs in articles, as use of SVHC substances in articles must be reported down the supply chain (see section "Articles" for further details).

It is expected that Annex XIV (substances subject to authorization) eventually will contain about 1,500-2,000 substances, growing at a relatively slow rate of 25 substances per year. Hence, it may take about 60 years to complete the list, as only a limited number of chemicals can be evaluated each year (Williams et al, 2009). A nongovernmental institution in the EU called ChemSec has recently published version 1.1 of their so-called SIN list (Substitute It Now). The SIN list consists of 356 substances (updated October 2009) that have been identified as Substances of Very High Concern based on the criteria (CMR, PBT and vPvB substances) established by REACH[7].

Substances subject to authorization will not be totally restricted – only certain uses will be authorized by ECHA. For example on the "recommendation for inclusion of the seven substances for authorization", the uses "metalworking and fat liquoring of leather" are exempted for the substance "short chained chlorinated paraffins", whereas no uses are exempted for the six other substances.

Restriction

In the future, regulators (Member State Authorities) may apply for a ban or restriction of a substance if it is too hazardous to be used safely. However, such a restriction requires a so-called Annex XV dossier, i.e. a risk assessment

[7] http://www.chemsec.org/list

accompanied with a demonstration that risk management measures are insufficient to control the risk, must be conducted beforehand.

The restrictions can be found in Annex XVII of REACH. Currently (May 2010), Annex XVII of REACH contains restrictions on 59 substances (group of substances), like e.g. use of certain phthalates in toys and use of PFOS in articles. This list is existing restrictions from the Council Directive 76/769/EC "relating to restrictions on the marketing and use of certain dangerous substances and preparations". This directive was repealed by 31.5.2009 as the restrictions were included in the REACH regulation by 1.6.2009.

Articles

An article within REACH is defined as 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 (Article 3(3)). This means that most commercial items (consumer products) are defined as articles, but there are special cases such as ball point pens that are defined as containers intended to deliver a chemical preparation.

Only substances in articles that intentionally are released must be registered under REACH if present in quantities greater than 1 tonne annually. This is for example teddy bears with a perfume scent. Chemicals that are unintentionally released during use are hence not covered, like phthalates migrating out of a toy over time.

If articles contain substances on the candidate list in a concentration above 0.1% (w/w), then the supplier has to provide sufficient information (as a minimum the name of the substance) to the recipient of the article to allow for safe use of the article. For consumers, however, the information about SVHC substances in the article must only be given upon request and within 45 days of the request (Article 33 of REACH). This requirement is independent of the total tonnage of the substance.

From 2011, EU producers or importers of articles must notify ECHA if their article contains a SVHC substance on the candidate list, but only if the SVHC substance is present in a concentration of above 0.1% and its quantities in the articles are above 1 tonne in total per year per company and if exposure to humans or the environment cannot be excluded during use and disposal of the article. For now the notification rule hence only applies for the 38 substances on the candidate list (August 2010).

Today, it is unclear how this 0.1% rule should be interpreted. Some EU Member States interpret the rule as 0.1% "as supplied", whereas other Member States (including Denmark) object to this interpretation and state that the 0.1% rule applies for each homogenous part of an article. One of the arguments is for example that it is impossible to use the 0.1% rule "as supplied" when import of a large containership is in question. It is impossible to make calculations or to pulverise and analyze an entire container ship. In such an example, it only makes sense to use the 0.1% rule for each component of the ship. This aspect is being revised at the moment and a new interpretation is expected in a new version of the "Guidance on requirements for substances in articles".

Substances integrated in articles are not subject to authorization, meaning that SVHCs in imported articles are not covered by the authorization. However,

SVHCs used in the manufacture of articles may require authorization. Restricted substances (REACH Annex XVII) cannot be used in the manufacture of articles in the EU, nor can they be present in any article imported into the EU.

2.1.1.2 Regulatory aspects

REACH allows for establishing limits for dangerous chemicals using a committee procedure (using comitology) for inclusion of restricted substances in Annex XVII (similar to the previous restriction directive).

The same committee procedure is used when a substance has been evaluated by a Member State and it has been decided to include a substance on the SVHC list as a candidate for an Annex XIV substance (substances subject to authorisation) – and again when it is decided to recommend substances for inclusion in Annex XIV.

2.1.1.3 Discussion of the Regulation

There is no doubt that REACH is a step in the right direction and that REACH in the long term will lead to safer use of chemicals (or restriction of unsafe chemicals). Now the burden of proof – that chemicals can be used safely – lies on the producers, which can only be seen as an improvement since this motivates the producers to "think twice" before they introduce new chemicals on the market.

REACH focuses on restriction and evaluation of substances and chemical products – the restriction on chemicals contained in consumer articles is very limited (discussed more later), and only chemicals imported or produced over 1 tonne annually are included in REACH.

Industry self-assessment

The registration process in REACH is based on the industry supplying ECHA with information about the chemicals – the chemical assessment is prepared by the industry (industry self-assessment). Only 5% of the chemical assessments will be quality controlled with respect to compliance with REACH information requirements. Hence, self-assessment by industry may in theory be based on missing toxicological information. The chemical safety assessment including all assumptions (choice of data, exposure, etc.) relies to a large extent on industry self-assessment, which may not be necessarily strict enough. Member States Competent Authorities will have limited capacity to carry out substance evaluations for verification.

Tonnage decides the extent of toxicological information required

The implementation of REACH will not lead to a complete knowledge of the toxicological and ecotoxicological information about all of the 143,000 substances that have been pre-registered at ECHA[8]. The type of information required in the dossier necessary for registration depends on the tonnage band. As illustrated in Table 2.1 mostly information about the physicochemical properties of the chemicals is necessary when the chemicals are produced or imported in amounts between 1-10 tonnes annually. A tonnage band of higher than 1000 tonnes is needed in order to get the full toxicological information, including data on carcinogenicity.

[8] The number of preregistered substances was according to ECHA about 150,000 substances. This number has, however, been reduced, because substances have been identified as being the same. (ECHA General report, 2008), (Rovida & Hartung, 2009).

When the companies made their pre-registrations, they also had to indicate when they plan to make their registration, i.e. in which tonnage band their substances belong. From this information it can be seen that of the about 143,000 that have been pre-registered with ECHA:

- about 54,000 of the substances are expected to be registered by the 2010 registration deadline
- about 60,000 substances are expected to be registered by the 2013 registration deadline, and
- about 29,000 substances are expected to be registered by the 2018 registration deadline (Rovida and Hartung, 2009), (ECHA press release, 2009).

These numbers indicate that only for less than 54,000 substances a complete technical dossier is required with all toxicological and ecotoxicological information. It is less than 54,000 substances because also substances that are CMR substances in tonnage of more than 1 tonne annually and PBT/vPvB substances with R50/53 in tonnage of more than 100 tonne annually have to be registered by the 2010 deadline along with substances in tonnage above 1000 tonnes annually. CMR substances and environmentally hazardous substances do not require a complete technical dossier. The information requirement follows the tonnage bands.

All in all this means that probably for less than one third of all the substances pre-registered we will in the future get full toxicological and ecotoxicological information about the substances. I.e. for two thirds of the substances we will not necessarily know of the carcinogenic effects, the long-term repeated dose effects or the developmental toxic effects as these tests only have to be carried out for the largest tonnage band (Williams et al, 2009). This constitutes a problem since it may very well be that some of the chemicals in the "two thirds", that do not come with a full toxicological datasheet, might be very problematic and constitute a problem that we will not know of before tests/evaluations have been carried out.

A way to solve this could of course be to require full datasets for all registered chemicals; however, this seems not to be practically possible within a limited timeframe.

Another problem with the tonnage requirements set in REACH is that it is only for chemicals produced or imported in amounts higher than 10 tonnes annually that a chemical safety report is required. This means that for chemicals in the tonnage bands below 10 tonnes annually the safety of the chemicals has not been assessed properly.

When it comes to chemicals sold in amounts below 1 tonne yearly, the situation is even worse since these chemicals are not included in REACH at all. In theory, this means that potentially hazardous substances used in small amounts (e.g. substances in nanoform) in e.g. consumer products can be outside the scope of REACH. This is a problem since being exposed to a small amount of a very dangerous chemical can constitute a greater problem than being exposed to higher amounts of a less hazardous chemical. And of course, there could easily be situations where a product could contain a large amount of a substance even though the total amount of the substance used by the manufacturer of the product is below 1 tonne yearly.

However, as by now, the pre-registration within REACH has resulted in the registration of around 143,000 chemicals (by 2.5 mio. companies). ECHA expected to see a registration of about 29,000 chemicals (Rovida & Hartung, 2009), thus the system is by now already handling a substantial larger number of chemicals than expected. Including substances sold below 1 ton per year would put additional strain on the system and thereby maybe result in an overall weaker evaluation due to lack of resources.

Yet, the exclusion of chemicals produced in amounts below 1 ton per year poses a problem that needs to be addressed.

Long implementation period of REACH

REACH has a very long implementation period. The phase-in registration deadlines are extending to 2018. After this, follow-up of registration dossiers have to be carried out (dossier evaluation, request for more information, Member States Competent Authority assessments and subsequent decision making). Therefore, REACH will not be "fully" implemented until years after the last registration deadline.

It will take even longer before the candidate list of the most hazardous substances (SVHCs) has been expanded to contain all relevant very hazardous substances. In Williams et al, 2009 it is stated that it is expected to take 60 years before Annex XIV (substances subject to authorization) is fully expanded to the expected 1500-2000 substances in the Annex. It is thus a very long transition period before all hazardous substances will be subject to authorization and thereby hopefully strongly limited in their use.

This means, that for the next 60 years consumers are exposed to a variety of substances that could pose a health risk. Seen from the consumers' viewpoint, this is not acceptable. Even when throwing in the argument that the industry needs time to deliver the required information, it still seems unacceptable.

The reason that causes the long evaluation process shall be found in the fact that "a lot of people have to agree" on whether a certain substance should be on the Authorization list. As a start the Member States have to agree on whether a substance should be on the SVHC list, and thereafter, the process of determining (and agreeing) on whether the substance should be put on the Authorization list begins.

Are authorisation and SVHC definitions strict enough?

Even though the very hazardous substances (SVHCs) will become subject to authorization, this does not necessarily mean that there will be a total phase out of these substances. The authorization will probably only be valid for some uses of the substances. Where no substitution is possible the use of the substances will be allowed if safe use can be demonstrated. Furthermore, substances integrated into articles are not subject to authorization – at least not if the products are produced outside of the EU.

SVHC substances are, as described earlier, defined as substances that are CMR, PBT, vPvB or substances with similar properties (e.g. endocrine disrupters). It could of course be discussed whether these criteria should be strengthened or whether substances that are only persistent (P), only bioaccumulative (B) or only toxic (T) should be considered as an SVHC, as not only SVHC substances, as defined today, are relevant from a consumer

perspective. For example, sensitizing substances and toxic substances are also of concern.

Poor product coverage in REACH

Apart from the restrictions contained in Annex XVII, REACH implements almost no restriction regarding content of chemicals in (consumer) products. Consumer articles imported into the EU can contain many different chemicals including SVHCs in concentrations above or below 0.1%. The content of SVHCs in consumer articles is not restricted – only an information requirement exists. The suppliers of the articles must inform about the content of the SVHCs in products, but only if the SVHC is included in the candidate list and the amount of SVHC is above 0.1% - and then only upon request of consumers (in the supply chain this information must be given automatically)! They have to ask first in order to get the information and even then they do not necessarily get the information right away. It may take up to 45 days before the information about the content of SVHCs is delivered to the consumer. Two independent tests carried out by the Danish Consumer Council and the Information Centre of Environment and Health in the spring of 2010 showed that this rule does not work in practise. No information was given to consumers in one of the tests, and in the other test, the Danish Consumer Council only received information from 40% of the suppliers/producers within the time limit (IMS, 2010). In practice, this means that consumers have little chance of avoiding products which contains SVHCs. However, it does not seem to be the appropriate way to control content of SVHCs in products since it cannot be expected that the general population knows of SVHCs nor the consequences of using products that contain them.

First and foremost, it is relevant from a consumer point of view that the most dangerous substances (SVHCs) are not even restricted in articles (consumer products). In the long run, the inclusion of the SVHCs in annex XIV (substances subject to authorization) will of course mean that (at best[9]) the substances may no longer be produced and hence, neither be used in consumer articles. This process may, however, take several years (estimates of 60 years or more).

Secondly, the concentration limit of 0.1% or 1000 ppm is debatable. 1000 ppm is a high concentration. Thresholds for SVHC are typically in the low ppm range or even below. Such substances are of particular concern if children are exposed and in case of multiple exposure from different consumer products.

There is also the discussion about how the 0.1% rule should be interpreted. As stated earlier it is now interpreted “as supplied”, whereas a rule of 0.1% for each homogenous part would be more appropriate for several reasons, as also described in a new Nordic Council report. They state when applying this 0.1% rule to “complex” products such as toys, shoes, etc., rather than each individual part, the SVHC concentrations will be “diluted”. Many complex products will escape the notification requirement and the level of protection may as a result be affected. They state in the report that there are considerable

[9] “At best”, as the annex XIV substances not necessarily will be restricted for all uses of the substance (article 60), and as mixtures are allowed a concentration of authorised substances over a certain threshold limit (0.1 % or the concentration limit that according to Regulation No. 1272/2008 results in a classification of the mixture as dangerous (article 56 of REACH)).

amounts of SVHCs imported through large volume articles that are not notified. For example, up to 900 tonnes annually of one individual SVHC contained in shoes could be imported into Europe without triggering information requirements. For desktop computers and a small product group such as pliers, the figure is over 40 and 3.5 tonnes respectively, according to the report. Furthermore, the report states that this dilution effect and information gap occur at random (Nordic Council, 2010).

Another important aspect is that the notification requirement is inadequate. ECHA must be notified if the content of SVHCs in an article is above 0.1% and its quantities in the articles are above 1 tonne in total per year per company and if exposure to humans or the environment cannot be excluded during use and disposal of the article. For now the notification rule hence only applies for the 38 substances on the candidate list (August 2010).

Furthermore, substances which are not deliberately added to the product, such as pesticides, are not covered by REACH either.

Hazardous chemicals in articles (consumer products) are therefore poorly covered by REACH. It may be possible in the long run that chemicals on the SVHC list automatically will be phased out of consumer products (articles) as articles containing SVHCs will be more difficult to sell. But this aspect remains to be seen.

For now the only way to restrict the use of very hazardous substances in articles (as well as in imported articles) will be to restrict the substances by listing the substances in annex XVII (restricted substances). This process is, however, also a time consuming process as the Member States have to prepare a so-called Annex XV dossier (a risk assessment accompanied with a demonstration that risk management measures are insufficient to control the risk). At the moment (May 2010) 59 substances or group of substances are restricted by annex XVII of REACH. The restrictions are, however, mostly valid for chemical products and not for articles (consumer products).

The interesting question that arises here is whether REACH should regulate consumer products or whether REACH should focus on the regulation of the chemicals themselves, and the regulation of content of chemicals in products should be regulated elsewhere. For now it seems that REACH has more than enough challenges by handling the existing requirements.

Finally, a big problem with REACH will be enforcement. Even if REACH was fully operational – i.e. all chemicals are properly registered or authorised, the SVHC list fully expanded and the necessary restrictions are made in annex XVII of REACH also to cover dangerous substances in consumer articles, any enforcement activity can only be a drop in the ocean - especially for consumer articles. All restrictions concerning consumer articles would need concentration limits as well as descriptions of the necessary test methods in order to make the REACH provisions operational. But even with concentration limits and testing methods in place, it will be very difficult to control and test more than just a tiny fraction of the consumer products available on the market.

2.2 Product legislation

2.2.1 General Product Safety Directive (GPSD)

2.2.1.1 Description of the Directive

The General Product Safety Directive (Directive 2001/95E/EC on general product safety) was adopted on 3 December 2001. It entered into force on 15 January 2002 and the deadline for its transposition by the Member States was 15 January 2004. It replaced an earlier General Product Safety Directive from 1992 (GPSD, 2001), (COM(2008) 905 final, 2009).

The GPSD is intended to ensure a high level of product safety throughout the EU for consumer products that are not covered by specific sector legislation (e.g. chemicals, cosmetics). According to the Directive "producers shall be obliged only to place safe products on the market" (Article 3 §1).

The Directive provides a generic definition of a safe product (Article 2(b)): "any product which under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:

- the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
- the effect on other products, where it is reasonably foreseeable that it will be used with other products;
- the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;
- the categories of consumers at risk when using the product, in particular children and the elderly." (Article 2 (b)).

The General Product Safety Directive does not contain any chemical requirements – only the indirect statement, that "products must be safe", which also refer to chemical safety.

Products must comply with this above definition of a safe product. If there are no specific national rules, the safety of a product is assessed in accordance with:

- European Standards,
- Community technical specifications,
- Codes of good practice,
- The state of the art and the expectations of consumers.

A numerous list of European harmonised standards based on the GPSD has been established. Examples are general safety requirements for outdoor furniture, stationary training equipment, children furniture, soothers for babies and young children.

In addition to the basic requirements to place only safe products on the market, producers must inform consumers of the risks associated with the products they supply. They must take appropriate measures to prevent such risks and be able to trace dangerous products.

Under the GPSD, the Member States are obliged to enforce the requirements on producers and distributors. They must appoint the authorities in charge of market surveillance and enforcement. The surveillance authorities have a wide range of monitoring and intervention powers.

The Directive provides for an alert system (the RAPEX system – rapid exchange of information on dangerous consumer products) between Member States and the Commission. The RAPEX system allows for the exchange of information between Member States via the National Contact Points and the Commission of measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers. Both measures ordered by national authorities and measures taken voluntarily by producers and distributors are covered by RAPEX. Every Friday, the Commission publishes a weekly overview of the dangerous products reported by the national authorities (the RAPEX notifications).

Under certain conditions (e.g. urgency is required or where Decisions are the most effective way of eliminating the risk), the Commission may adopt a formal Decision requiring the Member States to ban the marketing of an unsafe product, to recall it from consumers or to withdraw it from the market. A Decision of this kind is only valid for a maximum of one year. To date four Decisions of this kind have been made at Community level:

- A Decision on phthalates (1999) – ban of six phthalates in toys.
- A Decision on lighters (2006) – lighters must be child proof.
- A Decision on magnetic toys (2008) – magnetic toys must carry a warning label.
- A Decision on demethylfumarate (DMF) (2009) – ban on DMF in consumer products, such as sofas and shoes (EC Consumer Affairs, 2009).

These decisions are as mentioned only valid for maximum of one year. In the case of phthalates, restrictions of the phthalates have later been entered into the restrictions directive, which is now part of REACH (annex XVII). This means that only provisional (temporary) restrictions on chemicals can be made by use of the General Product Safety Directive.

2.2.1.2 Revision of the General Product Safety Directive

A revision of the General Product Safety Directive is planned. DG Health and Consumers published on May 18th 2010 the first consultation paper on the General Product Safety Directive[10] - this in order to get input to identified problems of the GPSD.

According to the web site of DG Health and Consumers, the “recurrent product safety alerts, either of global or regional relevance, have made it clear that we need a system that delivers information more rapidly, efficiently and consistently throughout the EU and which, at the same time, is flexible enough to adapt to the challenges of globalisation and continue to contribute to the EU internal market of safe products”.

In the consultation paper, it is stated that the average timeframe from the initial discussions on establishing the safety requirements until the publication of the reference of the standard in the Official Journal of the European

[10] http://ec.europa.eu/consumers/safety/prod_legis/GPSD_consultation/index_en.htm

Communities, can be estimated to about six years. A change is therefore needed.

It is also suggested in the consultation paper to take legal measures directly in the GPSD, i.e. establishing specific safety requirements directly applicable to economic operators in the GPSD that would apply to certain categories of products (DG SANCO, 2010) rather than just forming the basis for mandates to the European Standards Organisations.

These are the first discussions about revising the General Product Safety Directive and it seems as if there is a long way to go before a new Directive is adopted.

2.2.1.3 Regulatory aspects

The General Product Safety Directive does not provide an instrument (comitology) to establish chemical rules or restrictions of chemicals. Only emergency measures as described above (formal decisions) can be made for a maximum of one year.

A committee procedure (comitology) is, however, in place for the process of adopting product specific safety requirements which serve as a basis for mandates and existing (non-mandated) standards connected to the General Product Safety Directive.

2.2.1.4 Discussion of the Directive

The General Product Safety Directive is intended to protect the consumers from dangerous products. By dangerous products is meant products that are not safe because of the physical shape of the product, but also because of the content of dangerous chemicals. This project focuses on the chemical safety of consumer products.

The General Product Safety Directive does not set any chemical requirements whatsoever. The directive focuses on product safety, and the requirement of "products must be safe" does of course indirectly mean that the chemical safety of a product also has to be taken into account. However, as the directive does not set any chemical requirements it is difficult for both companies and authorities to know when a chemical content in a consumer product is safe.

As mentioned a long list of European harmonised standards that relates to the GPSD has been made. In some cases, the harmonised standards specify which chemical requirements that should be followed, like e.g. for soothers for babies and young children. In the few cases where chemical requirements have been specified in the harmonised standards, only a few chemicals are listed (like certain heavy metals and nitrosamines). However, almost all of these standards merely refer to the physical safety of the products; like e.g. the general safety requirements for outdoor furniture, stationary training equipment, children furniture, and soothers for babies and young children.

This means that chemical requirements are not a general feature in standards related to the General Product Safety Directive as chemical requirements only are mentioned in a very limited number of standards. This is a problem for many companies importing or producing consumer products as specific guidelines or specific limit values for chemical substances are much easier to handle and react on in contrast to the more loose statement in the GPSD: "the consumer products must be safe". In order to ensure that the consumer

products are safe with respect to the chemical content in the products, it is necessary to carry out a risk assessment of the chemical substances in the products and an exposure scenario (as it is called in REACH terms). This will require very specific chemical and toxicological qualifications by the importers and producers of consumer products – specific chemical qualifications that often are not present at the importers or producers.

This problem of non-existing requirements for specific dangerous chemicals is also a problem for the authorities as this makes enforcement more difficult and requires more resources. They also have to perform laborious risk assessments in order to prove that products are safe or not safe for consumers to use.

An example of the use of the "must be safe" statement in Denmark is an examination of erasers for children - see also Appendix 1 (Svendsen et al, 2007). A study was initiated by the authorities in Denmark (The Danish EPA). A chemical analysis of an eraser showed that the content of phthalates was so high that a child chewing on the erasers for more than a couple of minutes per day would lead to a risk of damages to the reproduction. The eraser was not defined as a toy as it was a simple rectangular white eraser; hence, the phthalate legislation for toys did not apply. The eraser was therefore withdrawn from the market as the product was not safe for the consumers. In order to reach the conclusion that the product was not safe, a chemical analysis of the product was carried out (migration analysis) and an exposure assessment/risk assessment was carried out – operations that are complicated and laborious for importers and producers of consumer products. From their point of view, it will be much easier to react on and to comply with a limit value of e.g. a maximum content of specific phthalates in the product or a maximum migration of specific phthalates from the product.

Every three years the Commission shall submit a report on the implementation of the GPSD to the European Parliament and to the Council (Article 19(2)). The latest report from January 14th 2009 concludes that the General Product Safety Directive has proven to be a powerful tool for ensuring a high level of consumer protection as it has helped to track down and eliminate a vast number of unsafe products from the European market. They mention in the report that the number of notifications via RAPEX has increased and has put the system under some strain, but they conclude that nevertheless it is a clear indicator of improved consumer protection at European level. They suggest that the standardisation provisions should be simplified to allow for greater flexibility e.g. lay down safety requirements for a specific category of products and thereby issuing a kind of framework mandate to the European Standardisation organisations (COM(2008) 905 final).

The Commission is correct in the sense that a long list of unsafe products has been withdrawn from the market. However, most of the unsafe products that are being withdrawn are withdrawn for physical reasons like choking, fire hazards, hazards for injuries, hearing damages etc., whereas withdrawal because of chemical hazards are more infrequent. In one month (September 2009), 70 notifications were made through RAPEX and 19 (27 %) of these notifications were due to chemical hazards. Of these 19 notifications due to chemical hazards none of the notifications was made by the use of "the products must be safe" statement. All of the 19 notifications were made because they do not comply with certain chemical legislation like e.g. REACH

annex XVII (DMF, phthalates, aromatic amines) or because they do not comply with the harmonised standards connected to the GPSD. This actually means that it is only in very few cases that notification on unsafe products is made based on the GPSD text itself – most notifications are made based on restriction of substances (REACH) or based on the harmonised standards connected to the GPSD.

Finally, the General Product Safety Directive does not provide an instrument to establish chemical requirements for consumer products other than emergency measures for one year and the instrument to establish standards. This means that only provisional rules can be set by use of the General Product Safety Directive.

The first thoughts and discussions about a revised General Product Safety Directive have started, but it is still too early to know which changes that will be made in the final revision. It is, however, difficult to see that more chemical requirements will be made unless the General Product Safety Directive is changed radically.

2.2.2 Toy Safety Directive

2.2.2.1 Description of the existing Directive

The Toy Safety Directive (Directive 88/378/EEC) was adopted on May 3, 1988. Different safety provisions in the EU Member States created unnecessary costs in the transaction between Member States, thus hampering the free movement of toys. The purpose of the Toy Safety Directive was therefore to remove obstacles to trade in toys between Member States, but also to guarantee an equally high level of toy safety across the EU.

The Toy Safety Directive lays down safety criteria or essential requirements which toys must meet during manufacture and before placing on the market. Toys must not be placed on the market if they jeopardize the safety and/or health of users when they are used as intended or in a foreseeable way, bearing in mind the normal behaviour of children (Article 2). The safety criteria cover according to Annex II general risks (protection against health hazards and physical injury) and particular risks (physical and mechanical properties, flammability, chemical properties, electrical properties, hygiene, and radioactivity).

For the chemical properties, it is specified that toys must be designed and constructed so that, when used as intended or in a foreseeable way, bearing in mind the normal behaviour of children, they do not present health hazards or risks of physical injury by ingestion, inhalation or contact with the skin, mucous tissues or eyes. Furthermore, limit values for the bioavailability (i.e. soluble extract) of certain heavy metals (Sb, As, Ba, Cd, Cr, Pb, Hg, Se) are set for the protection of children's health.

A number of harmonised standards exist under the Toy Safety Directive[11] (EN 71-1 to EN 71-8). All toys must bear a CE marking before marketed in the EU indicating conformity with the provisions of the Directive (Article 8). It is assumed that toys that comply with the harmonised standards are in conformity with the essential safety requirements of the Directive. However,

[11] List of harmonised standards under the Toy Safety Directive: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:227:0018:0019:EN:PDF

according to Article 7, products must be withdrawn from the market if they are likely to jeopardize the safety and/or health of consumers, even though the products are marked with the CE label (and thereby should comply with the requirements listed in the harmonised standards under this directive). Indirectly, this means that toys are not necessarily safe for consumers even though they comply with the requirements listed in the EN71 standards.

The following harmonised standards contain chemical requirements:

- EN71-3 "Safety of toys – Part 3: Migration of certain elements" – the requirements listed here cover migration requirements of certain elements (antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium).
- EN 71-4 "Safety of toys – Part 4: Experimental sets for chemistry and related activities".
- EN71-5 "Safety of toys – Part 5: Chemical toys (sets) other than experimental sets".
- EN71-7:2002 Safety of toys – Part 7: finger paints – Requirements and test methods".

2.2.2.2 Description of the New Toy Safety Directive

On June 30 2009, the new Toy Safety Directive was published (Directive 2009/48/EC). According to EU Enterprise[12] the old directive – the directive which is still valid – has in general worked well during its almost 20 years of existence. However, the technological developments in the toys market have raised new issues with respect to the safety of toys and made consumers express increased interests in this regard. The experience made with the operation of the existing Directive led to the conclusion that there was a need for updating and completing the safety requirements, in particular in areas such as noise and chemicals in toys.

The new Toy Safety Directive came into force on July 20, 2009 and will become a legal document in all Member States once it has been implemented into national legislation by January 20, 2011. The new measures must be applied from July 20, 2011. During the transitional period both the old and the new directives may be used.

Some of the major changes in the new directive are:

1. New chemical requirements
2. Evaluation of occurrence of hazardous substances in toys by the Commission

New chemical requirements

CMR-substances

Chemicals that are carcinogenic, mutagenic or toxic to reproduction (CMR-substances of category 1A, 1B or 2[13] under the new CLP Regulation (Regulation 1272/2008)) are no longer allowed in toys if the concentration is at or exceeds the concentration set for classification of mixtures containing these substances. According to the CLP Regulation this means that the following concentrations of CMR substances are not allowed in toys:

- Category 1A and 1B carcinogens and mutagens: ≥ 0.1%
- Category 1A and 1B reproductive toxicants: ≥ 0.3%

[12] www.ec.europa.eu/enterprise/sectors/toys

[13] Please not that CMR category 1A, 1B and 2 under the CLP regulation is originally called category 1, 2 and 3 under the old classification rules (which are still valid).

- Category 2 carcinogens and mutagens: ≥ 1.0%
- Category 2 reproductive toxicants: ≥ 3.0%
- For reproductive effects on or via lactation the limit is: ≥ 0.3%

These concentration thresholds are used in general, but if substance specific values exist these thresholds should apply instead of the general thresholds. Benzo(a)pyrene has, for example, a specific value for category 1B carcinogenicity of ≥ 0.01%.

However, these CMR substances may be used as components in toys anyway even if over the mentioned thresholds, if one or more of the following conditions are met:

- The substances/mixtures are inaccessible to children in any form, including inhalation, when the toy is used as intended or in a foreseeable way, bearing in mind the behaviour of children.
- A decision has been taken to permit the substance/mixture and its use (i.e. the substance is listed in Appendix A as nickel (CMR 2) for use in stainless steel already has been permitted). A decision may be taken if the use of the substance has been evaluated as safe in toys, if there are no suitable alternatives, and if the substance is not restricted for use in consumer articles according to REACH.

Furthermore, according to Annex II (point III.7) of the new Toys Safety Directive, the restrictions on the CMR substances do "not apply to materials that comply with the specific limit values set out in Appendix C[14]" (none set yet) "or until such provisions have been laid down to materials covered by and complying with the provisions for food contact materials set out in Regulation No. 1935/2004 and the related specific measures for particular materials".

Fragrances

55 listed allergenic fragrances must not be used in toys – only if the presence is technically unavoidable under good manufacturing practice and does not exceed 100 ppm. Another 11 allergenic fragrances must be declared if they are present in concentrations above 100 ppm.

Elements

Requirements on migration of 19 elements (aluminium, antimony, arsenic, barium, boron, cadmium, chromium (III), chromium (VI), cobalt, copper, lead, manganese, mercury, nickel, selenium, strontium, tin, organic tin, and zinc) will replace the existing migration restrictions on 8 elements (antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium). The migration limits are set for three different types of materials: 1) dry, brittle powder-like or pliable toy material, 2) liquid or sticky toy material and 3) scraped-off toy material.

In preamble no. 22 it is stated that the elements arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, should not be intentionally used in those parts of toys that are accessible to children. This is not stated as a direct requirement in the directive but is listed in the beginning as a statement of intent.

[14] Appendix C is "Specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth".

Nitrosamines and nitrosable substances
Furthermore, nitrosamines and nitrosable substances are prohibited for use in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth. Specific migration limit values are set.

Evaluation of occurrence of hazardous substances in toys
Finally, it is stated that the Commission systematically and regularly shall evaluate the occurrence of hazardous substances of materials in toys. These evaluations shall take into account reports of market surveillance bodies (e.g. RAPEX) and concerns expressed by Member States and stakeholders.

Adopting specific limit values for toys (< 36 months or in the mouth)
According to article 46(2) of the new Toys Safety Directive, the Commission may adopt specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth. When adopting the specific limit values, the packaging requirements for food as laid down in Regulation No. 1935/2004 must be taken into account, as well as the related specific measures for particular materials. The differences between toys and materials which come into contact with food must also be taken into account. The specific limit values will be amended in Appendix C (no limit values yet).

Evaluation of occurrence of hazardous substances in toys
In Annex II (safety requirements of toys), part III (chemical properties) point no. 9 it is stated that the occurrence of chemicals in toys should be monitored and evaluated by the Commission: "The Commission shall systematically and regularly evaluate the occurrence of hazardous substances in materials in toys. These evaluations shall take into account reports of market surveillance bodies and concerns expressed by Member States and stakeholders".

However, it is not specified what the consequences should be.

2.2.2.3 Regulatory aspects
The requirements listed in Annex II are valid for all toys, but according to Article 46 the Commission may adopt specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth, based on food contact legislation (Regulation 1935/2004).

This means that the New Toy Safety Directive does not provide an instrument (comitology) to establish new chemical requirements or restriction of new chemicals generally in toys. Only for toys for children below 3 years this is possible.

There is no comitology in place to change e.g. the existing levels allowed for CMR substances (0.1%, 0.3%, 1% and 3% respectively). This can only be done by amending the directive, which is a comprehensive and time-consuming process.

2.2.2.4 Discussion of the Directives
The Toy Safety Directive is an example of a directive where specific requirements for chemicals to some extent are set via the harmonised standards (EN71-3, -4, -5 and -7). It is practical – as the companies can carry out certain tests in order to find out if the requirements are met – but there are only eight specific elements for all kinds of toys and some requirements for specific toy categories (chemical toys and finger paints) that today are covered

by these standards. Many other hazardous substances are not covered by the existing harmonised standards. The standards EN71-9, -10 and -11 on organic chemicals in toys are NOT harmonised standards (i.e. they have not been recognized by the Commission).

The new Toy Safety Directive sets more requirements on chemicals: CMR substances, fragrances, nitrosamines, nitrosable substances and more elements are added to the list of chemical requirements. This is of course a positive development, but there are still no specific requirements for substances that are e.g. very toxic, toxic, skin sensitizers as well as endocrine disrupters, environmentally dangerous substances etc. Furthermore, it can be discussed whether the requirements (for the restricted substances) are set strict enough in order to "not endanger health":

- CMR substances are allowed in concentrations up to 0.1 % (some substances even up to 1 % and 3% (category 2 CM and R substances respectively)),
- the CMR substances are allowed in even higher concentrations if the substances are inaccessible to children in any form (e.g. only in accessible surfaces and no emission of the substances),
- the requirements set on fragrances open up for allowing trace levels of 100 ppm and some substances just need to be declared rather than being banned,
- and for some elements the migration limits are raised instead of being lowered. According to the Dutch background report "Chemicals in toys", it can be seen that the migration limits for e.g. antimony, barium, lead and mercury have been raised in certain cases (RIVM, 2006).

Therefore, the fact is that even though a ban has been set for CMR substances, it actually allows for quite high concentrations (up to 1 or 3% (10000 or 30000 ppm) or even higher, if a decision has been made to permit the substance). There is of course a difference in content and migration/emission levels so the migration or the emission of the substances should be even lower than 0.1 %, 0.3%, 1% and 3% respectively. Anyway, it is a high concentration of highly dangerous substances that are allowed – especially as the same substances may be found in many other consumer products that children also are exposed to. As mentioned, there is no comitology in place to change e.g. the existing levels allowed for CMR substances (0.1%, 0.3%, 1% and 3% respectively). This can only be done by amending the directive, which is a long process involving the Commission, the Council and the Parliament.

A new point mentioned in the new Toy Safety Directive is that the occurrence of chemicals in toys should be monitored and evaluated by the Commission (Annex II, part III, point 9). However, it is not specified what the consequences should be. To ensure that the existing knowledge of dangerous chemicals in consumer products always is used to the advantage of the consumer, the consequence should be that additional limits are established in case of chemicals of concern.

BfR, the German Federal Institute for Risk Assessment has reviewed the new Toy Safety Directive and states that the new directive does not sufficiently protect children's health. They wonder why the rules for food contact materials have not been applied (BfR, 2008). For food contact materials the release of CMR must not be detectable analytically. In the new Toy Safety

Directive, this requirement is only envisaged for toys intended for children under the age of 36 months (the mentioned article 46(2) and point III.7 of annex II of the new Toy Safety Directive). It is, however, unclear how this will work in practise for which reason ANEC (The European consumer voice in standardisation) has forwarded the following questions to the Commission[15]:

- If there is just one limit value in Appendix C (Specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth) does this mean that all CMR provisions do not apply any longer?
- If the limits are based on limits in food contact materials legislation they will essentially cover substances other than CMRs. Limits for non-CMRs established for food contact materials – what does this have to do with not banning CMR substances?
- The test conditions (temperature, test durations and simulants) are different for food contact materials testing and testing of toys. What precisely is meant with compliance with food contact materials legislation in terms of test parameters?
- Legislation of food contact materials is not yet fully harmonised and allows to some extent the use of nationally approved substances. What does this mean for toys?
- Food contact materials use a positive list approach, i.e. that materials not listed in the annexes of this legislation are not allowed. If only limits from the food contact materials legislation are used in the Appendix C of the new Toy Safety Directive, this does not mean that only the authorised food contact materials can be used in toys. What is the interpretation and intention of the Commission in this regard?

Furthermore, BfR (2008) states that for some elements the migration levels have been raised. Especially for lead (going from 90 ppm to 160 ppm) this is a problem, as even the smallest amount has been proven to have a negative effect on the development of intelligence in children. BfR also states that the new Toy Safety Directive does not protect sufficiently with respect to allergenic substances: Trace levels of allergenic substances are allowed and requirements for nickel, the most frequent trigger of contact allergies should have been set making use of the existing limit for products with prolonged skin contact like jewellery or buttons.

Furthermore, BfR states that unsafe toys are often found on the market, despite the fact that the manufactures must confirm their compliance with the safety requirements by using the CE mark. (BfR, 2008). By introducing the risk assessment that has to be carried out, the hope is that the Member States could carry out controls on this subject, thereby forcing the companies to actually consider if the toys are presenting a risk to children.

In another opinion on PAHs in toys, BfR (2009) states that the current limits on levels of PAHs in toys are too high to protect children's health. PAHs are classified as CMR. Benzo(a)pyrene would be allowed up to 100 ppm. Other PAHs could be present at levels up to 1000 ppm, and category 2 CMRs even at levels of 10,000 ppm or 30,000 ppm. BfR argues that their use should be as low as reasonably achievable (e.g. 1 ppm limit for benzo(a)pyrene), as the current PAH limits in the new Toy Safety Directive are clearly above what is

[15] Personal information from Franz Fiala, The Consumer Council at the Austrian Standards Institute.

technologically possible (shown by studies of toys). BfR recommends that regulations of CMR substances in toys in general should not refer to the content but rather to the migration as applied for plastic materials and articles intended to come in contact with foodstuffs (Directive 2002/72/EC). For these materials, it is required that the migration of CMR substances is undetectable (BfR, 2009).

All these issues illustrate that even though more chemical requirements are set for toys compared to the existing Toy Safety Directive, there is still a long way to go to ensure that the health of consumers (children) are not endangered. The first step will be to ensure that the sufficient requirements are set – the next step will be to ensure enforcement, which already today is a problem.

The European notification system RAPEX received in 2008 a total of 1545 "article 12" notifications meaning that products were presenting a serious risk to the health and safety of consumers. Of these notifications, 32 % or 498 notifications were related to toys and toys are thereby the product category that is responsible for the far most notifications (the same picture was seen in 2007). Products from China were responsible for over half of the total notifications. The reason for toys being responsible for the far most notifications could be the reason that standards with limitation values exist which makes it easier to see compliance or not compared to e.g. notifications because of the General Product Safety Directive.

The five most frequently notified risk categories in 2008 were (also including other products than toys):

1. injuries (366 notifications, 20%),
2. chemical (341 notifications, 19%),
3. choking (285 notifications, 16%),
4. electric shock (282 notifications, 15%),
5. fire (185 notifications, 10%).

It is not possible to see how large a percentage of the notifications that are due to chemicals for the product category toys. The general trend, however, is that the chemical notifications seem to be increasing (13 % in 2007) (European Commission, 2008). As mentioned under the General Product Safety Directive, the chemical notifications seem to arise because of toys not meeting the chemical requirements set out in e.g. REACH Annex XVII or because they do not comply with the harmonised standards.

2.2.3 ROHS

2.2.3.1 Description of the existing Directive

The ROHS (Restriction Of the use of certain Hazardous Substances) Directive was adopted on January 27, 2003 (Directive 2002/95/EC of 27 January, 2003). ROHS "came to life" because of, among other things, a review strategy in 1996 by the Commission that stressed the need to reduce the content of hazardous substances in waste, by e.g. limiting the presence of such substances in products (preamble no. 3). Furthermore, a council resolution in 1988 stated that environmental pollution and human health have to be protected, and an overall strategy that in particular restricts the use of cadmium and stimulates research into substitutes should be implemented (preamble no. 4).

ROHS restricts the use of lead (Pb), mercury (Hg), cadmium (Cd), hexavalent chromium (Cr (VI)), polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) in electrical and electronical equipment (called "EEE"). The maximum concentration limits for these substances are 0.1 % (w/w) in homogenous materials for all substances except cadmium where the maximum concentration limit is 0.01 % (w/w) for homogenous materials (Commission Decision 618, 2005).

ROHS is not valid for all electronic and electrical equipment – only for the following groups of EEE, and furthermore several exceptions exist (e.g. higher content of mercury is allowed in fluorescent lamps):

- Large household appliances
- Small household appliances
- IT and telecommunication equipment
- Consumer equipment
- Lighting equipment
- Electrical and electronic tools (with the exception of large-scale stationary industry tools)
- Toys, leisure and sports equipment
- Automatic dispensers

In article 4 of the ROHS Directive, it is stated that as soon as scientific evidence is available, the European Parliament and the Council shall decide on the prohibition of other hazardous substances and the substitution thereof by more environment-friendly alternatives which ensure at least the same level of protection for consumers.

2.2.3.2 The new ROHS proposal

In December 2008, a new ROHS proposal was presented (COM(2008) 809 final). The basic objective of the Directive has not been changed. The ultimate aim is still the elimination of certain hazardous substances from electrical and electronic equipment. No new substances are proposed to be banned. The main proposed modifications are[16] (COM(2008) 809 final):

- Two new annexes describing the products covered are added. The first describing the broad product categories and the second (amendable by the Commission) providing binding product lists within each category. "Medical devices" and "control and monitoring instruments" are added as new product categories covered.
- A mechanism for introducing new substance bans in line with the REACH methodology for restrictions (Article 69-72) is inserted to ensure coherence and maximise synergy with the work carried out under REACH. This means that a list of "priority substances" posing particular environmental concern will be assessed in line with REACH with a possible ban in the future. Detailed rules of this process will be developed through comitology. The Commission will invite ECHA to evaluate the substances concerned as a priority. Four substances are proposed as "priority substances" (Annex III in the new ROHS proposal). These are: Hexabromocyclododecane (HBCDD), DEHP, BBP and DBP.

[16] The main difference is described at the following website: http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/08/763&format=HTML&aged=0&language=EN&guiLanguage=en

- A permission to use non-compliant spare parts is extended to equipment benefitting from an exemption when placed on the market to prevent premature withdrawal of equipment from use.
- A 4-year maximum validity period for the exemptions is set to stimulate substitution efforts and shift the burden of proof in line with REACH. New criteria such as availability and reliability for granting exemptions are introduced.
- Articles 7-17 are all new and introduce product conformity assessment requirements and market surveillance mechanisms. A CE label for electrical and electronical equipment is introduced. The CE label will in the future also mean that the chemical requirements in ROHS are met.

2.2.3.3 Regulatory aspects

The existing ROHS Directive does not provide an instrument (comitology) to establish new chemical requirements or new restrictions of chemicals. However, the new ROHS proposal is introducing a comitology to change the annexes which include bans of chemicals (Annex IV) and candidate for bans ("priority list" – Annex III). This will allow for faster decision making.

2.2.3.4 Discussion of the Directive

The restriction on use of Pb, Hg, Cd, Cr VI, PBB and PBDE will of course limit the total exposure to consumers of these substances. Both when consumers use the products directly, but mainly indirectly by lowering the content of these substances in our waste streams and thereby also the emission of these substances to the environment.

It can, however, be questioned:

- whether the concentration limit sets are strict enough,
- why the ROHS directive does not cover all groups of EEE (medical devices and monitoring and control instruments are not covered (but are covered in the new ROHS proposal (COM(2008) 809)),
- why so many exemptions exist,
- why not more hazardous substances are covered,
- or why the directive does not cover other consumer products than electrical and electronic equipment.

It is positive that the Directive gives room for inclusion of a restriction of other hazardous substances in the future – however, only when scientific evidence is available. Hopefully in about 10 years when REACH is fully implemented, we will know much more about the hazardous effects of many more chemicals so the legislation could cover all very hazardous chemicals. Therefore, it is positive that the new ROHS proposal is linking with REACH in terms of decision making, meaning that substances that REACH has shown to be problematic then can be a subject for the "priority list" (Annex III) of the new ROHS proposal and thereby in the future also be restricted in EEE.

The Öko-Institut has made a study on hazardous substances in electrical and electronic equipment, not regulated by the ROHS Directive. They concluded that substitutes exist and are available on the market for a large number of applications in EEE for the phase-out substances that they propose in the study. They suggest that ROHS should be expanded also to cover prohibition of the following substances:

- TBBP-A (tetrabromo bisphenol A) due to formation of dangerous degradation/reaction products during the collection and treatment of EEE.
- HBCDD (hexabromocyclododecane) due to being a PBT substance and due to formation of dangerous degradation/reaction products during the collection and treatment of EEE.
- DEHP (bis (2-ethylhexylphthalate)) due to being a CMR substance and due to formation of dangerous degradation/reaction products during the collection and treatment of EEE.
- BBP (butylbenzylphthalate) due to being a CMR substance.
- DBP (dibutylphthalate) due to being a CMR substance. (Öko-Institut, 2008).

Four of these substances (HBCDD, DEHP, BBP, DBP) are listed in Annex III of the new ROHS proposal. Annex III includes substances for priority assessment that will lead to possible restrictions ("priority list"). The intention is to review the substances by using a methodology based on the process set out in the REACH Regulation (articles 69 to 72).

When looking at some of the opinions from the industry they generally oppose of this method and to include extra substances in ROHS as the substances in articles are already covered by REACH. However, this is not entirely true. The substances are on the candidate list/SVHC list (Substances of Very High Concern), but these substances are not prohibited/regulated in articles imported into the EU – only by an obligation to inform about the content of the substances in the articles if above 0.1 % down the supply chain (but information to consumers must be given only upon request!) and only by a notification to ECHA if the total import of the substances in articles is also above 1 tonne. It may be possible that the notification and the obligation to inform about the content of these substances will be enough to phase out the substances but in order to make sure that the substances are not used in imported articles like electrical and electronic equipment, a ban – by including the substances in ROHS – is necessary.

Therefore, it is positive that the new ROHS proposal introduces a comitology to change the annexes which include bans of chemicals (Annex IV) and candidate for bans ("priority list" – Annex III), as this will allow for faster decision making. Hopefully the link with REACH will lead to problematic substances being restricted in ROHS as soon as they are identified as problematic in REACH.

2.2.4 Energy related products

2.2.4.1 Description of the Directive

Directive 2005/32/EC and the amending Directive 2008/28/EC establish a framework for the setting of eco-design requirements for energy-using products. The purpose was to make sure that energy-saving measures are taken already in the design phase of the products as this is the most cost-effective way to facilitate environmental improvement.

This Energy-Using Products (EUP) Directive was in October 2009 replaced by the Energy-Related Products (ERP) Directive. The original plans by DG Environment were to expand the directive to all environmental issues and all products but the plans were halted by DG Enterprise. Therefore, the result

was only a slight expansion of the directive from energy-using products to energy-related products.

The Directive does not introduce directly binding requirements for specific products, but does define conditions and criteria for setting requirements regarding environmentally relevant product characteristics. It is stated in Article 3 that Member States shall take all appropriate measures to ensure that energy using products covered by certain "implementing measures" may be placed on the market and/or put into service only if they comply with those measures and bear the CE marking. According to Article 15 (5), the implementing measures shall all meet the following criteria: "health, safety and the environment shall not be adversely affected" (one of several criteria mentioned in the Article).

The eco-design directive for energy-relating products is a framework directive that gives the opportunity for issuing EU regulations with limit values for the energy-use of specific products ("the implementing measures"). By August 2010, this has been done for nine product categories (under the former energy-using directive):

- Standby and off mode electric power consumption of electrical and electronic household and office equipment (Reg. 1275/2008)
- Simple set-top boxes (Reg. 107/2009)
- Non-directional household lamps (Reg. 244/2009 and amending Reg. 859, 2009)
- Fluorescent lamps (Reg. 245/2009 and amending Reg. 347/2010)
- External power supplies (Reg. 278/2009)
- Refrigerators and freezers (Reg. 643/2009)
- Televisions (Reg. 642/2009)
- Electric motors (Reg. 640/2009)
- Circulators (Reg. 641/2009)

More regulations are on its way on products such as:

- Washing machines
- Central heating pumps
- Computers
- Room air conditioning appliances, local air coolers and comfort fans
- Boilers
- Tertiary lightings

With the expansion to energy-related products, also products that have an influence on energy consumption when they are in use – like insulation materials, windows, and doors - are expected to be covered.

Until now (August 2010), nine implementing measures have been published and are in force as stated above. In all of the nine regulations, it is mentioned in the preamble that "The ecodesign requirements should not affect functionality from the user's perspective and should not negatively affect health, safety or the environment". However, none of the regulations are setting chemical requirements – only requirements with respect to energy consumption or the like are set.

Regulation 244 and 245 about lamps (light bulbs) are nevertheless setting the requirement that the amount of mercury contained in the lamps should be stated on the packaging in mg Hg. This is stage 2 information that does not

enter into force before September 2010. It is specifically mentioned in these regulations that requirements for the content of mercury are set by the ROHS directive (Directive 2002/95/EC).

2.2.4.2 Regulatory aspects

These implementing measures mentioned above are adopted by a committee procedure (comitology). This means that the directive provides an instrument to establish new requirements for different product groups. As mentioned above, the requirements set are energy-related and not related to chemicals (restriction of chemicals).

A consultation forum is introduced in the process of establishing the implementing measures. It is stated in article 18 that "in respect of each implementing measure, a balanced participation of Member States' representatives and all interested parties concerned with the product or product group in question, such as industry, including SMEs and craft industry, trade unions, traders, retailers, importers, environmental protection groups and consumer organisations" must be ensured. "These parties shall contribute, in particular, to defining and reviewing implementing measures, to examining the effectiveness of the established market surveillance mechanisms and to assessing voluntary agreements and other self-regulation measures". In theory, this gives stakeholders a possibility to influence the decision making. The German Öko-Institute is the principal advisor in the case of consumer organisation[17].

2.2.4.3 Discussion of the Directive

The principle of the framework Directive is in general good as health, safety and environmental aspects should be considered in the entire life cycle of the products. However, in practise no chemical requirements have been set in the adopted regulations that are based on the Energy-using Products Directive. One reason for this is of course that the ROHS Directive also covers the same energy-using products and thereby sets limits for the content of some heavy metals and flame retardants.

In the revised Energy-Related Products Directive, the content of hazardous chemical substances and strengthening of the impact on consumer health due to chemical exposure is not brought up – the loose statement about the products "should not adversely affect health, safety and the environment" has stayed the same but this does not help if the intentions with future regulations only are to regulate on the energy consumption and not on the content/migration of hazardous chemicals. Hopefully, when implementing measures are taken to set requirements for energy-related products not covered by ROHS, like windows and doors, chemical requirements will be set as well.

It is positive that the implementing measures are adopted by a committee procedure which means that the directive provides an instrument to establish new requirements for different product groups. This allows for faster decision making. However, the original intention of covering all environmental aspects and all products has been strongly diluted in the ERP Directive. This could have given the opportunity to include also chemical aspects in a wide range of consumer products. From a consumer viewpoint the slight expansion from energy using products to energy-related products is insufficient.

[17] Personal communication with Franz Fiala, The Consumer Council at the Austrian Standards Institute.

Furthermore, it is positive that Environmental NGOs and consumer organisations can influence the decision making of adopting the implementing measures. Of course, the real decision making is characterised by a strong industry influence and other problems, but nevertheless the process is the best possibility for Environmental NGOs and consumer organisations to be included in the process of protecting the environment and health of consumer.

2.2.5 Personal protective equipment

2.2.5.1 Description of the Directive

The EU initiated Directive 89/866/EEC relating to personal protective equipment (PPE) in order to ensure equally safe products throughout the EU. The purpose of the PPE Directive is to have some basic requirements which PPE must fulfil in order to ensure the health protection and safety of users (Article 1). All PPE covered by the Directive must be CE-marked (Article 13) and satisfy the basic health and safety requirements laid down in Annex II (Article 3).

Annex II of the directive lists requirements regarding health and safety that PPE must satisfy. This includes aspects such as design principles, protection against mechanical impacts, physical injuries, heat and fire etc. However, the interesting requirement listed with respect to the chemical safety of consumers is the requirement called "Innocuousness of PPE – suitable constituent materials" that states:

- "PPE materials and parts, including any of their decomposition products, must not adversely affect user hygiene or health".

This requirement is the only area that deals with chemical hazards in the PPE Directive. This requirement ensures that PPE materials (including any of their decomposition products) must not adversely affect user hygiene or health. This means, according to the PPE Guidelines (2009), that the constituent materials of the PPE cannot (in the foreseeable conditions of normal use) release or degrade to release substances generally known to be toxic, carcinogenic, mutagenic, allergenic, teratogenic or otherwise harmful. The Guideline also states that particular attention should be paid to the presence of plasticizers, unreacted components, heavy metals, impurities and the chemical identity of pigments and dyes.

The PPE Guidelines (2009) is a common interpretation and application of the PPE Directive (even though the relevant national transposition of the directive is legally binding). The PPE Guidelines have been prepared by DG Enterprise and Industry of the European Commission in collaboration with Member States, European industry, European standardisation and Notified Bodies.

A comprehensive list of harmonised standards (> 250) is affiliated with the PPE Directive (Commission communication, 2009). These harmonised standards are tools for ensuring conformity of a PPE to the basic safety and health requirements. However, as stated on the EU website (Enterprise – Personal Protection Equipment), the harmonised standards may not cover all health and safety requirements of a given PPE, they only cover those explicitly mentioned in the standards.

The harmonised standards primarily list requirements that are connected to physical hazards and not chemical hazards. Some standards include chemical requirements (but only chromium VI requirements) such as:

- EN ISO 20345:2004 Personal Protective Equipment – Safety footwear, that requires a test for the content of chromium VI in the leather (limit value 10 mg/kg, i.e. the chromium VI content must not be detectable according to EN ISO 20344:2004 Personal Protective Equipment – Test method for footwear).
- EN ISO 340:2004 Protective clothing – General requirements that set requirements for chromium VI content (limit value 3 mg/kg), nickel release from metals (in line with EU REACH annex XVII), pH value of the clothing, and carcinogenic amines from azo colorants.
- EN ISO 420: 2003 Protective gloves – General requirements and test methods that set requirements for chromium VI content (limit value 3 mg/kg) and pH value.

2.2.5.2 Regulatory aspects

No committee procedure to change the requirements is available in the PPE Directive. This means that the directive has to be changed in order to change the requirements.

2.2.5.3 Discussion of the Directive

Of course, the PPE Directive protects the consumers (at work or at home) from potential physical harm and chemical harm (by providing a physical barrier from the chemicals) but it is also stated in the Directive that the Personal Protection Equipment in itself must not adversely affect user hygiene or health.

As for the General Product Safety Directive the harmonised standards primarily list requirements that are connected to physical hazards and not chemical hazards. This means that chemical requirements are not treated in general in the standards related to the PPE Directive as chemical requirements only are mentioned in a very limited number of standards. This is a problem for many companies importing or producing PPE as specific guidelines or specific limit values for chemical substances are much easier to handle and react on in contrast to the statement in the Directive: “materials, including their decomposition products must not adversely affect user health”.

Even though the PPE Guideline states that particular attention should be paid to the presence of plasticizers, unreacted components, heavy metals, impurities and the chemical identity of pigments and dyes, this is not transferred into practise by a direct requirement in many of the standards related to the PPE Directive.

2.2.6 Construction products

2.2.6.1 Description of the Directive

The EU adopted the Construction Products Directive on 21 December 1988 (Council Directive of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products).

The Construction Products Directive (CPD) is a kind of labelling directive linked to national building regulations and does essentially not establish product requirements – and thereby no chemical requirements either. As stated on the EC Enterprise and Industry website[18]: "The objective of the CPD (and the CPR alike) is thus not to define the safety of construction products, but to ensure that reliable information is presented in relation to their performance. This is achieved by providing, mainly in standards, a common technical language, to be used not only by manufacturers, but also by public authorities when defining their requirements on construction works, directly or indirectly influencing the demands placed on the products to be used in them".

According to Annex I of the directive there are essential requirements that – not the individual construction products must satisfy – but what construction works must satisfy. Construction products must be suitable to build construction works which are fit for their purpose. Therefore, the directive does not set product requirements. These essential requirements are:

- Mechanical resistance and stability
- Safety in the case of fire
- Hygiene, health and the environment
- Safety in use
- Protection against noise
- Energy economy and heat retention

In terms of "Hygiene, health and the environment", it is specified that "the construction works must be designed and built in such a way that it will not be a threat to the hygiene or health of the occupants or neighbours, in particular as a result of any of the following:

- The giving-off of toxic gas
- The presence of dangerous particles or gases in the air
- The emission of dangerous radiation
- Pollution or poisoning of the water or soil
- Faulty elimination of waste water, smoke, solid or liquid wastes
- The presence of damp in parts of the works or on surfaces within the works."

According to Article 3 the essential requirements shall be given in a concrete form in interpretative documents. These interpretative documents are a link between the essential requirements and the standardization mandates, mandates for guidelines for European technical approval or the recognition of other technical specifications.

The manufacturer of construction products are responsible for the attestation that products are in conformity with the technical specifications set out by CEN in the harmonised standards (Article 13 and 4).

A construction product is presumed to be fit for its intended use if it bears the CE marking which attests the conformity of the construction product to technical specifications (harmonized standards, European Technical Approvals and national technical specifications).

[18] http://ec.europa.eu/enterprise/sectors/construction/construction-products/index_en.htm

According to the EU website (EU Enterprise – Construction) more than 500 harmonised standards exit within the area of construction products – of course some of the listed standards are revisions of former standards.

In conclusion, the CPD provides a framework for a harmonised testing and declaration scheme, but the building regulations are in the remit of the Member States. Member States are free to specify product requirements but must use the harmonised specifications. This means that the use of the construction products is regulated at the national level.

With regard to chemical requirements this means that Member States can specify chemical requirements, as for example by setting a requirement on the emission of formaldehyde from construction products, but this has to be done by each Member State. The CPD does not allow for setting requirements for all European countries.

2.2.6.2 New proposal for a Construction Products Regulation

A new regulation laying down harmonised conditions for the marketing of the construction products is proposed to replace the existing Directive (proposal of 23 May 2008 (COM(2008) 311 final).

The goals of the regulation proposal of May 2008 are the same as those of the Construction Products Directive: to foster the free movement and use of construction products in the internal market. The aim of the revision is to attain these goals more easily, more transparently, more efficiently and at lower costs. The regulation would keep many of the core elements of the Construction Products Directive.

As for the CPD, the objective of the Construction Products Regulation (CPR) is not to define the safety of construction products, but to ensure a framework for harmonised testing and declaration schemes.

Annex I, where the essential requirements are listed for hygiene, health and the environment, has been changed a bit in the proposal for a regulation. In contrast to the existing Directive, the entire life cycle of the construction works is now mentioned and it is specified that emissions of dangerous substances, volatile organic compounds, greenhouse gases or dangerous particles into indoor or outdoor air, are not wanted (Annex I of Regulation proposal).

In the proposal is stated that each construction product which is covered by a harmonised technical specification (harmonised standard or European Technical Assessment) must carry CE marking. With the CE marking the manufacturer guarantees that the product complies with the information in its "declaration of performance" (Annex III). The declaration of performance is a new instrument in the proposal. It is proposed to be drawn up according to a catalogue of essential requirements in the area where the product is intended to be placed on the market.

Somewhere in the process, the Swedish government suggested to include in this declaration of performance information about the content of specific hazardous substances in construction products. Later this proposal was taken up in the first EU Parliament reading on the proposed Construction Products Regulation: according to Annex IV of the text adopted in April 2009 (P6_TA(2009)0320), the declaration of performance must also contain

information about the following hazardous substances in the construction products:

- Substances of very high concern (substances on the candidate list of REACH)
- PBT (persistent, bioaccumulative and toxic) substances according to REACH
- vPvB (very persistent and very bioaccumluative) substances according to REACH
- Substances with certain classifications:
    - Carcinogenic, mutagenic and toxic to reproduction category 3
    - Substances with chronic toxicity (R48)
    - Environmentally hazardous substances with possible long term effect (R50-53)
    - Ozone depleting substances (R59)
    - Substances which may cause sensitization by inhalation (R42)
    - Substances which may cause sensitization by skin contact (R43)
- Priority hazardous substances according to the Water Framework Directive (2000/60/EC)

These requirements have, however, been criticised intensively by the industry. For example the European Association of polyurethane insulation (called BING) argues that "a mere list of dangerous substances in the product without a risk assessment does not provide any added value as the consumer will not know the concentration of these substances nor he will be able to conclude whether a specific end-use application could lead to a risk potential. A substance may be hazardous without causing risk, as long as there is no exposure to it. Another substance might be less hazardous but could be released in such doses that it causes a significant risk. It would indeed be the wrong signal if products were deselected simply because they contain certain substances although they show a better environmental life cycle performance than other products and, in addition, do not pose health risks"[19]. BING argues that using the requirements that only rely on the classification of the substances are in contradiction to REACH that is using a risk assessment approach.

EuroWindoor, an umbrella organisation of the European association of fenestration and door sector for the three frame materials metal, wood and plastics, and the infill material glass, argues[20] in line with BING and states that these suggestions for the declaration of performance (mentioned above) will result in double regulation (i.e. REACH is already regulating hazardous substances). However, this is not entirely true for articles. EuroWindoor also argues that a complete declaration of hazardous materials contained in construction products will be misleading as it would lead to a considerable information overload for consumers.

At the moment (May 2010), it seems that these suggestions have been rejected and are not part of the modified legislative proposal from the Commission (COM(2009) 579 final 2008/0098 COD).

[19] http://www.pu-europe.eu/site/fileadmin/Position_papers/BING_on_CPR_-_content_of_dangerous_substances_11-06-09.pdf

[20] Position on draft amendments to Commission proposal for Construction Products Regulation (dated 19th February 2009). EuroWindoor position, 27th February 2009. http://www.faecf.org/Download/Papers/EuroWindoor%20position%20on%20amendments%20for%20CPR%200902%20final.pdf

2.2.6.3 Discussion of the Directive

Neither the CPD nor the proposed CPR is an instrument to set requirements for chemicals in construction products, as they only are instruments that provide the framework for ensuring harmonised testing and declaration schemes. Furthermore, as the requirements themselves have to be prepared by the individual Member States, the CPD/CPR is not an instrument to ensure common European requirements for chemicals.

An opinion on risk assessment on indoor air quality by SCHER (Scientific Committee on Health and Environmental Risks) states that indoor air may contain over 900 different chemicals, particles, and biological materials with potential health effects. The concentrations of these chemicals are usually higher indoors than outdoors and people generally spend more time indoor than outdoor. SCHER states that protection of sensitive populations is best achieved by reducing the exposure and recommends that all relevant sources that are known to contribute should be evaluated. One of the sources mentioned is building materials (SCHER, 2009).

As mentioned in some of the examples of Annex 1 to this report, the concentrations of chemicals in our indoor environment are close to or are in some cases higher than the tolerable daily intake values (TDIs) set for these individual substances. This means that in order to solve the huge problems of indoor air that are affecting human health (e.g. we do not know how all the chemicals combined are affecting us), we need to ensure that chemical requirements are also set for building materials. As mentioned, neither the CPD nor the proposed CPR is an instrument to set requirements for chemicals in construction products.

In a report from the European Commission (report no. 24), it is described that in order to meet the need for improved consumer protection with respect to building materials, different kind of labelling systems for material emissions have been developed in many European countries and by industrial organisations. However, there is a big difference between these labelling schemes. Therefore, the report states that there is a strong need for harmonisation of material labelling systems. (European Commission, Report no. 24, 2005).

Today, requirements for emissions from construction products are sparse. It is primarily voluntary labelling systems for material emissions that are available in different EU countries. Germany has an assessment scheme (AgBB) which is linked to the mandatory Building Code and currently mainly applied to floor coverings. However, an extension to other product groups is envisaged. A manufacturer therefore only has to declare the substances in Germany – and also this just for a limited number of products. At present, efforts are being made to establish a harmonised EU scheme for emission labelling of construction products[21].

Another problem is that the declared values according to CPD/CPR might just reflect current legal limits which are relatively high. As an example formaldehyde could be indicated as < 0.1 ppm measured in a test chamber rather than indicating the actual value. Then one could not even use the

[21] Has been discussed at the conference "Sustainable construction labelling: user needs" 21 October, Brussels.

declaration for a voluntary scheme requiring a lower emission value (e.g. requiring a threshold of 0.05 ppm formaldehyde).

To conclude, this means that requirements for chemical emissions from construction products are needed, but the CPD (or CPR) does not seem to be the right place for such requirements, as they are only framework legislation that focuses on harmonised testing and declaration schemes.

2.3 Review of present "coverage" of nanosubstances

The above review of chemical requirements in existing regulation does not include nanomaterials. However, since recent information regarding nanosubstances, such as increasing production volumes, capabilities to cross biological barriers and increased biological activities of nanosubstances (when compared to bulk counterparts), have caused increased awareness of the health impacts related to nanosubstances, it is assessed that in order to perform a reasonable review of chemical requirements, it is necessary to look at the nanomaterials as well. Thus, this section deals with the current "coverage" of nanosubstances.

The knowledge related to nanosubstances impact on health is limited. At present there is, among other things, a lack of information. During the past years some efforts have been put into clarifying the challenges related to handling nanosubstances. The findings of four recent "studies" are presented in the following sections. The four studies are:

1) A PhD thesis from February 2009 entitled "Regulation and Risk Assessment of Nanomaterials – Too Little, Too Late?

2) A Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on "Regulatory aspects on nanomaterials".

3) A study on the need for further information regarding nanomaterials performed by Milieu/RPA in September 2009 on behalf of DG Environment.

4) A case study where a hypothetical registration of nanosilver has been conducted entitled "Nanomaterials under REACH. Nanosilver as a case study" performed by RIVM in 2009.

Together, these four studies give a reasonable outline of the present "coverage" of nanosubstances – as well as hints to gaps and potential legislative improvements. However, it should be mentioned that several other studies have been performed related to regulation of nanomaterials. For example the publications:

a. "The appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials" (June 2007), which is an opinion from the scientific committee SCHENIR.
b. "Risk assessment of products of nanotechnologies" (January 2009), which is an opinion from the scientific committee SCHENIR.
c. "Legal appraisal of nano technologies (2007) commissioned by the German UBA and carried out by Öko-institut and Sofia (Society for Institutional analyses)

d. "Limits and prospects of the "incremental approach" and the European legislation on the management of risks related to nanomaterials" (2006) from the Technical University of Denmark.

The first two studies mentioned (the reviews by SCHENIR) are not directly addressing regulation, but the risk assessment methods used in legislation including the REACH technical guidance documents. Both of the latter studies (c. and d.) identify the need for regulatory actions. However, in this study the focus will be on the four studies mentioned above.

Finally, the actions that ANEC (European consumer voice in standardisation) and BEUC (The European Consumers' Organisation) call for on the subject of nanotechnology in a joint position paper from June 2009 will be summarised.

2.3.1 PhD thesis on existing regulation's ability to handle nanosubstances

A PhD thesis from February 2009 (Hansen, 2009) examined whether existing regulation is adequate in terms of regulating nanosubstances. The study found that although nanomaterials might be covered by the general scope of many of the existing legislative frameworks, it is often unclear whether the current regulation is applicable when it comes to specific nanomaterials and their diverse applications. The study found the main problems to be:

- Requirements to do safety evaluations/gather information are triggered by production volumes (tonnage) not tailored to the nanoscale.
- There is a profound lack of (eco)toxicological data.
- Risk thresholds and occupational exposure limits cannot be established with existing methodologies (thresholds are not tailored to the nanoscale, but based on bulk material).

According to the study the only amendment that has been implemented is the withdrawal of the exemption status of carbon and graphite under REACH. It is also stated in the PhD thesis that several governments have chosen to implement voluntary environmental programs (VEPs), arguing that this is the only viable option for the time being. However, many of the key elements for a successful VEP (incentives to participate for various stakeholders, agency guidance, technical assistance, signed commitments, periodical reporting, quality of information and transparency in design, reporting and evaluation) have not been fully addressed in the currently implemented VEPs on nanomaterials.

2.3.1.1 Conclusions from the PhD thesis

All in all, the study finds that the existing regulation is not adequate to deal with nanomaterials (neither in the short term nor the long term), and that too little is being done currently to amend existing regulation.

The study recommends that current regulation should be adapted immediately to reflect the challenges posed by nanomaterials. However, the study also concludes that risk assessment should be abandoned as the primary decision making tool, due to a number of difficulties (lack of information, difficulties in monitoring nanomaterial exposure in workplaces and the environment, as well as the fact that biological pathways of nanomaterials are still largely unexplored). In short, we cannot wait until the risk assessment methods are available because this can take a long time. The study suggests

using alternative decision tools such as MultiCriteria Decision Analysis, Adaptive management, and Bayesian decision.

MultiCriteria Decision Analysis (MCDA) has already been applied on nanomaterials (Hansen, 2009). The purpose of the MCDA method is to evaluate and choose among different decision alternatives based on multiple criteria using systematic and structured analysis in contrast to "ad hoc" decisions. Key issues in MCDA methods are:

- who defines what the initial criteria are
- what alternatives are available to the decision maker
- how the different criteria are translated into a numerical score in order to rank the different alternatives (quoted from Hansen, 2009).

The Adaptive management is probably the decision making tool that is most often mentioned when dealing with complex and uncertain risks. However, it has still to be applied to nanomaterials. Adaptive management sees the management of a risk as a process consisting of many small decisions rather than a "one hit"decision. In Adaptive management the decision maker takes a decision, and subsequently the decision is treated as a hypothesis that needs to be tested and validated. Monitoring is then implemented to see whether the hypothesis should be rejected or confirmed. If the hypothesis is rejected a new decision is made, and the process starts all over again (Hansen, 2009).

The Bayesian decision making (or Bayesian statistics) uses the knowledge from past experiences to tell something about the probability of future scenarios. Here a decision is made on the basis of evidence available at the time and as new and more evidence becomes available, the decision may be changed.

The PhD thesis emphasizes the importance of exploring these methods and evaluates the usefulness of these methods in relation to regulation of nanomaterials.

All in all, the study recommends that all nanomaterials should be treated as new substances under REACH and that nanomaterials are registered based on a threshold and unit different than mass. The PhD thesis also suggests that more non-technical support should be given through publishing of various newsletters, agency guidance documents on determining various nanomaterial characteristics, (eco)toxicological testing and monitoring. Also disincentives should be implemented – such as creating a list of companies not participating in the program, but known to manufacture nanomaterials.

2.3.2 The Commission's comments on regulatory aspects of nanomaterials

2.3.2.1 Nanosubstances in REACH

According to the Commission (SEC (2008) 2036) there are no provisions in REACH that refer explicitly to nanomaterials. However, the Commission believes that nanomaterials are covered by the "substance" definition in REACH.

Within REACH, manufacturers and importers will have to submit a registration dossier for substances that they manufacture or import at or above 1 tonne per year. At or above 10 tonnes/year, the registrant will be obliged to produce a chemical safety report. Furthermore, if deemed necessary for the

evaluation of the substance, the European Chemicals Agency can require any information on the substance, independent of the minimum information requirements of REACH.

When an existing chemcial substance, already placed on the market as a bulk substance, is introduced on the market in nanoform, the registration dossier will have to be updated to include specific properties of the nanoform of that substance. The required information includes different classification and labelling as well as additional risk management measures. Additional testing may be required. The Commission recognizes that existing test methods may need to be modifyed, but until then the test will have to be carried out according to already existing methods.

For SVHCs, authorisation and restriction schemes apply regardless of quantities manufactured, thus nanomaterials would be included. The Commission states that current provisions regarding quantitative triggers may have to be modified, thus as opposed to the PhD thesis the Commission still believes in quantitative triggers/thresholds.

2.3.2.2 Nanosubstances in products

The Commission also comments on nanomaterials within product legislation. They state that where products are subject to pre-market control (e.g. medicinal products, novel foods, plant protection products) the assessment and management of risks in relation to nanomaterials can be verified by authorities.

The Commission states that it is especially relevant to have in mind the obligation to review, modify or cancel authorisations, if there are indications that any of the relevant requirements are no longer satisfied, or if development in the scientific community requires new actions (reactive approach). Furthermore, they state that products that are placed on the market without specific pre-market procedural requirements (products subject to the general product safety directive, e.g.) must be verified at the level of market surveillance for compliance with legal requirements. Furthermore, they point out that authorities at all times can verify the risk assessment and risk management strategy at the premises of the manufacturer.

2.3.2.3 Conclusions from the Commission

As opposed to the conclusions presented in the PhD thesis above, the Commission concluded (SEC (2008) 2036) that current EU legislation does to a large extent cover risks in relation to nanomaterials and that those risks can be dealt with under the current legislative framework. However, they acknowledge that current legislation may have to be modified and state that documents that support implementation, particularly in relation to risk assessment/test methods, adopted within the current legislation, will have to be reviewed in order to ensure that they effectively address nanomaterials. Furthermore, they admit that a knowledge gap exists and needs to be closed.

The Commission states that “where the full extent of a risk is unknown, but concerns are so high that risk management measures are considered necessary, as is currently the case for nanomaterials, measures must be based on the precautionay principle”. They also conclude that there is a need for rapid improvement of the scientific knowledge basis to support the regulatory work. Data is needed in the following areas:

- Data on toxic and eco-toxic effects as well as test methods to generate such data.
- Data on uses and exposures throughout the lifecycle of nanomaterials or products containing nanomaterials, as well as exposure assessment approaches.
- Characterisation of nanomaterials, development of uniform standards and nomenclature, as well as analytical measurement techniques.
- For occupational health aspects, the effectiveness of a range of risk management measures including process enclosure, ventilation, personal protective equipment like respiratory protective equipment and gloves.

A number of Commission working groups, organisations etc. are now focusing on closing the knowledge gab and the Commission intends to report on the progress after 3 years (which would be in 2011).

2.3.2.4 Reaction of the EU Parliament on the Commission paper

The EU Parliament has reacted on the Commissions comments on the regulatory aspects of nanomaterials in the document "Nanomaterials. European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials" (EU Parliament resolution, 2009). In this resolution, the EU Parliament states that they do not agree with the Commission's conclusion that current legislation in principle covers the relevant risks relating to nanomaterials. They also "deplore the absence of a proper evaluation of de facto application of the law in the light of the actual nature of nanomaterials". In other words, the EU Parliament does not agree with the Commission on the regulatory aspects of nanomaterials and calls for a (proper) regulatory review within two years.

2.3.3 Milieu: Analysis of data need for regulation of nanosubstances

As the Commission as well as the PhD thesis points out there is a profound lack of knowledge regarding nanosubstances. Thus, Milieu with support from Risk & Policy Analysts was commissioned by DG Environment to advise on the need for additional data reporting on nanomaterials, the options for such reporting and to provide recommendations for an EU scheme. The Milieu study consists of two parts – one focusing on nanomaterials and labelling, and the other on nanomaterials and REACH. In the labelling part, they advocate for a regulatory framework for nano reporting beyond REACH, which can be perceived as further evidence of REACH being deficient.

Below is described some of their main findings from the part about nanomaterials and REACH:

2.3.3.1 Which are the main substances at the nanoscale currently on the market

They conclude (Milieu RPA, 2009) that the presence of nanomaterials on the EU market has been based on claimed statements from the manufacturers/suppliers, thus some uncertainties exist as regards to the precise number.

Furthermore, they conclude that the "parent substances" of many nanomaterials are relatively common substances (silver, carbon, zinc oxide, silica, titanium dioxide and gold). However, many other parent substances exist, including inorganic compounds (natural clays) and organic compounds

(polymers and biopolymers). Finally, they conclude that relatively few nanomaterials are used in a variety of products, but that a considerable amount of nanomaterials is under development.

2.3.3.2 Milieu study findings in relation to REACH

The Milieu study finds the following four scenarios possible for nanomaterials within REACH:

1) If the nanomaterial is considered to be the same substance as the bulk form of the same chemical element or compound, then registration of the substance would include the nano-form and its uses. Where a registrant subsequently introduces a different nanoform of the substance to the market, the registration dossier would have to be updated. However, the substance would be exempt from registration if the total quantity involved was less than one tonne per year. Nevertheless, all the other REACH and CLP provisions will apply to the substance as well as to its nano-forms;

2) If the nanomaterial is considered to be a distinct substance from the bulk form of the same chemical element or compound, then the nanomaterial would be exempted from the registration if the quantities involved were less than one tonne per year. However, all the other REACH and CLP provisions would apply to the nanomaterial;

3) If the nanomaterial is considered to be a distinct substance from the bulk form of the same chemical element or compound and the quantities involved were greater than one tonne per year, then registration of the nanomaterial would be required; and

4) Some substances (such as polymers) are exempt from REACH and, as such, polymers (and other exempt substances) in nano-form would not require registration in any case. However, even in such cases the CLP provisions would apply.

2.3.3.3 Whether and how these substances will be registered under REACH

Some well established substances which include nano-forms (carbon black, silica and titanium dioxide) have been assigned EC numbers[22], pre-registered and, in some cases, registered under REACH as "phase-in" (existing) substances. However, no substance, which only exists in nanoform, has been assigned an EC number and therefore no such substance can be registered as a phase-in substance.

One of their key findings is that the parent substances used in many nanomaterials (silver, carbon, zinc oxide, silica, titanium dioxide and gold) have been pre-registered under REACH – and furthermore that many of these registrations are in the > 1000 t/yr band, which means a fairly high level of toxicological data is required for the parent substance.

Amongst those substances which are less commonly found in nanomaterials, there are many high volume substances for which registration is planned for 2010 (such as aluminium, calcium peroxide, tungsten disulphide). According to the pre-registrations five specific entries for nanomaterials have already been registred. Though, according to Milieu it appears that there are relatively

[22] EC number, also known as EC-No and EC#, is the seven-digit code that is assigned to chemical substances that are commercially available within the European Union.

few cases where the production/import quantities of the parent substance fall into the low tonnage band (< 100 tonne/year).

Milieu found two main groups of nanomaterials which will not be covered by REACH registration:

- Those that are exempted from REACH such as those based on polymers (e.g. polyesters and PET) and biopolymers (such as micelles).
- Those manufactured/imported in very low volumes (less that 1 tonne/yr) including, perhaps, some complex metal1-metal2-oxides which have not been pre-registered.

The Milieu study also states that the REACH Competent Authorities anticipated concerns with the assessment of nanomaterials supplied in small amounts. It is believed that many nanomaterials will be produced in small amounts, thus below the one tonnage threshold and the Commission agreed to encourage their voluntary registration. The Commission also agreed to encourage the early registration of low tonnage phase-in nanomaterials to allow for their assessment ahead of their 2018 registration deadline.

2.3.3.4 What relevant information will not become available (from the REACH process)

It is possible to set up a wide range of scenarious as to whether the relevant information on the use of nanomaterials will become available through REACH.

According to Milieu, many substances due to be registered in 2010 will require a Chemical Safety Assessment (CSA), and for some of these the nanomaterial may be included. An example could be where a particular use is limited to the nano-form of the substance because in order to ensure that the Exposure Assessment (EA) contains the full range of uses of the substance, there will a need to be a reference to that use which relies on the nano-form of the substance.

However, there are many other scenarios where nano-specific information (on uses) may not be provided including (quoted from Milieu):

- Nano-form is used alongside non-nano-forms in particular uses. In the absence of specific guidance to the contrary, it is possible that some users (and/or manufacturers/suppliers) would not[23] highlight the use of nanomaterials;
- Nano-form is used in products covered by other legislation (for example, use of nano-coatings in drink bottles or nanoparticles in cosmetics). In such cases, it is unlikely that the CSA would make reference to the associated safety/risk implications of such uses;
- Nano-form is based on a substance which is not classified under DSD[24]/CLP[25] and therefore does not trigger an EA under REACH

[23] The word "not" is not written in Millieu RPA (2009), but it is assumed to be a misprint.

[24] Dangerous Substance Directive. Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

[25] Classification Labelling and Packaging Regulation. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

- Nano-form is based on a substance which is exempt from some provisions of REACH (polymers, biocides, very low tonnage compounds, etc.).

Milieu also states that it possible that manufacturers/importers will submit risk assessments which include detailed information on physicochemcial properties, toxicology and ecotoxicology on both the bulk and nano-form of some substances. However, they believe that further guidance from ECHA is likely to be required and that this further guidance could include requirements of information about surface specific activity, dimensions and structure, e.g. of the nanosubstance.

2.3.4 RIVM: A case study on registration of nanosilver

RIVM (the Dutch National Institute for Public Health and the Environment) has carried out a case study on nanosilver where in theory they have tried to carry out a registration within REACH on nanosilver. They concluded that some adjustments are needed in REACH to assess and control the risk of nanomaterials. The information on substances to be provided under REACH is not sufficient to determine the specific properties of nanomaterials or to assess how these properties affect their behaviour and effects in humans and the environment.

By conducting a hypothetical registration of nanosilver it was investigated whether REACH is suitable for assessing the safe use of nanomaterials. From this it appeared that no definition of a nanomaterial is present and that a relevant measure for expressing harmfulness and exposure is as yet not known. In addition, the standard information requirements are insufficient to assess hazard and exposure. They are also insufficient for a proper characterisation of the nanomaterial. Consequently, it cannot be determined to what extent the nanoform of a substance corresponds to the non-nanoform of the same substance. Furthermore, it is unclear whether current risk reduction measures and extrapolation methods in risk assessment, as established for non-nanomaterials, are applicable to nanomaterials.

Therefore, RIVM proposes an adapted set of minimum information requirements to be applied to all nanomaterials to be registered under REACH, independent of their volume of production and import. These requirements allow a risk assessment of nanomaterials (Quoted from RIVM, 2009).

2.3.5 Joint position paper from ANEC/BEUC June 2009

A Joint ANEC/BEUC position paper from June 2009 entitled "Nanotechnology: Small is beautiful but is it safe?" called for the following actions:

- Clear definitions of nanomaterials and nanotechnologies as the lack of definitions leads to legal uncertainties and hampers the development of regulatory requirements;
- The precautionary principle to be applied in the field of nanotechnologies;
- The safety of nanomaterials to be assessed by knowledgeable independent scientific committees before they can be used in

consumer products with which consumers come in direct, close or regular contact or in products leading to discharges to the environment;
- Adequate safety and risk assessment methodologies taking account of all characteristics of nanomaterials;
- Existing European legislation relevant to nanotechnologies to be adapted in order to safeguard consumer health and safety, as well as the environment;
- Legal safety requirements to be adapted or established (eg. limit values for certain nanomaterials in products) and standardisation to be only used to establish test methods and other technical specifications;
- Increased transparency about the use of nanomaterials and labelling of consumer products containing nanomaterials in particular products with which consumers come in direct, close or regular contact;
- Effective participatory processes in order to allow citizens to fully engage into decisions which will have an impact on their everyday life (quoted from ANEC/BEUC, 2009).

2.3.6 Discussion of present "coverage" of nanosubstances

As presented above there seems to be some disagreement on whether REACH is suited to handle nanomaterials/substances. Some argue that REACH is inadequate to address the potential risks of nanosubstances while others (the Commission) argue that REACH can handle nanomaterials and needs only some modifications at the implementation level (e.g. guidance documents). The EU Parliament does, however, disagree with the conclusions of the Commission on this issue and the case study from RIVM also shows that REACH clearly has some gaps when it comes to handling nanosubstances in a registration. This is of concern as recent research has shown that nanoparticles in consumer products can be released to human sweat (see Annex 1 to this report for a more detailed description).

Nanomaterials can, as well as other chemicals, be produced in small amounts below 1 tonne per year which means that these nanomaterials/substances will not be registered. Only nanomaterials which have a bulk counterpart produced in > 1000 tonnes annually would of course be registered with a full dossier.

A major concern in terms of toxicological information requirements related to nanomaterials is the fact that the extent of information requirements in REACH increases with increased manufacture/import. Thus, substances registered in the low tonnage band (1-10 tonnes/year) will not have a chemical safety report and even though the substance is produced in an amount above 100 tonnes/year, there is e.g. no requirement related to carcinogenic properties unless the substance is produced in an amount above 1000 tonnes/year (a production volume which nanomaterials will not necessarily achieve).

The finding of Milieu RPA (2009) that the parent substances used in many nanomaterials have been pre-registered under REACH – and furthermore that many of these registrations are in the > 1000 t/yr band is interesting – especially when combined with the statements from the Commission (SEC (2008) 2036) saying that when an existing chemical substance, already placed on the market as bulk substance, is introduced on the market in a nanoform

the registration dossier will have to be updated to include specific properties of the nanoform of that substance. The required information includes different classification and labelling as well as additional risk management measures.

However, even if a substance (bulk and nanomaterial) exceeds the 1000 tonne/year limit it is far from clear that the toxicity tests have to be performed for the bulk substance as well as the nano-form. And even if a company tried to perform both tests, there is still the problem that suitable test methods for nanomaterials may not be available. There is no institutional framework to develop nano specific information requirements for a tailor made case-by-case risk assessments as requested by scientific committees such as SCENIHR[26] bearing in mind that standard risk assessment methods may not be adequate or sufficient.

Theoretically, of course, the possibility of ECHA being able to require any information on the substance if deemed necessary independent of the minimum requirements of REACH means that REACH does hold the possibility of evaluating nanomaterials. However, it is highly doubtful whether this opportunity would be extensively applied in practice.

The Commission's suggestion of using existing test methods until newer better adapted methods are developed includes a high risk of uncertainty and does not seem to be the right approach – if one takes the precautionary principle as a guideline. Here it should be mentioned that the Commission states in its conclusions that, due to high concerns, it is important that measures to handle nanomaterials are based on the precautionary principle. This seems to contradict the approaches suggested by the Commission. The Commission's comment on the importance of reviewing the implementation of REACH regarding nanosubstances with a view to modifying procedures if new knowledge becomes available also clearly bears a resemblance to a re-active approach which is not desirable.

The Commission seems to take assurance in the market surveillance for compliance with legal requirements regarding nanosusbtances/materials – an approach that holds several weaknesses. First of all, the legal requirements regarding nanomaterials are not in place (difficulties with testing methods, etc.), and secondly it is doubtful whether a market surveillance approach is sufficient to secure no nano-related risks to the consumer. Their comment on the fact that at all time authorities can verify the risk assessment at the premises of the manufacturer seems a weak proposal of a way to secure no nano-related risks to the consumer since in practise these evaluations of risk assessments at the manufacturer probably will not take place due to lack of resources.

Due to the huge uncertainties of the scientific understanding of the risks associated with nanoparticles the discussion paper by the Öko-Institute/BEUC/EEB (2008) suggests that the Ecolabel should not be given to consumer products which contain manufactured nanomaterials and structures which could be released into different environmental media. This approach relies heavily on the precautionary principle.

The information above suggests that for nanomaterials a different path is needed including elements such as the following:

[26] Scientific Committee on Emerging and Newly Identified Health Risks

- A modification of the REACH tonnage philosophy by reduction or elimination of the thresholds for registration (1 tonne), preparation of the chemical safety report (10 tonne) and specific information requirements depending on production volumes outlined in annexes VII to X.
- The need to provide exposure scenarios even if not classified as dangerous or as PBT/vPvB.
- A clear provision that separates test data has to be provided for the nanoforms of substances.
- Establishment of additional information requirements for nanomaterials including the option to provide specific data needs for certain classes of nanosubstances stipulated by an independent scientific committee and adopted by Comitology.
- Insurance that all nano registrations (not just a small fraction) are subject to a dossier and substance evaluation.

The revised REACH rules need to be complemented by provisions in product regulation including approval procedures as e.g. in the Cosmetics Directive".

One way or the other, it is important to make sure that the call for more information regarding nanomaterials does not become (as might be the case at the moment) a substitute for action.

In a conference report from the 5th International NanoRegulation Conference in 2009, the Director of DG Environment sums up the problems with nanomaterials and REACH very well (Quoted from The Innovation Society, 2010):

"REACH certainly provides the framework but it may need to be fine tuned to make sure it provides the same protection for nanomaterials as it does for ordinary chemicals. Technology and research move fast. So fast that some Member States felt the need to think of introducing their own, supplementary national rules to be sure that nanomaterials are properly managed. This would not be opportune from the point of view of the internal market."

"So, we may conclude that, with REACH, nanomaterials seem under control. But, there are important questions to be answered for nanomaterials: What falls below the threshold is a risk to health and the environment?
For standard chemicals, the tonnage threshold is generally considered appropriate. Is this equally true for nanomaterials? Or for novel materials that will likely first enter the market in small quantities?"

"The tonnage threshold is one concern. The other concern is time/calendar. The lower tonnages are only registered by 2018, 9 years from now. This is an eternity in terms of nanotechnology which was not widely known only 5 years ago. Can we afford to sit back and wait until the REACH registration deadlines have expired to find out what nanoforms are on the market?
We would like to know the risks now and whether they are controlled. Which nanomaterials are dangerous and which are not? These questions are very important. It is not only a scientific problem, but also a problem for society, for the legislators and for the confidence in these new products. Who produces nanomaterials? Where do they end up? And: Who comes in contact with them? Companies that produce nanomaterials can answer some of these questions but unfortunately nobody has a good overview at this time of development."

"REACH does have the potential to provide a good overview, but possibly too late and possibly only partially."

"One further major concern regarding REACH is that nanomaterials are not specifically mentioned in the Regulation. Therefore, companies may tend to provide only information for the bulk form and may not sufficiently clearly distinguish the nanoform with its specific properties, uses and risks".

2.4 Conclusions of review

In this section, the conclusions from the different sections are listed. The different points will be discussed in more details in chapter 3.

The overall conclusion is that the current legal framework is insufficient because very few chemical requirements in general exist for consumer products. Chemical requirements are:

- missing entirely in the General Product Safety Directive (only "products must be safe"),
- inadequate in REACH, Toy Safety Directive and ROHS (too few substances restricted or not strict enough to protect human health),
- or just related to regulations in Member States (Construction Products Directive).

Another reason for the insuffiency of the current legal framework is that the regulations do not allow to set proper limit values and to adopt them quickly by using a committee procedure (comitology) – except for the proposed revised ROHS directive and the restrictions of REACH (annex XVII). The new Toy Safety Directive only allows for this for toys for children up to 3 years of age.

Other conclusions to be mentioned from the review are:

- Weak phrases that are difficult to act on by producers/importers are used – e.g. "products must be safe" or "human health may not be endangered". Should be replaced by either specific limit values or harmonised standards that set limit values for specific substances so companies know what to act on.
- REACH has many good intentions but there is a long implementation period and procedures (e.g. for substance evaluation, authorisation restrictions) are rather slow.
- The data requirements of REACH depend primarily on the amount of substance sold and not on the hazardness of the substances.
- REACH implements almost no requirements towards content of chemicals in consumer products.
- REACH relies to a large extent on industry self-assessments.
- Market surveillance of illegal consumer products (because of hazardous chemical substances) could be much more focused and more intense to ensure that only safe products are on the market.
- The RAPEX notifications (chemical notifications) show that notifications are mainly made due to the lack of compliance with restrictions on chemical substances. Only few notifications (if any) are made due to "products must be safe". This means that loose statements do not seem to work for market surveillance either. It is much easier to handle limit values.

Furthermore, the following conclusions can be made on the present coverage of nanosubstances within REACH:

- Whilst the Commission considers the current regulatory framework sufficient to address risks relating to nanomaterials and only in need of some modifications at the implementation level, this position seems more than doubtful and is also not supported by the EU Parliament.
- REACH only requires registration for substances produced in amounts above 1 tonne per year. Not all substances and nanosubstances are therefore included. However, the parent substances of many nanosubstances have already been pre-registered – many of them in the > 1000 ton/year band.
- REACH information requirements and other provisions (e.g. preparation of a chemical safety report) rely on the tonnage philosophy which may not be appropriate for nanosubstances that can be produced in relatively small amounts.
- A nanomaterial that has a bulk counterpart will have to comply with the information requirements applicable for the sum of the nano and bulk form. For instance, if this total amount is produced in > 1000 tonnes annually the substances would, of course, be registered with the most extensive data set. In theory, the registration dossier of the bulk form of a chemical substance should include specific consideration concerning the nano form of the substance (or be updated when a nano form of an existing bulk substance is placed on the market. However, even if bulk and nano form exceed the relevant information triggers it is far from clear whether the foreseen toxicity tests have to be performed for the bulk substance as well as the nano form.
- In addition to standard information requirements, nano specific data may have to be defined in a flexible way e.g. by an independent scientific committee.
- Only a small fraction of registration dossiers will be evaluated by ECHA and the Member States. However, it is advisable that dossier and substance evaluations are carried out for all nanosubstances.
- Existing testing methods on nanosubstances may not be appropriate and will have to be adopted.
- The Commission takes assurance in market surveillance for compliance with legal requirements regarding nanosubstances/materials. However, in absence of clear-cut assessment rules the enforcement bodies will encounter difficulties in taking action.
- The REACH rules should be adapted taking into account the points above and need to be complemented by provisions in product regulation including approval procedures as e.g. in the Cosmetics Directive.

3 Identifying and discussing gaps in current legal framework

As demonstrated by the review of chemical requirements in the selected specific legislation a number of gaps exist in the current legislation. When discussing/developing an approach to cover chemical risks across all product groups, it is necessary to look at the regulation scheme from a broader perspective. Below a number of more "general" gaps are discussed in terms of consequences and potential solutions.

3.1 Limited consumer product regulation

First of all the review shows that the current European legislation framework has a very limited consumer product regulation.

- In REACH, the product regulation is reduced to the few restrictions on consumer products in Annex XVII of REACH, like restriction of phthalates in toys, PFOS and similar substances in textiles etc. The part about SVHCs in articles is only an information requirement – no restriction of SVHCs does exist.
- In the General Product Safety Directive, consumer products are regulated by the "products must be safe"-term which is difficult or nearly impossible to act on for both producers and authorities.
- Both the Toys Safety Directive and ROHS are examples of consumer product legislation. However, it can be discussed whether they are strict enough to protect human health from chemical exposure from these groups of consumer products. Too few substances are restricted and in some cases too high concentrations of dangerous substances are allowed.
- The Personal Protective Equipment Directive is also an example of consumer product legislation. However, this directive does mainly cover human safety (physical, mechanical) and hardly chemical safety.
- Finally, the Construction Products Directive also is an example of consumer product legislation. However, no chemical requirements are set and each Member State can implement further regulations. However, these do not apply to the other Member States.

3.2 Use of weak phrases instead of specific limit values

Chemical requirements are not a general feature in standards related to the General Product Safety Directive or in many other product related regulations. Instead of using specific limit values or other more "solid" requirements, many of the directives use "weak phrases" such as "the consumer product must be safe", "use less toxic substances" or "may not harm human health" etc.

This is a problem since many companies cannot handle these weak phrases because, in order to make sure that their product complies with the phrase "being safe for the consumer", they would have to carry out a risk assessment

(including exposure scenarious related to the specific product) of each of the chemical substances in the product. This would require very specific chemical and toxicological qualifications by the employees at the company – qualifications which they probably do not have, especially within the small and medium sized companies.

However, this is also a problem for the authorities as they have to prove that a chemical is dangerous for health or the environment before they can take action. This process is very resource demanding as the authorities need to carry out a comprehensive risk assessment.

Thus, the result is no action at all (or at least very limited action by both companies and the authorities because of e.g. lack of resources or competences). However, by introducing specific limit values both companies and authorities would be able to take (much easier) actions towards complying with the directives – i.e. testing the product for content of the substance in question and comparing to the limit values.

Another argument supporting the use of limit values is the fact that a number of non-compliances related to exceeding limit values are reported through the RAPEX system whereas very few (if any) RAPEX alerts have been seen related to non-compliance with the "the product must be safe" phrase; the latter probably because it is difficult to check whether the product complies or not.

3.3 Ad-hoc based regulation

It seems that the majority of regulations regarding chemicals are based on an ad-hoc approach meaning that chemicals are only regulated when they have proven to cause problems.

The term have proven covers situations in which a substance is being identified as hazardous based on observed human-health effects (as for instance severe allergic reactions to hair dyes). However, the term also covers situations in which toxicological studies (somewhere in the world) have indicated that a substance might possess problematic properties. These studies then result in regulation of the substance in question.

Examples of ad-hoc based regulations are phthalates in PVC plastics, bisphenol A in polycarbonate plastic, and dimethylfumarate in furniture (consumer articles).

It is difficult to unravel exactly how these regulations begin to take shape but it is assumed that they typically arise from "sudden concerns" related to the specific chemical. Someone starts investigating the substances and then more and more studies show "unwanted" effects that finally, after many years, results in a regulation (as in the case of the phthalates) or in the case of dimethylfumerate where people suffer health problems before action is taking.

This ad-hoc approach towards regulating chemicals is a problem mainly due to the fact that it is a re-active approach. Re-active approaches are not the optimal solution for regulating chemicals since they require "accidents" or "chance discovery" before we can act/create regulations – but the aim is to ensure "no accidents" related to chemical exposure.

Thus, one of the great challenges is to move the regulation scheme away from the re-active/ad-hoc approach and towards a more pro-active approach.

At the moment, we only regulate substances when we have sufficient toxicological information (= reverse precautionary principle). This could be interpreted as a re-active approach – though, a re-active approach that in time (as REACH is implemented) slowly ensures a higher safety for the consumers. However, even when REACH is fully implemented, there will still be numerous gaps in the knowledge of the chemical substances which is not desirable – and products will not necessarily be safer.

If this should be transformed into a pro-active approach, the precautionary principle should be 'activated' and we should regulate/ban substances we do not have enough toxicological information about ('guilty until proven otherwise'). However, this solution seems not practical since it instantly would remove a large amount of products from the market.

One way or the other, it is, however, important to deviate from this ad-hoc based regulation we experience today.

3.4 Only a small number of products/chemicals covered by regulations

One of the other obvious major gaps in our present legislation on chemicals in consumer products is the fact that existing regulations only cover a small part of the number of products/chemicals on the market.

One way or the other, the goal must be to control/regulate all dangerous substances in all consumer products.

The approach so far has been to regulate certain/specific substances (when they have been found to cause problems) in certain/specific products/product groups. The procedure of creating these regulations often takes several years and requires a large amount of toxicological information as well as man-hours. Given the appropriate time (and toxicological information), this approach, however, does increase the safety of the consumer (move us in the optimal direction, i.e. covering more chemicals in more products) – though, the question is whether this approach is the best and fastest way towards the goal.

So far, the approach seems to have the following limitations:

- Ad-hoc based, meaning "accidents" must happen before a substance is regulated.
- Requires large amounts of toxicological information, which will not be available for many years to come.
- Requires unrealistically many years of work/man-hours until the goal is reached (all dangerous substances regulated in all product groups).
- Does not cover new products that do not fall under existing product groups (as new specific regulation needs to be developed related to the new product group).
- A product may have to comply with many different, separate legislations regarding chemicals (for instance, a toy with electrical components must comply with chemical requirements in the Toy directive as well as the RoHS directive). Thus, companies must be able to manage a large amount of different legislation. This requires a

lot of resources which is often a problem, especially in small/medium sized companies.

It could be considered whether a more holistic/horizontal approach would be more appropriate, an approach that would not include the limitations mentioned above.

Of course, the general product safety directive does cover all products in a somewhat holistic way, but the chemical requirements are almost non-existing and the use of "weak phrases" such as 'the consumer products must be safe' makes the directive useless in terms of securing no chemical risks for the consumers; one reason being that it is impossible for the producers to comply with the phrase "safe" without having limit values to lean against. They simply do not know how to handle this (especially SMEs).

3.5 Insufficient market surveillance of consumer products

A common position paper from ANEC and Orgalime calls for a more effective pan-European market surveillance system. A system that, among other things, should make sure that cheaters do not take advantage of the scattered national enforcement of European legislation (ANEC and Orgalime, 2009).

As the position paper points out it is important to have harmonized effective surveillance systems related to secure compliance with the different regulations. However, in order to have effective market surveillance systems, the regulatives behind must be designed in such a way that they support surveillance. This once again stresses the uselessness of the "weak phrases" within the General Product Safety Directive and supports the idea of implementing limit values (which can be easier "checked" for compliance).

Conversely, it is important that market surveillance also feeds rule making by reporting back with information about which chemicals that are identified in specific products to enable limit setting for these. This is, as mentioned, pointed out in the new Toy Safety Directive: the occurrence of chemicals in toys should be monitored and evaluated. However, it is not specified what the consequence should be. To ensure that the existing knowledge of dangerous chemicals in consumer products always is used to the advantage of the consumer, the consequence should be that additional limits are established in case of chemicals of concern. The feedback loop should be part of a systematic evaluation programme involving also other sources of information.

3.6 Life cycle aspects not considered

There is a wide agreement that the whole life cycle of a product/chemical should be taken into account when assessing its environmental and human effects. However, performing an LCA of a chemical is not an easy task and requires large amounts of information and ressources. Implementing a kind of consideration towards life cycle aspects seems more appropriate. Indeed, LCA is not the tool to address chemicals – much more development is needed in this field.

When using life cycle thinking other issues emerge, like e.g.:

- Are hazardous substances used in the production of the substance considered?
- Are hazardous substances released or formed during incineration, recycling or other waste treatment? (We may very well not be exposed to the hazardous substances when we use the consumer products but we can be exposed via the environment during/after waste treatment).
- Are hazardous degradation products formed in the environment?
- Are hazardous substances formed during metabolism in the human body?

The current legal framework does not include considerations towards life cycle thinking:

- The General Product Safety Directive, the (new) Toy Safety Directive and the Personal Protection Equipment Directive address only health and safety issues of the consumers/users and ignore environmental issues as well as other life cycle stages.
- The Construction Products Directive (as well as Construction Products Regulation) only addresses the immediate environment of buildings.
- ROHS seeks to address both health and the environment and includes not only use, but also disposal/recovery – thus, a slight element of life cycle thinking is included here. However, production and earlier stages of the life cycle of the products are not considered.
- REACH addresses some stages of the life cycle by looking at the properties of the chemicals and forcing producers to think about the exposure of the chemicals in use (exposure scenarios). However, REACH has many gaps – in particular with respect to products, but also that exposure scenarios are not carried out for all chemicals. Furthermore, chemicals used in the production outside of Europe are not relevant and all environmental impacts not related to the impacts of a particular chemical are outside the scope (e.g. depletion of resource, energy consumption, and emissions during raw material acquisition and production, transportation of chemicals).

However, it seems outside the scope of any chemical regulation and an impossible task to cover all life cycle aspects of a chemical. Perhaps in the field of eco-label issues like green chemistry – e.g. production of chemicals from renewable resources – this could be an issue. On the other hand, this aspect should not be forgotten and should be considered when designing a new framework for chemicals in Europe striving for more completeness.

3.7 Multiple exposures not considered in all cases

In the discussion of toxic and hazardous substances, it should be mentioned that in principle all substances are hazardous – it is only a question about how large a dose that is needed for a toxic effect. However, in this report, when the phrases “hazardous substances” and “toxic substances” are used, this refers to the substances that are classified as hazardous, i.e. the substances that are hazardous in relatively small amounts.

When performing a risk assessment of a product, it is important to consider the following issues:

- Type of exposure (exposure pathway)
- Duration of exposure

- Toxicity of the substances (all chemicals are hazardous – it is a matter of the dosis)
- Dose/concentration of the substances

Today risk assessment is carried out on a substance basis – a chemical-by-chemical basis. An issue that often is not included in risk assessments of chemicals (in e.g. consumer products) is multiple exposure to a single chemical, i.e. is the consumer exposed to the same chemical from different sources?

These multiple exposures have to be added in order to calculate the total daily exposure to a specific substance. However, the typical method in risk assessment of a product is to include only the specific substance in question because the "background exposure" from all other sources most often is unknown (except for e.g. heavy metals where some background exposure is known via food, the environment etc.).

If for example a risk assessment is carried out on the content of a specific phthalate in e.g. an eraser (due to concerns related to children chewing on the eraser when doing their homework), then the risk assessment normally is carried out as a single exposure situation – "chewing on an eraser". In the example mentioned in Annex 1 to this report "Erasers (2007) – Danish EPA", this was the case. However, also other exposures of the same phthalate measured in other products in this investigation were included. Thus, this example took into account exposures from schoolbags and pencil cases as well. However, as the many examples shown in Annex 1 demonstrate, phthalates are also found in many other children products, textile prints, children tooth brushes, ski mittens, jackets, bed linen, football T-shirts, plastic shoes, balloons, game console components, different construction products, and in our indoor environment. In order to calculate the real risk, all these exposures should be added, as the project "The exposure of two-year-olds to chemical substances. Survey of chemical substances in consumer products" from Tønning et al. is an example of (also described in details in Annex 1 to this report). This report showed that when taking multiple exposures into consideration, an obvious risk arose – related to children being exposed to large amounts of phtalates. (The report also took into account multiple exposures to different chemicals with the same effect – discussed in the Section "Combination effects" below).

In the existing chemical legislation, there are no clear explicit rules consistently embedded for setting limit values and it is therefore a judgement of the individual risk assessor whether and to which extent multiple exposures are taken into account. In case of bans this is, however, not relevant as the limit normally is set at the level of detection.

In the many thousand pages of REACH guidance documents, the combined uptake of chemicals is only mentioned briefly. It is stated in "Guidance on information requirements and chemical safety assessment. Chapter R.15: Consumer exposure estimation" (ECHA, 2008a) that combined uptake can be considered. It is stated that "if a consumer is exposed to a substance in a particular consumer product via different routes (oral, inhalation and by skin), or if the same substance is present in several consumer products that are likely to be used in combination, the contribution of each route or product to the total risk due to exposure can be summed". This is a bit more elaborated in "Guidance on information requirements and chemical safety assessment. Part

E: Risk characterisation" (ECHA, 2008b). However, only the part about exposure via various routes (oral, inhalation and by skin) is elaborated. In the new 2010 version of the Chapter R.15 guidance (ECHA, 2010), the mentioning of combined exposure via different consumer products has been deleted entirely. To conclude, the REACH Guidance documents state that multiple exposures can be considered – not must be considered – and it is not mentioned how exactly it should be considered.

The harmonised standard for toys EN71-3 "Migration of certain elements" is one of the few examples where multiple exposure to the heavy metals is taken into account. The migration limit value for the eight metals listed in the standard is based on the bioavailability limits given in the Directive (1988) which constituted a specific percentage of the total daily exposure value and, in fact, also of the TDI (tolerable daily intake) value (typically 5 or 10%).

A somewhat different approach has been used in the new Toy Safety Directive. Here, a certain percentage of the TDI value was used for the different migration limits (can be found in RIVM, 2006). The new Toy Safety Directive operates instead of one migration limit value with three different migration limit values:

- Scraped off material
- Dry, brittle, powder-like or pliable material
- Liquid or sticky material

As the RIVM report operates with different amounts of toys that a child is exposed to for the three different cases, the migration limit values hence differ. As a result, some of the limit values have worsened for some of the heavy metals.

Hence, the important point is that any chemical legislation should take multiple exposures into account like what is done for the Toy Safety Directives.

3.8 Combination effects

Another issue is the combination effects of chemicals. As mentioned in the box below, combination effects are the combined effect of different chemicals – where the effects of the chemicals combined can be greater than the sum of the individual effects.

In this area – combination effects related to exposure from several different chemicals – the knowledge gab is huge. During the last few years, more and more surveys/tests have shown that exposure to different chemicals in small amounts cause higher effects than it is expected of the individual substances alone (Christiansen et al, 2009; Kortenkamp et al., 2009). This is colloquially called "the combination effect" or "the cocktail effect", and is sometimes being ranked alongside synergistic effects in the media (i.e. when the word cocktail effect or combination effect is used in the media, it is used with the meaning of the chemicals have synergistic effects).

Definitions:

We see combination effects or cocktail effects (as the popular title) as the overall description of the effects different chemicals may have, when consumers are exposed to different chemicals at the same time. The combination effect may then be additive, synergistic or antagonistic.

Combination effects (or cocktail effects)

- A combined effect of two or more substances or organisms which is greater than the sum of the individual effect of each (Eionet).
- The response of a biological system to several chemicals, either after simultaneous or sequential exposure (Danish EPA, 2009). Note that this does not necessarily indicate a synergistic effect.

Additive effects

- An effect in which two substances or actions used in combination produce a total effect the same as the sum of the individual effects. (The Free Dictionary, Your Dictionary).
- Additive effect is the overall biological effect two chemicals acting together and which is the simple sum of the effects of the chemicals acting independently (Biology online).

Synergistic effects

- A violation of value-additivity in that the value of a combination is greater than the sum of the individual values. (The Free Dictionary).
- Acting together, enhancing the effect of another force or agent (Biology online).
- A state in which the combined effect of two or more substances is greater than the sum of the separate effects. An effect whereby two toxic substances together have more of an impact than anticipated (Eionet).

Antagonistic effects

- This is the consequence of one chemical (or group of chemicals) counteracting the effects of another chemical, the opposing chemicals cancel out each other's effects (Biology online).
- The situation in which two chemicals upon interaction interfere in such a way that the action of one partially or completely inhibits the effects of the other (Eionet)

An expert workshop on combination effects of chemicals was held in Denmark in January 2009 with participation of 15 experts in this area from the USA, Holland, Germany, UK, Sweden, Finland (ECHA) and Denmark (Danish EPA, 2009). The conclusion of the workshop was that:

- There is evidence that the uncertainty factors generally used today in risk assessment may lead to underestimation of risks. Therefore, the applied uncertainty factors offer insufficient room to allow for combination effects for all possible realistic mixtures of chemicals.
- A specific "mixture assessment factor" is currently not employed in the traditional chemical-by-chemical risk assessment and there is little to suggest that commonly used uncertainty factors are overly protective.
- A disregard of the combination effects was considered undesirable and not in line with currently available empirical evidence.
- The application of dose addition is recommended as a default until evidence to the contrary appears. Dose addition is based on the idea that all chemicals act as if they are dilutions of one another with an identical mechanism of action (= result in the same toxic effect). However, the different chemicals may differ in their relative toxicity. This should be taken into consideration by performing cumulative risk assessment.
- To alleviate concerns about combination effects, it would be possible to adopt a specific assessment factor (an extra uncertainty factor) in the traditional chemical-by-chemical risk assessment, even without further data.
- More information about combination effects of endocrine disrupters is required. Today, the data gap is large.

- In REACH, cumulative risk assessment for multiple chemicals from multiple sources, routes, and pathways is only addressed to a very limited extent in the current guidance. Other relevant European legislation does not contain a mandate for cumulative risk assessment for multiple chemicals from multiple sources, routes, and pathways.

A recently published report in Denmark "Survey and health assessment of the exposure of 2-year-olds to chemical substances in consumer products", which has been commissioned by the Danish EPA, has looked at the overall chemical exposure to endocrine disrupting chemicals for children at the age of two (Tønning et al, 2009). The age of two has been chosen as the primary target group as children of this age use consumer products like older children but still put everything in their mouth. The study has looked at all consumer products that two-year-olds are in contact with during a day and have used a cumulative risk assessment where dose addition has been assumed. The results show that, as a worst case, the total exposure of many different endocrine disruptors like PCB, parabens, phthalates, pesticides etc., is definitely a risk of endocrine disrupting effects. The main exposure is due to pesticides residues in food, PCB's and phthalates in the indoor environment and parabens in cosmetics. This study is the first of its kind (looking at combined exposure and multiple exposures of chemicals from consumer products) commissioned by the Danish EPA in Denmark.

The study supports the importance of taking additive effects into account when evaluating chemicals risks to the consumers.

A newly published report commissioned by DG Environment of the European Commission supports this viewpoint. The conclusion from this report (Kortenkamp et al., 2009) is that the EU can and should assess and manage the risks from exposure to chemical mixtures (better known as the "cocktail effects") in order to avoid underestimation of risks that might occur under the current paradigm of considering substances on a chemical-by-chemical basis.

The report has investigated the toxicity of mixtures of chemicals after simultaneous exposure and how risk assessment should be carried out on this mixture of chemicals in order to account for combination effects. Other conclusions from the report, which are very similar to the conclusions from the expert workshop mentioned above, are:

- There is strong evidence that chemicals with common specific modes of action (= result in the same toxic effect) work together to produce combination effects that are larger than the effects of each mixture component applied singly.
- There is consensus in the field of mixture toxicology that the customary chemical-by-chemical approach to risk assessment might be too simplistic. It is in danger of underestimating the risk of chemicals to human health and to the environment.
- Mixture effects cannot be ruled out even when all components of a mixture of substances with diverse modes of action (= result in different toxic effects) are present at their individual NOAELs (= No Observed Adverse Effect Levels estimated for a single chemical exposure).
- The currently available scientific evidence as well as pragmatic considerations support the idea of adopting dose (concentration)

addition as the preliminary default concept for the assessment and prediction of mixture effects.

- Therefore, a future European guideline for the assessment of chemical mixtures should go beyond the reach of currently existing regulatory approaches and should extend its scope to the protection of ecosystem structure and function from the detrimental effects of chemical mixtures.

Furthermore, the report states that one thing is the simultaneous exposure to mixture of chemicals – this seems to be possible to predict by using the dose (concentration) addition method – another issue is the toxic effects of mixture of chemicals already present in human tissues. Unfortunately, there are still considerable knowledge gaps concerning the mixture of chemicals present in human tissue.

Kortenkamp et al. (2009) also looked at how the existing EU regulations take this mixture toxicology into account. They conclude that assessments of cumulative risks to humans and the environment resulting from simultaneous or sequential exposure to multiple chemicals from different sources via multiple routes are non-existing in today's European legislation. But when looking at mixture toxicity alone, REACH and CLP take this into account to some extent. The classification regulation (CLP) of course states how chemical mixture should be classified, and REACH – although mainly focusing on individual chemicals – provides guidance on how substances that are mixtures (such as petroleum products) are to be assessed for their PBT/vPvB properties.

3.9 Lack of information on chemicals in consumer products

In general, there is a lack of information about chemicals in consumer products. This lack of information can be split up in two different areas that will be discussed in details below:

1. We do not know of the dangerous properties of all 143.000 chemicals.
2. We may very well know which dangerous chemicals that are typically present in specific types of consumer products but the overall picture of chemicals in consumer products is not known.

Today, we only have profound toxicological and ecotoxicological knowledge of very few of the 143,000 chemicals that exists in total[27]. Of course, this will change when REACH is fully implemented – then we should know more about the toxicological and ecotoxicological properties of the chemicals used in the largest quantities. Furthermore, we should be closer to a more "exact" classification of the substances – or that is at least the intention of REACH. Today, we experience irregularities in classification of the substances as different producers may classify the same substances in different ways. Of course, this is due to a lack of toxicological and ecotoxicological information about the chemicals. However, even though REACH should ensure more knowledge of toxicological and ecotoxicological effects of chemicals, comprehensive information will probably only be gathered for less than one third of the 143,000 substances as only the substances in the highest tonnage

[27] About 143,000 chemicals in total have been pre-registered at ECHA. http://apps.echa.europa.eu/preregistered/pre-registered-sub.aspx#whatisthislistheader

band require a complete technical dossier with all information (as discussed under the review section about REACH). This means that for two thirds of the substances we will not necessarily know of the carcinogenic effects, the long-term repeated dose effects, or the developmental toxic effects as these tests only have to be carried out for the largest tonnage band (Williams et al, 2009).

This actually means that we do not know of all the dangerous substances that can be present in consumer products today, simply because our knowledge of which substances that are dangerous is not complete today. Hopefully, this will change in the future with the implementation of REACH but as mentioned above, the information will still not be complete for all existing chemicals.

Secondly, our knowledge of which chemicals that are present in consumer products is not complete. We know of specific issues (ad hoc issues) like phthalates in PVC plastics, bisphenol A in polycarbonate plastic, and parabens in cosmetics, because these issues have submerged to the surface when enough toxicological information has been gathered and has shown the negative health effects. However, the total picture of problematic chemicals in consumer products is not complete.

This is mainly due to lack of legislation in the area. Producers are not obliged to and do not give information about the content of different substances in consumer products. Importers, distributors, and retailers do not know of the chemicals in the consumer products and the only way to find out is by performing chemical analysis of the products. These chemical analyses are expensive and especially expensive, when you do not know what to look for. Most often, chemical analyses are carried out in order to check that products comply with different limit values set by legislation, such as phthalates in toys – hence information about dangerous chemicals in consumer products seems to be identified mostly "by chance" when market monitoring (that only covers a very little part of the market) is carried out in the different EU countries.

However, due to the implementation of REACH, it has been an obligation within the EU since October 2008 to inform down the product chain when chemicals on the SVHC list are present in articles in concentrations above 0.1%. However, it is a problem (especially during the first years of REACH) to know if the missing information from the supplier of the content of SVHCs above 0.1% means that no SVHCs are present in the article or that the supplier does not know of their obligation to inform. Another problem is that the importers of articles into the EU will have difficulty in obtaining the information about the chemicals in the articles from his supplier as there is no obligation for his suppliers to provide such information.

Under the auspices of UNEP Chemicals, activities that relate to information on chemicals in products are ongoing. In 2006, a policy framework called Strategic Approach to International Chemicals Management (SAICM)[28] was adopted under UNEP. One of the objectives set out by SAICM is "to ensure for all stakeholders, that information on chemicals throughout their life cycle, including where appropriate, chemicals in products, is available, accessible, user friendly, adequate and appropriate to the needs of all stakeholders. Appropriate types of information include their effects on human health and the environment,

[28] http://www.saicm.org/index.php?ql=h&content=home

their intrinsic properties, their potential uses, their protective measures and regulation." (UNEP, 2009).

In February 2009, an informal workshop on stakeholders' information needs on chemicals in articles/products was held. The primary conclusion of this workshop was that current efforts and capacities to provide information about chemicals in articles/products and alternatives are not sufficient for informed decision making to protect human health and the environment throughout the life-cycle of articles/products. During the workshop, different groups discussed this issue and came up with the following remarks:

- Information exchange is a key factor to enabling actors to avoid hazardous chemicals and to manage risks to users and the environment.
- Traders in articles do not know the chemical content of their articles. A system is needed whereby purchasers/retailers can be given adequate information on request from manufacturers.
- There is a need to elaborate guidance on how information on chemicals in articles should be provided.
- Global action is necessary – among other things in the form of globally harmonized systems.
- No structured proactive information sources exist – thus information is produced on a reactive basis.
- Detailed Material Safety Data sheets (MSDS) are a main source for individual chemicals but the information stops at article production.
- Need to develop a safety data sheet for articles – a so-called Product Declaration Form. This may include relevant chemicals content, relevant risks etc.
- There is the need for a global system of information exchange on chemicals in articles, bearing in mind the entire supply chain.
- Need of a comprehensive list of articles that should be covered. REACH does not cover this adequately.
- Need of prioritizing chemicals to include. How? Important to focus on SVHC.

This UNEP initiative addresses the exposure of dangerous chemicals in a different way. Of course, one way is to ban all dangerous chemicals in consumer products – the other way is, as presented here, to ensure more information about the chemicals in consumer products with a kind of MSDS for articles. The latter should enable the consumers to be able to make an informative choice between products based on the content of chemicals. However, this requires that the typical consumer has a high knowledge of impacts related to different chemicals which cannot be assumed to be likely. The burden to shift the decision on choosing which chemicals that are allowed in a consumer product should not lie on the consumer, but on authorities.

It is necessary to know more about chemicals in consumer products in order to limit the use of dangerous chemicals in consumer products, but a MSDS for consumer products may not be very helpful for consumers – the best way (from a consumer viewpoint) will be to ensure that dangerous substances simply are not present in consumer products so that consumers do not have to have a high knowledge about chemicals. However, it may be necessary in the beginning to make use of both methods and implement it in legislation:

- Implement a kind of MSDS for articles on a world wide basis.
- Increase restriction of dangerous chemical substances in articles.

3.10 Nanosubstances currently not regulated properly

The present "coverage" of nanosubstances in REACH has been discussed thoroughly in section 2.3 "Review of present "coverage" of nanosubstances" and will not be discussed in details here once again.

In section 2.2, the shortcomings of product regulation to adequately address chemical hazards have been highlighted. Of course, these deficiencies also apply to nanosubstances. The investigated legislation also does not contain any nano specific provision.

Up to now the only European law that incorporates requirements regarding nanomaterials is the Cosmetics Regulation (1223/2009). It contains an obligation of economic operators to notify the Commission of any nanomaterial present in cosmetics prior to it's placing on the market allowing the Commission at any time to consult the relevant scientific committee (Scientific Committee on Consumer Safety - SCC) and – based on its opinion - propose restrictions. Further, all ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets. The Commission shall also publish a catalogue of all nanomaterials used in cosmetic products placed on the market. Colorants, preservatives, and UV filters are subject of approval procedures (positive list approach). Hence, nanomaterials used for these purposes are subject of a pre-market evaluation (even if the bulk form is already approved).

The new Cosmetics Regulation is a very important reference point for future nano specific provisions in other product regulation.

A recent example of nanosilver in textile consumer products shows that nanoparticles in consumer products can be released to human sweat (se Annex 1 to this report for a more detailed description). Therefore, it is important that we know of the effects of nanosubstances and that the nanosubstances are regulated on equal terms as their bulk counterparts.

3.11 Limitations in the regulatory frame

As discussed in the review, one thing is the generally missing chemical requirements in the existing legislation. Another thing is that the limitations in the regulatory framework do not allow for adding new chemical requirements such as limit values or changing existing ones quickly by using a committee procedure (comitology) – except for:

- The restrictions of REACH (annex XVII) where new substances can be restricted by adding them to the annex.
- The proposed revised ROHS directive, where new substances can be restricted (Annex IV) and new substances can be proposed for restrictions ("priority list – Annex III).
- The new Toy Safety Directive, but this is only the case for toys for children up to 3 years of age – not for toys in general.

In the other directives mentioned (General Product Safety Directive, Personal Protection Equipment Directive, and Construction Products Directive/Regulation) the only way to add chemical requirements will be to

change the directives, which is a very long process. In case of the Construction Products Directive/Regulation, only declaration requirements are possible but no restrictions.

The Energy Related Products Directive does have a committee procedure, but no chemical requirements are set. Only requirements with respect to energy are set.

4 Establishing a horizontal approach to cover chemical risks across all product groups

Based on the previous discussion, this section aims at suggesting a horizontal approach to cover chemical risks across all product groups.

The development and implementation of a horizontal approach for chemicals in products seems all the more urgently needed as a study by the Danish EPA has shown (by using QSAR models) that approximately 30,000 chemicals ought to be classified as hazardous, as opposed to the 7000 that today are classified as hazardous (Niemelä et al, 2009). This huge number makes it nearly impossible to set specific limit values for all hazardous chemicals used in consumer products and underlines the need for a horizontal approach, in which general requirements would be set for groups of chemicals (e.g. carcinogenic) instead of specific requirements for each individual chemical.

In order to develop this horizontal approach, it is necessary to discuss a wide range of possible solutions – solutions regarding the "location" of the new "horizontal approach" within the existing legal framework and solutions regarding which chemicals should be regulated (and how). The following discussion is thus split into the subsequent two parts:

- A discussion of possible "locations" of the horizontal approach within the existing legal framework.
- A discussion of the chemicals that should be covered by the "horizontal approach".

4.1 Legislation framework

As mentioned previously, the purpose of this project has been to suggest a horizontal approach to cover chemical risks across all product groups. The following options could be possible solutions as regards to the "location" of the horizontal approach and these will be discussed in more details below:

- Expanding the existing directives to cover chemicals.
- Establishing specific chemical legislation for all specific sectors.
- Establishing a new horizontal directive for chemicals in products.
- Extending REACH to cover products better.
- Expanding the ERP directive to cover chemicals and all products.

4.1.1 Expanding the existing directives to cover chemicals

An obvious solution could be to expand all the directives related to products with chemical requirements. However, this option is first of all contrary to the idea of a horizontal approach and in many of the existing directives there may be a problem with lack of chemical competence within the administrative framework in charge of the different directives. Thus, implementing chemical requirements in these directives may not have the desired effect.

Secondly, existing product legislation is limited in scope (e.g. addresses only safety aspects). Hence, chemical aspects outside this scope would have to be covered elsewhere. The establishment of chemical restrictions or provisions relating to the release of substances to the indoor air would not be compatible with the basic concepts of the Construction Products Directive/Regulation.

Finally, there are a lot of directives. In order to change them all, enormous resources would be required and the process would probably take many years to complete. The directives would also have to be changed drastically in order to be able to allow for future changes when e.g. new knowledge becomes available within the area of chemicals. For instance, all the directives would need to have a committee procedure (comitology) in place so the necessary chemical changes can be made, when needed. Bearing this in mind, it seems like changing all the directives is not the optimal solution since this would be too comprehensive a task.

4.1.2 Establishing specific chemical legislation for all specific sectors

Another option could be to establish specific chemical legislation for a specific sector which complements other existing legislation for that sector – like for instance ROHS. The advantage would be that the chemical requirements could be tailored to that specific sector. Of course, the option would need to have a committee procedure in place, like the new ROHS proposal, that ensures that new chemical requirements could be established if needed and when needed. As in case of expanding the existing directives, the key problem is that product specific legislation runs counter to or at least does not facilitate horizontal approaches.

The clear disadvantage would be – as for the option of expanding all existing directives - that too many resources would be required to create the necessary number of specific directives.

4.1.3 Establishing a new horizontal directive for chemicals in products

Another option could be to establish a new horizontal directive for chemicals in products. The directive should be a broad directive that covers in principle all products (unless specifically excluded) addressing the human health and environmental dimension. Chemical requirements could be set for groups of chemicals in general (e.g. ban of CMR substances) for some or all kinds of products or specific requirements (limits for specific chemicals) for particular products. Such a chemical products directive could use some of the structural elements given in the EUP/ERP Directive (comitology, consultation forum, general and product specific research projects and implementing measures). This would also allow for systematic screening and assessment of chemicals in particular product groups. To ensure that product specific expertise (also related to production technology, performance characteristics, etc.) is available one should also consider the setting up of product specific experts groups (as in case of the EU Ecolabel).

The advantage of a chemical products directive – contrary to the first option – would be that the required chemical expertise is present in the development, maintenance and enforcement of the legislation. It may also be beneficial that only one authority would be in charge of its implementation.

A serious problem with this approach is that such regulation would be entirely new and, most likely, resistance to its adaption might be quite substantial.

Another disadvantage would be that the directive would be focusing on chemicals – other environmental aspects related to products would have to be covered elsewhere.

4.1.4 Extending REACH to cover products better

Another obvious solution could be to extend REACH to cover products better or more appropriately. Instead of merely having information requirements in articles (consumer products), REACH should be extended to set chemical requirements for articles too. This could somehow be linked to the SVHC definition of chemicals, but could/should also include other dangerous chemicals.

This solution would be beneficial in the way that all chemical regulations would be joined in just one regulation and would be placed where restrictions of chemical substances in products (annex XVII) already exist, and – equal importantly - where the adminstrative framework has the required competences to evaluate risks related to chemicals. This solution would also cause any changes in restrictions of chemicals to be performed only once (and at the same place).

However, the question is whether this would be a practical solution. REACH has already turned out to be much more comprehensive than anticipated. Including chemical requirements for products would put an additional burden on the REACH system, a burden it may not be able to handle.

Secondly, it does not seem likely that there is willingness to make major changes in the REACH system. And major changes would be needed to timely and adequately address the product dimension and to incorporate all the elements including more horizontal approaches such as bans of SVHC substances for one or more product groups, product or sector specific concepts like indoor air schemes, provisions for exceptions, systematic evaluations of chemicals per product group and chemicals in products databases, positive list approaches, requirements for technical documentation, product specific experts groups, assessment of technical needs and substitution options, stakeholder involvement, etc.

Finally, the same disadvantages apply for this option as for the option related to the horizontal directive for chemicals mentioned above – that other environmental aspects would not be covered.

4.1.5 Expanding the ERP directive to cover chemicals and all products

Another option could be to expand the ERP directive to cover chemicals and all products. In fact, it was already planned by DG Environment to expand the former Energy Using Products Directive to cover all products and all environmental dimensions. However, this was dismissed because of pressure

by DG Enterprise[29] and the result was a slight expansion from "energy using products" to "energy related products".

To build upon the already existing idea to broaden the directive and to cover chemical aspects as well seems a promising approach, the more so as recital 39 paves the way: "The Commission should, on the basis of the experience gained from applying this Directive, Directive 2005/32/EC and implementing measures, review the operation, methods and effectiveness of this Directive and assess the appropriateness of extending its scope beyond energy-related products. Within that review, the Commission should consult Member States' representatives as well as concerned interested parties". This would result in both chemicals and other environmental aspects, such as energy, being covered in one single directive.

One huge advantage of this approach would be that the approach is already executed within the field of eco-labelling, where environmental aspects and chemical aspects are covered side by side. This would bring around the possibility of dealing with baseline criteria in European legislation and higher levels of criteria in the field of eco-labelling – however based on the same principles. Thus synergies could be used to establish both sets of requirements in a resource efficient manner, perhaps even by using similar structures (experts groups).

This last option seems to represent the best possibility for combining a horizontal approach for chemical and other environmental aspects with a product specific dimension. However, it is an option that requires significant changes of the existing legislation but this would be the case for any option chosen anyway.

4.2 Chemical framework

Above we discussed how and where the chemical restrictions could be implemented. In this section, we discuss the content/framework of the "chemical restriction" itself.

Generally, there are three options regarding the chemical framework.

- The use of positive lists (that today is used within the area of additives allowed in food),
- The use of negative lists (that is generally the practice in legislation today), or
- A combination of the above (which is used in the legislation for cosmetic products).

No matter the option chosen for the chemical framework, the following issues also have to be addressed (due to the fact that "all chemicals are poisonous it is only a matter of the dose required"):

- The level of strictness – which type of chemicals should be restricted?
    - Which chemical toxicological properties should be excluded or
    - Which chemical toxicological properties should be allowed?
- The concentration level
    - Which levels/concentrations should be allowed in the consumer products?

[29] Information from personal communication with Franz Fiala, The Consumer Council at the Austrian Standards Institute.

- Framework
    - How should the chemical framework be incorporated in the legal framework?
        - Is there a need for product specific requirements?
        - Is there a need for allowing exemptions?
        - Is there a need for information/declaration requirements?

These options are discussed in more details below. The types of chemical that should be restricted are discussed together with the concentration level as these two subjects are somewhat connected.

4.2.1 Framework

First of all, the overall ideas to the chemical framework are discussed.

4.2.1.1 Use of a positive list

A positive list in a regulatory context refers to a list of chemicals, of which all necessary information for a chemical safety assessment is present (toxicological data, exposure routes, etc.) and which has been evaluated by an independent scientific committee. Only substances, which – bearing in mind the intended application – have been found acceptable are included in the list with or without additional restrictions (limits).

Use of a positive list would by far be the best approach seen from an idealistic health perspective. The consumers would not be exposed to any dangerous substances through consumer products and the consumer would never have to make decisions about which consumer product to buy as one product would be equally safe as another similar product.

Moreover, from the viewpoint of the producer, there would be no doubt about what kind of chemicals he would be allowed to use and it would be very easy for authorities to monitor and check if the legislation is followed or not. Furthermore, this approach takes the precautionary principle into account. Only substances that we know are safe would be allowed to use in consumer products.

Of course, the major disadvantage is that we today do not know of all the dangerous properties of all chemicals, thus the positive list would be rather limited at the time being. Even though REACH will be fully implemented by 2018, there are still many years to go until we have sufficient amount of toxicological data as REACH fully implemented do not ensure a knowledge of all toxicological data on all registered substances. However, this approach could be used for certain substances in certain articles. For instance, it would be quite beneficial to make use of positive lists in case of flame retardants. The concern that these substances – often not properly evaluated and subject of criticism - do harm, has blocked the setting of flammability requirements based on the philosophy that no flammability requirements mean no flame retardants. In addition, the problem is that the flame retardants have to be fit for the purpose, i.e. in case of garments they must not be washed out. A positive list could also take care of ensuring the continued functionality of the chemicals used (otherwise a costly and time consuming wash out test will be required).

Even though this approach of using a positive list may be appealing, it does, however, not seem to be realistic for many years to come – at least not for a wide range of products. It was difficult enough to introduce the "burden of proof lies with the producers" with REACH and one can imagine huge resistance from the industry if this burden of proof was to be expanded to consumer products as well in the form of positive lists (even though some consumer products may already be included in the exposure scenarios prepared by REACH today – e.g. spray paint).

If the positive list approach was to be introduced in the future, it is, however, obvious that this list should be linked to REACH and the resulting classifications in the CLP regulation somehow.

Hence, the idea of using a positive list will not be discussed further in this report but it should be noted that it ought to be taken into consideration in future chemical legislation.

4.2.1.2 Use of a negative list

The present way of regulating chemicals is by use of negative lists – listing categories of chemicals that are not allowed to be used or only allowed under certain conditions. From a consumer point of view, the use of negative lists does, however, not take the precautionary principle into account as substances we know nothing about today are allowed to be used in consumer products.

Using negative lists seems, however, more realistic when taking the current legislative framework into consideration – as well as the industry's ability and resources to perform risk assessments, analytical tests, and chemical-substitutions (on an almost daily basis).

In order for a negative list to be accepted by the industry, it is, however, essential that a reasonable and not impossible base line is set. Where the limit should be with respect to types of chemicals restricted and levels of limit values in consumer products will be discussed in more details in section 4.2.2 The level of strictness/concentration level.

The idea of the horizontal base line approach is that certain very hazardous chemicals should be banned from all consumer products if the chemical is present in the product above a specific concentration or emits/migrates above a certain amount (discussed more later on). However, in some cases, this may require exceptions on either a product specific level or in special cases. This is also discussed in more details below.

An example of a very ambitious variant of a negative list approach can be found in the new concept called Cradle to Cradle[30]. This concept uses the idea for a product that in order to be Cradle to Cradle certified, the majority of the substances used must be either "green" (no classification or only classified as mildly irritating) or "yellow" (no serious dangerous properties like carcinogenic, sensitising etc. and "only" classified as harmful (R20, R21, R22) or irritating (R36, R37, R38)). Different levels of certifications can be reached (basic, silver, gold and platinum) and the higher the certification level, the stricter criteria for the content of chemical substances. However, a common element is that "grey" substances (i.e. substances that we do not have information on) are as a general rule not allowed, at least not for a long period. See more details in the box below.

[30] http://c2c.mbdc.com/

The concept of chemical requirements in Cradle to Cradle certification (simplified and only examples are given)

100 ppm limit

All substances and materials in a product must be known down to a 100 ppm level

Grey substances

Grey substances are substances where no information about the toxicity of the substance exists or where there on some areas are missing data.
A maximum of 5% of grey substances is allowed and only for a period of 6 months – otherwise, the grey substances automatically will become red.

Examples of "green", "yellow" and "red" substances illustrated below

	Green substances	Yellow substances	Red substances
Cancer	No	Not in humans	Yes
Endocrine disrupting	No		Yes
Toxicity acute	No classification	R22 Harmful if swallowed "R21" Harmful in contact with skin. "R20" Harmful by inhalation	R25 Toxic if swallowed "R24" Toxic in contact with skin. "R23" Toxic by inhalation
Irritation	None or mild	Mild to moderate R38 Irritating to skin R37 Irritating to respiratory system. R36 Irritating to eyes	Severe irritation R34, R35 Causes (severe) burns
Sensitising	No	Equivocal data	Yes
Aquatic toxicity	No classification	R52 Harmful to aquatic organisms	R50 Very toxic to aquatic organisms R51 Toxic to aquatic organisms

The certification levels:

Basic certification level:

- A maximum of 5% grey substances is allowed for 6 months – otherwise, they will be red
- Red substances are allowed, but a plan for substitution/phase-out must be available within 6 weeks. No re-certification is possible with red substances in a product.

Silver certification level:

- A maximum of 5% grey substances is allowed for 6 months – otherwise, they will be red
- Red substances are allowed, but a plan for substitution/phase-out must be available within 6 weeks. No re-certification is possible with red substances in a product.

Gold certification level:

- No red and grey substances allowed

Platinum certification level:

- No red and grey substances allowed
- 50% of all substances/materials must be green

The Cradle to Cradle certification requires that all substances and materials in a product are identified down to a limit of 100 ppm. This means that in order to get a certification all suppliers need to send information – often confidential information to the company applying for certification – or as often is the case – directly to the certification body. The first experiences with this certification

scheme have shown that it is very difficult and time-consuming to find information about all chemical substances and materials down to the 100 ppm level.

During the development of a new "Cradle to Cradle" product, the company is asked to produce its own list of materials/chemicals that are allowed to be used with respect to the listed criteria. Thus, creating a list of potential usable materials/chemicals and developing the product based on these. In order to develop the product radically, new "thinking" (re-design, substitution, etc.) is often required as some chemicals simply no longer can be used.

4.2.1.3 Use of a combination of positive and negative lists

Another solution could be to use a combination of positive and negative lists as in the case of the Cosmetics Directive at the moment. Some substances are not allowed to be used in cosmetics and for some group of substances like e.g. colouring agents and preservatives only the colours and preservatives listed on the positive list in the Directive are to be used in cosmetic products.

A similar approach could be used in a horizontal approach for all consumer products. For some specific product groups, it could perhaps be easier to introduce a positive list rather than a negative list.

Another use of the positive list approach in combination with a negative list approach could be to restrict the most hazardous substances by a horizontal negative list for all consumer products and during a considerable transition period introduce a positive list approach. Timed to be fully implemented/active when REACH has been fully implemented and we have further toxicologial information about the registered chemicals.

4.2.1.4 Need for product specific requirements and special cases?

As mentioned earlier, it may be necessary to supplement the horizontal base line requirements for chemicals not allowed in consumer products with extra product specific requirements and exemptions. As demonstrated in ROHS, certain exemptions are necessary. For example mercury must be allowed in compact fluorescent lamps even though mercury is toxic to reproduction category 1B as mercury is necessary in order to produce compact fluorescent lamps that can produce light. Of course other of such cases may be needed.

However, the opposite situations may also be the case. There may be cases – for example certain toys that especially small children will chew and suck on – where more strict concentration limits have to be set for specific substances or a specific group of substances. In these cases, it may also be relevant to set different restrictions based on for example stricter concentrations or migration/emission levels instead. In addition to provide the option to deviate from generic restrictions upwards and downwards, there is, of course, also a need to establish bans or limits for specific substances not covered by horizontal requirements (e.g. for sensitising substances). These substances should be identified regularly and in a systematic manner based on market surveillance reports and stakeholder opinions (see provision in new Toy Safety Directive).

There may also be special cases that need a special regulation. For example indoor emissions from construction products where the requirements instead of being a content limit should be based on an emission limit or a resulting emission after a certain period of time in a certain room volume.

Furthermore, use of nanomaterials could be a special case where specific requirements could be set for use of nanomaterials in consumer products inspired by the example of the Cosmetics Regulation, i.e. incorporating the need of approvals and/or notification requirements, in particular for products which may release free nanoparticles, establishment of a publicly accessible database showing the use of nanomaterials in products, restrictions of specific substances (the Environment Committee of the EU Parliament called for the restriction of the use of nanosilver and long multi-walled carbon nanotubes in ROHS) etc.

Of course, all these special cases or product specific requirements should be possible to incorporate in the existing legislation by use of a committee procedure so that new additions to the regulation can be done fairly easy and without having to change the existing legislation every time.

4.2.1.5 Need for information/declaration requirements?

As discussed in section 3.9 Lack of information on chemicals in consumer products, a UNEP Chemicals initiative (UNEP, 2009) points out the need for a Product Declaration Form – a kind of safety data sheets for articles. However, this UNEP Chemicals initiative mentions this declaration possibility as an option instead of setting requirements for chemicals in consumer products. This solution is absolutely not desirable seen from a consumer's viewpoint as very few consumers are capable of making the correct "healthy" decisions based on a declared content of chemicals in the products.

However, the combination of a kind of consumer product declaration and a horizontal restriction of chemicals in consumer products may be the perfect choice for several reasons. First of all, a mandatory declaration scheme would increase our knowledge about which dangerous chemicals that are present in which type of consumer products. This would be helpful also in the process of limiting the dangerous chemicals only in the type of products or type of materials where the limitations will be needed and where the chemicals can be found. This could also save companies a lot of non-necessary expenses to chemical analysis.

Secondly, a declaration scheme of consumer products may be able to educate consumers – at least the more interested and educated ones. Today, many consumers are unaware of the fact that dangerous chemicals are present in everyday consumer products and that they may be affecting our health. Of course, the information in the declaration scheme should be balanced in order not to appear too overwhelming and thus have the opposite effect on consumers – resignation and passivity.

Finally, a mandatory declaration scheme in the EU on consumer products would also force the manufactures outside the EU to gather this type of information in order to be able to sell consumer products on the European market. This will bring us one step closer to full information about the content of chemicals in consumer products.

However, one could argue that if we have implemented a horizontal approach banning all very hazardous chemicals over a certain threshold, there would be no need for a mandatory declaration scheme as the dangerous chemicals to be declared would not be present in the consumer products. This is of course true to some extent, but there could and should be a difference between the

hazardous substances being banned from consumer products and the dangerous substances that have to be declared in consumer products. The difference could and should be both with respect to the hazardness of the chemicals and the concentration limit present. The most dangerous chemicals should be banned from all consumer products, whereas all dangerous substances ought to be declared.

As in the case of the Cradle to Cradle certification, there would have to be some rules for the level of information required for each material/chemical in a consumer product. In the Cradle to Cradle certification, a limit of 100 ppm has been chosen, thus the concentration of all materials/chemicals must be reported down to 100 ppm. This seems to be a reasonable level. It is difficult to avoid the presence of impurities in any materials and to some extent such impurities should be accepted. However, using a limit of 1000 ppm (0.1%) seems too high as some very dangerous substances may cause problems in concentrations below 0.1%. However, using a limit of 100 ppm is challenging with respect to supplier communication. It can be a very time consuming process to contact suppliers in order to achieve (in most cases) confidential information. Of course, another way out is to carry out a chemical analysis but this is expensive, especially if you do not know what to look for. The use of chemical analysis is also used within the Cradle to Cradle certification (if it is not possible to account for the full content down to the 100 ppm level).

The question is whether this product declaration scheme should be somewhat in line with the existing Safety Data Sheets under REACH where all substances/materials classified as dangerous have to be reported in concentration intervals. Confidential information could be masked but the concentration level and the classification of the substance should be reported.

Perhaps, when more products have been certified according to the Cradle to Cradle principles their experiences with the 100 ppm declaration limit could be reviewed and taken into consideration.

4.2.2 The level of strictness/concentration level

In this section, the level of strictness within the chemical framework, i.e. the concentration level and the level of dangerousness of the chemicals that should be set as a general horizontal requirement for dangerous chemicals in consumer products are discussed.

It is obvious that the level of strictness depends on whether or not a positive list, a negative list or a combination of them both is used. In this section we assume the use of a negative list as the horizontal base line approach. This could be combined with sector or product specific positive lists.

4.2.2.1 Which dangerous chemicals should be restricted in consumer products in a generic way?

A study commissioned by BEUC (The European Consumer's Organization) and EEB (The European Environmental Bureau) and carried out by the Öko-Institut (Institute for Applied Ecology) is entitled "The path to sustainable use of chemicals in products: The European eco-label as a signpost". Discussion paper was published in December 2008. In this paper, the Öko-Institut proposes a horizontal approach to restrict dangerous chemical substances by use of the classification of the substances. The intention is that this horizontal approach should be used across all product groups within the field of eco-

labelling. The horizontal approach has been illustrated in the box below (Öko-Institut/BEUC/EEB, 2008).

Of course, requirements used in a horizontal European framework valid for all consumer products should not be as strict as suggested for use in eco-labelling, as eco-labelled products still need to be superior on both health and environmental issues compared to "regular" consumer products. However, the basic concept as suggested by the Öko-Institute could be used in a less strict manner – or, alternatively, the bar is raised in the eco-label system (or a mix of both).

Öko-Institut/BEUC/EEB (2008):
Suggestion of criteria for excluding problematic substances in eco-labelled products

Substances classified as dangerous to human health and to the environment according to specific **risk phrases**

- They suggest no use of substances which are classified with at least one R phrase mentioned (or the related classifications of the GHS system (now CLP)) in Box 5 page 20 of the report.
- The paper suggests both R phrases (Directive 67/548/EEC, Directive 1999/45/EC) and the new GHS (now CLP) characterisation system.
- The exclusion of substances according to R phrases varies at present time according to product. They suggest a common list of R phrases for problematic inherent properties of substances which should not be allowed in the Ecolabel (see list page 20 of the report).
- If a specific product group, ingredient or synthesis by-product which corresponds to the above mentioned R-phrases cannot be avoided, concentration limits, which probably will be in the ppm range, should be set.

Carcinogenic and mutagenic substances of reproductive toxicity (CMR 1,2,3)

- They suggest exclusion of CMR substances through the related R-phrases R40, R45, R46, R49, R60, R61, R62 and R63.
- They suggest exclusion of CMR category 1, 2 and 3 (latter based on animal test results).
- They also suggest exclusion of substances that are human carcinogens (IARC1), probable human carcinogens (IARC 2A) and possible human carcinogens (IARC 2B).

Toxic substances

- Should not be included in Eco-labelled products.
- They suggest exclusion of toxic substances through the related R-phrases R23, R24, R25, R26, R27 and R28.

Neurotoxic substances, **immunotoxic** substances, **allergens** and **sensitisers**

- Should not be included in Eco-labelled products.
- Partly covered by R phrases (R 43 and R67).
- Take into account results that indicate allergenic etc. properties – even if the substance is not classified according to the R phrases yet.

Endocrine disrupting substances

- They suggest excluding endocrine disrupting substances.
- However, R phrases and GHS classification do not cover this class of substances entirely, thus they suggest exclusion based on "substances classified as endocrine disruptors Category I or II, within the EU Strategy on endocrine disruptors".
- Furthermore, they suggest that all endocrine disrupting chemicals, which have been identified as chemicals of equivalent concern on a case-by-case basis in the context of REACH and further investigations on endocrine disrupting chemicals should also be excluded.

Persistent or **bioaccumulative** substances

- They suggest exlcusion based on the international agreement on persistent and bioaccumulative toxicants, the OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic. The EU has also signed the agreement (eliminating the release of these substances into the marine environment

Öko-Institut/BEUC/EEB (2008):
Suggestion of criteria for excluding problematic substances in eco-labelled products

by 2020).

- Exclusion of persistent substances opposed to REACH which considers persistence only in combination with other properties as being "of high concern" (PBT and vPvB).
  - The assessment of persistency of a substance in the Ecolabel should include its degradation products and, if relevant, its combustion products of a substance.
  - R phrases do not take into account persistency alone, neither does GHS… therefore, they refer to test/lab results.
- Exclusion of bioaccumulative substances as opposed to REACH which considers persistence only in combination with other properties as being "of high concern" (PBT and vPvB).
  - R phrases and GHS do not give the possibility of classifying substances that are only bioaccumulative. Furthermore, REACH sets very narrow criteria for bioaccumulation in comparison to criteria which are set by other regulations such as OSPARCOM
  - They recommend using bioaccumulation criteria as given in OSPAR Annex XII (substances should not have a bioconcentration factor> 500 or a figure > = 4 for the logKow). Additionally, they suggest taken into account uptake mechanisms through the food chain and through air and whether there are rising trends in humans and the environment.

Substances with **other problematic** hazardous properties

- They suggest excluding these substances with other problematic hazardous properties based on the "Substitute it now" (SIN) list recently published by the International Chemical Secretariat (ChemSec), a non-profit organisation dedicated to working towards a toxic free environment. It lists 356 high concern substances that fulfil the REACH criteria for substances of very high concern.
- They suggest that until a proper toxicological and ecotoxicological assessment framework for nanomaterials is in place, the Ecolabel should not be given to consumer products which contain manufactured nanomaterials and structures which could be released into different environmental media.

A suggestion for use of the classification of chemicals when determining which chemicals should be restricted in all product groups could be to use the SVHC definition as used in REACH. This would restrict the use of the following substances in all consumer products:

- CMR substances in category 1A and 1B (similar to category 1 and 2 as mentioned by the Öko-Institute),
- PBT substances,
- vPvB substances,
- and endocrine disrupters (as the SVHC definition also includes other substances with serious effects to human health or the environment, or substances that give rise to an equivalent level of concern as CMR substances).

However, this approach only restricts the most dangerous chemical substances. It could be discussed whether other toxic substances (substances that are only toxic (T)) should be restricted as well – though perhaps with a higher allowed concentration limit. Sensitising substances could also be considered restricted as well. However, today we do not even restrict these substances in cosmetic products which we daily apply to our skin in a generic way, so whether the industry would accept a general ban on these substances is questionable.

However, there is not doubt that if the chemicals chosen are based on the definition for SVHCs this will make the preparation of the regulation easier and the link to REACH will become more natural.

Finally, as mentioned earlier, it must of course be possible to change the requirements for the chemicals to be restricted by using a committee procedure. However, by linking to the SVHCs as defined in REACH, the restricted substances will be increased as the list of SVHCs increases.

4.2.2.2 Which concentration limit should be chosen?

If using the SVHC definition for the chemical substances to be restricted from all consumer products, it could be obvious to use the concentration limit of 0.1% as used in REACH as well.

However, this concentration limit may be too high for some very hazardous substances. Furthermore, as discussed earlier, multiple exposures can still result in health impacts even though the concentration limit of 0.1% is pursued for all consumer products. Hence, it is of crucial importance that the legislative framework allows for the setting of stricter limits and provides a procedure for this whenever a generic limit is used.

It is very important that a general measureable limit is set as both companies and authorities will benefit from having a precise and measurable limit value to compare with information given from suppliers or obtained by use of chemical analysis.

One objection from industry could easily be that it is wrong to restrict the content of hazardous substances in the products if the consumers are not exposed during use. This is indeed a valid argument if the life cycle approach is not considered. As for the heavy metals restricted in ROHS, it is of course a matter of restricting the total amounts of heavy metals in circulation as the heavy metals are not degraded during waste treatment and thus can cause health impacts on mankind after waste treatment. Therefore, the life cycle aspect has to be considered.

It is correct that e.g. some organic substances will not have a health impact during use, if the migration or emission of the substances is very small. They may not have an impact on the environment during or after waste treatment either, if the compounds are degraded easily in the environment or is broken down during incineration of waste. Therefore, it may be correct in some cases to use migration limit values and/or emission limit values instead of content limit values. However, a problem may be that analysis methods have to be well defined in order to avoid disputes.

Use of migration limit values and/or emission limit values could be used in special cases or e.g. for special product groups like toys, as mentioned earlier.

There is still the huge problem related to multiple exposures and combination effects (knowledge gab). The concentration limits of the hazardous substances have to be sufficiently low in order to take the multiple exposures and the risk of combination effects into account.

One result of the expert workshop on this subject was that by adopting a specific assessment factor (an extra uncertainty/safety factor) in the traditional chemical-by-chemical risk assessment, the concerns about combination effects could be reduced (Danish EPA, 2009). This extra safety factor could be used in special cases where especially dangerous substances are present and to protect certain consumer groups (e.g. children). It is a tremendous task to

carry out risk assessment on all hazardous chemicals in all consumer products in order to set the limit values where necessary. This is also in contradiction to a horizontal approach that also would be easier to follow, to apply to, and to implement.

It is also possible to use a percentage of the TDI values – Tolerable Daily Intake (if this has been established for the substance in question), as it is used in the Toy Safety Directive. Again this is a laborious task and should only be used in special cases for specific dangerous substances and specific product groups.

A way to solve this could be to use a limit value that is equal to the detection limit for a specific prescribed migration analysis method. Then it is ensured that the migration is as low as possible (of what we are able to detect) and the total risk to human health will therefore be kept at a minimum.

4.3 Implementation measures

Of course such a horizontal restriction of chemical substances in consumer products also has to be succeeded by a monitoring scheme for authorities with spot checks etc. that ensures that the requirements in the horizontal regulation are followed.

The information obtained during the spot checks should be gathered and used to either lower limit values in special cases if necessary or even the opposite could be the case – that some limit values have to be set less strict because new information about the content of a specific chemical in a specific consumer product cannot be substituted or is not possible to produce in the required low content.

4.4 The suggested horizontal approach – in short

Thus, in short, the horizontal approach suggested in this study includes the following elements:

- Expansion of the ERP Directive to include generic and specific chemical restrictions for all products. Thus, the ERP Directive should be expanded to cover all products rather than just energy related ones and to cover a multitude of environmental aspects mirroring the EU Eco-label Regulation at a somewhat lower level of ambition. This offers opportunities for synergies and efficient resource use.

- The approach for chemical restrictions may rely on positive lists, negative lists, or a combination of both.

- The generic approach for restrictions of chemicals in consumer products should be based on the definition of SVHCs in REACH (i.e. to ban substances falling in this category such as carcinogenic, mutagenic, toxic for reproduction, etc.). However, it should be further considered (in expert groups) whether further categories of chemicals should be included (as for instance sensitising substances or substances that are toxic).

- The general concentration limit of the chemicals restricted by the generic approach should be set at 0.1% (as in REACH) for any homogenous component of the product.

- It should be further discussed whether in some cases (or in which cases) the relevant type of limit-requirements should be based on migration or emission levels instead of content or concentration.

- It should be possible to allow for exemptions for certain substance in certain consumer products.

- It should be possible to establish more specific chemical requirements in special cases (like products emitting dangerous substances to our indoor environment) or for specific groups of products (like e.g. toys addressing a certain consumer group) or specific chemical substances not covered by generic restrictions. In these cases, a risk assessment must be performed. Perhaps an extra uncertainty/safety factor could be used in order to account for the combination effects or for multiple exposures. Risk assessments including possible exemptions should be assessed by an independent scientific committee (e.g. SCHER).

- A product declaration scheme should be introduced for all consumer products. It is suggested that all chemicals classified as hazardous with a content of 100 ppm or higher should be declared. Concentration intervals should be stated.

- The legal framework should include the possibility of changing the chemical requirements by using a committee procedure.

- A systematic assessment of the occurrence of chemicals in (certain) products should be carried out.

- Establishment of an adequately funded and more efficient market surveillance system including random tests and control measurements.

- The random tests carried out by the authorities should give feedback to the process of establishing limit values for special chemical substances for special consumer products. If necessary, the special limit values could be changed or new could be adopted – again by use of a committee procedure.

5 Recommendations for further work

The horizontal approach to restriction of hazardous chemical substances in all consumer products described in this report is and should be considered as a starting point for a discussion and further development.

It is recommended that both the suggestion of chemicals to be restricted and the concentration limit level should be discussed further in an expert group. An important topic to discuss should be whether further chemicals (as for instance sensitising substances or substances that are toxic) should be included.

Likewise, it should be discussed more thoroughly whether the limit values should be based on content values or migration/emission limit values – or a combination of these as discussed earlier. The latter could be relevant in the case of limit values for special product groups or in special cases.

Furthermore, it is recommended to go further into details about the framework for special cases, exemptions, and special product groups. This framework must be in place before the horizontal approach is implemented. It could be an advantage to establish an overview of the cases where exemptions and special cases would be needed.

The possibilities of introducing the use of “positive lists” should also be explored further. During the exploration of this subject, areas which already implement the use of positive lists should be examined further as regards to negative and positive experiences.

Finally, there is a need for a discussion of how we make sure that multiple exposures and combination effects are taken into account when setting limit values for a single consumer product.

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Annex 1 – Examples of problematic chemicals in consumer products

Content of Annex 1

Annex 1: Summary and conclusions

This annex describes examples of hazardous substances that have been found in consumer products. In some areas there are chemical requirements, e.g. for phthalates in toys and azo dyes in textiles. However, in many consumer products no chemical requirements are set, other than the statement that "the products may not present a risk to human health". This risk can only be established by performing a risk assessment (if accidents have not happened, as in the case of Bindeez pearls which is described as an example in this annex).

The main purpose with these example is to illustrate that having a content of hazardous substances in consumer products (whether it being elevated or small amounts) is unfortunately common. The examples are based on chemical analysis – either only for a specific group of compounds (e.g. phthalates or heavy metals) or for several groups of compounds. Some of the tests carried out have shown that in some cases the tested products contain illegal amounts of restricted substances. However, the focus has not been to illustrate this but to illustrate which types of chemicals that can be found in legal consumer products on the European market.

The examples in this appendix illustrate that dangerous chemicals in consumer products are common and support the criticism regarding the current European regulatory framework on chemicals in consumer products being insufficient.

In the table below, the different chemicals identified in the listed examples are summarised. It should be mentioned that not all the performed tests have analysed for all the listed groups of chemicals. For instance, all-weather clothing was only tested for content of fluorinated compounds. This product may very well contain phthalates, heavy metals, flame retardants, formaldehyde, aromatic amines, DBT, TBT, or other organostannic compounds as well as other problematic substances.

Table 0-1 Examples of problematic chemicals found in consumer products. The table represents an overview of what has been identified. Not all products have been tested for all the mentioned groups of chemical compounds.

Example	Year	Phthalates	PAHs	Heavy metals	Flame retardants	Formaldehyde	Aromatic amines	Halogenated hydrocarbons	Fluorinated compounds, PFOS	DBT, TBT organostannic compounds	Other problematic substances
Miscellaneous products – child-care articles											
Hazardous substances in prams	2009	x	x		x			x		x	x
Phthalates in products for children	2009	x									
PAHs in teething rings, children tooth brushes and running bikes	2008	x									
Hazardous substances in baby products	2008	x				x					x
Erasers	2007	x	x	x							
Miscellaneous products – clothes/textiles											
Nanosilver in textiles	2010										x
Phthalates in ski mittens	2010	x									
Hazardous substances in jackets	2009	x				x			x		x

Example	Year	Phthalates	PAHs	Heavy metals	Flame retardants	Formaldehyde	Aromatic amines	Halogenated hydrocarbons	Fluorinated compounds, PFOS	DBT, TBT organostannic compounds	Other problematic substances
and mittens											
Chemiclas in bras	2009	x					x			x	x
Children bed linens and football T-shirts	2009	x		x		x		x		x	x
Phtalates in T-shirts	2008	x									
PAHs in rain proof clothes	2008		x								
Chemicals in bed linens	2008			x		x		x			x
Chemicals in bath towels	2007			x							x
Fluorinated pollutants in all-weather clothing	2006								x		
Night clothes	2005					x					x
Toxic childrenswear	2004	x		x		x				x	x
Miscellaneous products – shoes											
Environmental toxicants in leather shoes	2009			x		x	x	x			x
Hazardous chemicals in plastic shoes	2009	x	x	x						x	
Miscellaneous products – shoe care products/impregnating agents											
Fluorinated compounds in impregnating agents	2008								x		
Hydrogenated carbons in shoe care products	2005										x
Toys											
Test of toys on the German market	2009	x	x		x		x	x		x	
Balloons	2009	x					x				
PAHs in outdoor toys	2008		x								
Bindeez pearls	2007										x
Wooden toys	2005										x
Formaldehyde in children tents	2004					x					x
Test of toys on the European market	2004	x		x	x	x					x
Electronics											
Hazardous substances in games console components	2008	x		x	x						x
PAHs in hair dryers and heart rate monitors	2008		x								
Hazardous substances in iPhones	2007	x		x	x						
Toxic chemicals in computers	2006			x							x
Personal protection equipment											
Working gloves	2009	x		x				x		x	
Children ski helmets	2006			x							x
Construction products											
Hazardous substances in wood preservatives	2009			x		x					x
Phthalates in do-it-your-self products	2009	x									
Hazardous substances in floorings	2008	x	x	x						x	
Phthalates in grout	2008	x									
Phthalates in air fresheners	2007	x									
Silicone based grouts	2007	x								x	x
Indoor paint	2007					x					x
Lacquers	2007			x		x					x
Construction products	2007					x					x
Indoor climate	2006	x			x	x			x		x
Other relevant examples											
Endocrine disrupting substances that two-year-old children are exposed to	2009	x									x

1 Introduction

The current regulatory framework in the European Union to protect consumers from chemicals contained in consumer articles has been criticized for being entirely insufficient.

This annex gives a number of examples supporting this criticism.

1.1 Purpose

The purpose of this annex is to list existing examples, investigations and/or chemical analysis of problematic chemicals found in consumer products. Some of the tests carried out have shown that in some cases the tested products contain illegal amounts of restricted substances. However, it is not the main purpose to illustrate with these examples. In most of the examples there is a lack of legal limits for the identified hazardous substances which means that the products are only “illegal” if they contain an amount of hazardous substances that presents a risk to human health. This risk can only be established by performing a risk assessment.

Hence, the main purpose of presenting these examples is to illustrate that a content of hazardous substances in consumer products, whether it is in elevated or small amounts, unfortunately, is common.

1.2 Method used

An Internet search has been performed in order to locate examples of problematic chemicals in consumer products.

The search performed is not absolute – meaning that only a few examples of hazardous chemicals found in consumer products have been described. It is possible to find many more examples – from the sources used in this annex as well as from other sources.

2 Sources used

The following information sources have been used:

- Reports from the Danish EPA on surveys of chemicals in consumer products
- Reports from other authorities
- Greenpeace and/or other relevant NGO reports
- Different tests carried out by consumer magazines, e.g. the German Öko-test
- Searches on the Internet.

These information sources are described in more details below.

2.1 The Danish EPA

The Danish EPA has published over 100 surveys of chemicals in consumer products during the past 10 years. Generally speaking, hazardous substances have been identified in all surveys. However, the amounts of the hazardous substances are in far from all cases in concentrations that can result in health effects but common for the projects is that the health risk is assessed only by looking at the migration/emission from the product in question individually. The projects listed in chapter 3 Examples are the projects where the surveys conclude that the chemical substances present in or migrating/emitting from the products can pose a potential health risk.

In two projects, the Danish EPA has looked at the total effect of many different consumer products. One project focused on the concentration of hazardous chemicals in the indoor climate and another project focused on the total exposure of endocrine disrupting chemicals from consumer products relevant for two-year-old children. Both projects concluded that there is a potential health risk. The projects are further discussed in chapter 3 Examples.

2.2 Reports from other authorities

Of other authorities can be mentioned the Norwegian Climate and Pollution Agency (former called SFT) and the German Federal Environment Agency.

2.3 Greenpeace and/or other relevant NGO reports

Surveys about hazardous chemicals in different consumer products have been listed as some of the examples in the next chapter. Surveys from the following NGOs have been listed:

- Greenpeace
- Swedish Society for Nature Conservation
- The Danish Consumer Council
- The Danish Information Centre on Environment and Health

The Danish Information Centre on Environment and Health is an independent information centre with the purpose of informing consumers about environmental and health related problems in consumer products. They receive their funding from the Danish EPA. They list examples of hazardous substances found in consumer products in Denmark as well as internationally.

2.4 Different tests carried out by consumer magazines, e.g. the German Öko-test

The German magazines Öko-test and Test often test consumer products for the content of hazardous substances. Some of their most recent tests are included as examples.

2.5 Searches on the Internet

Other than the above searches on the Internet has been performed. This has resulted in examples from e.g. the Thailand National Nanotechnology Center.

3 Examples

This chapter lists a number of examples of problematic chemicals found in consumer products. The list, which is not an exhaustive list, covers the examples as listed in Table 3-1.

The list primarily covers examples of problematic chemicals found in consumer products that are not "illegal", meaning that there are no restrictions on these substances in the described in consumer products. This means that examples such as lead found in paint in toys are not mentioned as lead in paint in toys is already illegal according to European legislation. However, some of the examples mentioned may have resulted in a withdrawal of the products from the market as a potential health risk (as calculated in a risk assessment) is in violation with the EU general product safety directive.

Table 3-1 Examples of problematic chemicals found in consumer products

Example	Source	Year
Miscellaneous products – child-care articles		
Hazardous substances in prams	Test (German magazine)	2009
Phthalates in products for children	Danish Information Centre for Environment and Health	2009
PAHs in teething rings, children tooth brushes and running bikes	Öko-test	2008
Hazardous substances in baby products	Danish EPA	2008
Erasers	Danish EPA and Öko-test	2007
Miscellaneous products – clothes/textiles		
Nanosilver in textiles	Thailand National Nanotechnology Center	2010
Phthalates in ski mittens	Norwegian Climate and Pollution Agency	2010
Hazardous substances in jackets and mittens	Danish EPA	2009
Chemiclas in bras	Öko-test	2009
Children bed linens and football T-shirts	Öko-test	2009
Phtalates in T-shirts	Swedish Society for Nature Conservation and Danish EPA	2008
PAHs in rain proof clothes	Öko-test	2008
Chemicals in bed linens	Öko-test	2008
Chemicals in bath towels	Swedish Society for Nature Conservation and Danish EPA	2007
Fluorinated pollutants in all-weather clothing	Friends of the Earth Norway	2006
Night clothes	Austrian Standards Institute	2005
Toxic childrenswear	Greenpeace	2004
Miscellaneous products – shoes		
Environmental toxicants in leather shoes	Swedish Society for Nature Conservation	2009
Hazardous chemicals in plastic shoes	Swedish Society for Nature Conservation and Danish EPA	2009
Miscellaneous products – shoe care products/impregnating agents		
Fluorinated compounds in impregnating agents	Danish EPA	2008
Hydrogenated carbons in shoe care products	Danish EPA	2005
Toys		
Test of toys on the German market	Öko-test	2009
Balloons	Öko-test	2009
PAHs in outdoor toys	Öko-test	2008
Bindeez pearls	Danish Information Centre for Environment and Health	2007
Wooden toys	Danish EPA	2005
Formaldehyde in children tents	Danish EPA	2004

Example	Source	Year
Test of toys on the European market	Danish Information Centre for Environment and Health	2004
Electronics		
Hazardous substances in games console components	Greenpeace	2008
PAHs in hair dryers and heart rate monitors	Öko-test	2008
Hazardous substances in iPhones	Greenpeace	2007
Toxic chemicals in computers	Greenpeace	2006
Personal protection equipment		
Working gloves	Öko-test	2009
Children ski helmets	Austrian Standards Institute	2006
Construction products		
Hazardous substances in wood preservatives	Öko-test	2009
Phthalates in do-it-your-self products	Danish Information Centre for Environment and Health	2009
Hazardous substances in floorings	Öko-test	2008
Phthalates in grout	Danish Information Centre for Environment and Health	2008
Phthalates in air fresheners	NRDC	2007
Silicone based grouts	Öko-test	2007
Indoor paint	Öko-test	2007
Lacquers	Öko-test	2007
Construction products	German Federal Environment Agency	2007
Indoor climate	Danish EPA	2006
Other relevant examples		
Endocrine disrupting substances that two-year-old children are exposed to	Danish EPA	2009

The examples are divided in different categories which resemble the legislation reviewed in the report (General Product Safety Directive, Toy Safety Directive, RoHS, Energy Related Products Directive, Personal Protection Equipments Directive, and Construction Products Directive).

3.1 Miscellaneous products

3.1.1 Child-care articles

3.1.1.1 Hazardous substances in prams (2009) – Test (Germany)

The German magazine Test tested in 2009 14 different prams and pushchairs for babies and small children. The test also included a test for PAHs (polyaromatic hydrocarbons), phthalates (DEHP, DBP, BBP, DINP, DIDP, DNOP), chlorinated paraffines, flame retardants, organostannic compounds, nonylphenol and formaldehyde. None of the 14 prams/pushchairs was without all these groups of hazardous substances. Some prams/pushchairs only tested positive for formaldehyde, others tested positive for PAHs and flame retardants or for phthalates and flame retardants (Test No. 9, 2009)

3.1.1.2 Phthalates in products for children (2009) – Danish Information Centre for Environment and Health

In 2009, the Danish Information Centre for Environment and Health has analysed 13 different consumer products for children. Eight of the 13 products contained phthalates. The products were: leather jacket (imitated leather), pencil case, oilcloth, dinner mat, seat cover for a car with pockets for books etc., shower curtain, reflector with the child's name, and a bean bag.

The phthalates DEHP (26 %), DINP (3.2 %), and DIBP (6.2 %) were found in the maximum concentrations as listed. The highest concentration of DEHP

was found in a shower curtain and a children's leather jacket. (Danish Information Centre for Environment and Health, 2009a).

3.1.1.3 PAHs in teething rings, children tooth brushes and running bikes (2008) – Öko-test

Öko-test has tested teething rings, children tooth brushes and running bikes (the handles) and found Polycyclic Aromatic Hydrocarbons (PAHs) that are known for their carcinogenic, mutagenic, and teratogenic properties in amounts between 1000 and 10,000 μg/kg (1-10 ppm). In one teething ring and in 4 of the running bikes the amount was higher than 10,000 μg/kg. (Öko-test 4, 2008).

3.1.1.4 Hazardous substances in baby products (2008) – Danish EPA

In 2005, the Danish EPA investigated different products intended for baby use. The products were: pillows for baby feeding, nursing pads, baby foam mattresses, disposable foam wash cloths, baby carriers and textile cover on prams. All products were analysed for the content of hazardous substances and all baby products contained measurable amounts of more than one compound classified as hazardous to health and/or the environment. However, no substances with hazardous health risks were found in the products but the exposure from this type of products contributes to the total exposure from other consumer products.

The analysed pillows for baby feeding emit formaldehyde which in higher concentrations is carcinogenic by inhalation and may cause sensitization by skin contact. The assessment shows that the worst case migration to skin may contribute significantly to the acceptable daily intake.

Furthermore, phthalates were found in a nursing pad. DINP was found in high concentrations (over 14 %), and DINP was also found migrating to sweat. (Danish EPA No. 90, 2008).

3.1.1.5 Erasers (2007) – Danish EPA and Öko-test

As a part of the programme "Survey of chemical substances in consumer products", the Danish EPA investigated in 2006 the content of hazardous substances in school bags, toy bags, pencil cases, and erasers. The purpose of the project was to test plastic-like products. Toy bags are obviously regarded as toys, but school bags, pencil cases, and erasers are only considered as toys if the appearance of the products appeals to children. Only some of the products were considered as toys – the rest was not.

The test showed that school bags and toy bags primarily are made of textile with plastic parts of PVC with phthalates as plasticizers and that 9 out of 26 erasers contained phthalates. Four of the erasers contained DEHP and one of the erasers in an amount of over 40 %. For this eraser the migration of DEHP and the health risk was analysed. The conclusion was that the content of DEHP in the eraser could present a health risk if a child daily chews the eraser or puts into the mouth.

Furthermore, four products with high amounts of lead and cadmium were found (lead: 475 ppm to 4600 ppm (the legal limit in Denmark is 100 ppm), cadmium: 250 ppm to 400 ppm (the legal limit in Denmark is 75 ppm)). (Danish EPA No. 84, 2007).

These results of phthalates in erasers were confirmed by the German Öko-test magazine that tested 20 erasers and found one or more of the phthalates DEHP, DBP, DINP, DIDP, and BBP in 15 of the erasers. Eight of the erasers contained more than 0.1 % phthalates. (Danish Information Centre on Environment and Health, 2007b).

Furthermore, Öko-test tested for Polycyclic Aromatic Hydrocarbons (PAHs) that are known for their carcinogenic, mutagenic, and teratogenic properties in erasers. Three erasers contained PAHs in amounts between 1,000 and 10,000 μg/kg (1-10 ppm). In five erasers, the amount was higher than 10,000 μg/kg. (Öko-test 4, 2008).

3.1.2 Clothes/textiles

3.1.2.1 Nanosilver in textiles (2010) – Thailand NNC

The National Nanotechnology Center in Thailand has analysed different textile products that claimed to be coated with nanosilver in order to prevent bacterial growth. It turned out that not all of the analysed textile products contained silver, but the most interesting part about the investigation was that silver was released from the different fabrics into artificial sweat to a varying extent in up to 322 mg/kg of fabric weight. (Kulthong et al, 2010).

These finding raise concerns about the potential effects of the release of larger amounts of antibacterially active silver on human skin.

3.1.2.2 Phthalates in ski mittens (2010) – NCPA

The Norwegian Climate and Pollution Agency has found the phthalate DEHP in 22 % (w/w) in some black rubber material of three different types of ski mittens on the Norwegian market. According to an assessment of the Norwegian Climate and Pollution Agency, the content is considered as a health risk as DEHP is toxic to the reproduction and is embryotoxic. The ski mittens have been withdrawn from the market. (Norwegian Climate and Pollution Agency, 2010).

3.1.2.3 Hazardous substances in jackets and mittens (2009) – Danish EPA

In the above mentioned project from the Danish EPA that focused on the total exposure to endocrine disrupting substances for two-year-old children, the products children jackets and mittens were also analysed for the content of hazardous substances.

The analysis performed showed that the small plastic/rubber piece often used on children jackets so the children easier can zip their jacket contained phthalates like DEHP and DBP. This is a problem as small children often put this into their mouth and chew or suck on it. Migration of phthalate (DBP) was seen from the small plastic/rubber piece on the zipper.

Other hazardous substances found in most jackets and mittens were styrene, fluorinated compounds (used for impregnation), phthalates, formaldehyde, and isocyanates. (Danish EPA No. 103, 2009).

3.1.2.4 Chemicals in bras (2009) – Öko-test

Öko-test tested for halogenated organic compounds, problematic colours, dibutyltin (DBT), tributyltin (TBT), and other organostannic compounds, heavy metals, and optical brighteners in 25 different women bras (in black).

18 of the bras contained halogenated organic compounds and 6 of the bras contained problematic colouring agents (aromatic amines) such as p-aminoazobenzol, aniline, benzidine, and disperse orange 37/76 which all are considered as carcinogenic. Furthermore, Disperse Orange 37/76 is considered allergenic, mutagenic, and reprotoxic.

11 of the bras contained traces of DBT, TBT, or other organostannic compounds, and 2 of the bras contained strongly elevated levels of either DBT (i.e. > 250 μg/kg) or other organostannic compounds (i.e. > 2500 μg/kg). DBT and TBT are pesticides which are used to prevent pest attack in the textiles. The compounds are also suspected as human endocrine disrupters.

Furthermore, 18 of the bras contained optical brighteners and one of the bras contained the heavy metal antimony. Finally, the endocrine disrupting chemical DEHP (diehtylhexylphthalate) was found in one of the bras. (Öko-test 4, 2009).

3.1.2.5 Children bed linen and children football T-shirts (2009) – Öko-test

In 2009, the German test magazine Öko-test tested children bed linens and children football T-shirts. The test showed that:

- Seven out of eight of the children bed linens contained optical brighteners, half of the tested children bed linens contained halogenated hydrocarbons, and one bed linen contained formaldehyde.
- All of the 18 tested children football T-shirts contained optical brighteners. Dibutyltin, antimony, and organic phosphor compounds were found in several of the 18 T-shirts. Finally, phthalates, triclosan, and chlorinated organic compounds were found in some of the T-shirts. (Öko-test 12, 2009).

3.1.2.6 Phtalates in T-shirts (2008) – SSNC

In 2008, the Swedish Society for Nature Conservation examined 20 different T-shirts on the Swedish market with some kind of print on the T-shirts. In 19 of the 20 T-shirts either one or more of the six phthalates (DEHP, DBP, BBP, DINP, DIDP, DOP), which are banned in toys in the EU above certain concentrations, were detected – for some of the T-shirts even in very high concentrations. The highest detected concentration of DEHP was 22 % of the weight of the print on the T-shirt. BBP was found in concentrations up to 7.3 %, DINP in concentrations up to 7.9 %, and DIDP in up to 2.6 % of the weight of the print. DEHP, DBP, and BBP are officially classified as endocrine disrupting substances, and furthermore, DEHP and BBP are suspected carcinogens. Of the investigated phthalates, DEHP, BBP, and DBP are present on the list of Substances of Very High Concern (REACH). (Swedish Society for Nature Conservation, 2008a).

3.1.2.7 PAHs in rain proof clothes (2008) – Öko-test

Öko-test tested for Polycyclic Aromatic Hydrocarbons (PAHs) that are known for their carcinogenic, mutagenic, and teratogenic properties in rain proof clothes (trousers). Ten trousers contained PAHs in amounts between 1,000 and 10,000 μg/kg (1-10 ppm), and in two trousers the amount was higher than 10,000 μg/kg. (Öko-test 4, 2008).

3.1.2.8 Chemicals in bed linens (2008) – Öko-test

Öko-test tested for formaldehyde, halogenated organic compounds, heavy metals, and optical brighteners in 25 different bed lines. 10 of the bed lines contained more than 20 ppm formaldehyde, 9 of the bed lines contained halogenated organic compounds, and 2 of the bed lines contained heavy metals – one contained chromium and one contained nickel. Finally, 14 of the bed lines contained optical brighteners. (Öko-test 11, 2008).

3.1.2.9 Chemicals in bath towels (2007) – SSNC

In 2007, the Swedish Society for Nature Conservation examined 20 different bath towels on the Swedish market. All of the examined bath towels contained nonylphenolethoxylate. Nonylphenolethoxylate is degraded to the environmental toxin nonylphenol in the environment. Nonylphenol is also considered as an endocrine disrupting substance. The highest concentration measured was 1 %.

Other hazardous substances were found as well – primarily heavy metals such as arsenic (in 1 of 20 samples), cadmium (in 2 samples), cobalt (in 5 samples), chromium (in all samples), copper (in all samples), nickel (in all samples), lead (in 19 samples), antimony (in 7 samples), vanadium (in 13 samples), and zinc (in 19 samples). Some of the contents of the heavy metals were assessed to be high. (Swedish Society for Nature Conservation, 2007).

3.1.2.10 Fluorinated pollutants in all-weather clothing (2006) – Friends of the Earth Norway

Four windbreakers/jackets for children were analysed for the content of fluorinated chemicals such as perfluorooctanyl sulfonate, PFOS, fluortelomer alcohols (FTOH), and perfluorocarboxylic acids (PFCA). The compounds are widely used as impregnating agents, but in recent years their problematic properties have been identified and investigated. The substances are extremely stable in the environment and the levels in the environment are now close to the levels that have been proved to produce harmful effects in laboratory experiments. The substances accumulate in wild life and humans, and they have been linked to health effects such as metabolic disorders (thyroid diseases)[31], higher levels of cholesterol[32], lowering of semen quality in men[33], and impairment of the fertility of women[34]. (Friends of the Earth Norway, 2006).

These results have been confirmed by the analysis carried out in the project for the Danish EPA No. 103 (2009) that focused on the total exposure to endocrine disrupting substances for two-year-old children. In this project

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[31] Association between Serum Perfluoroctanoic Acid (PFOA) and Thyroid Disease in the NHANES study. Environmental Health Perspectives. http://ehsehplp03.niehs.nih.gov/article/fetchArticle.action?articleURI=info%3Adoi%2F10.1289%2Fehp.0901584

[32] Exposure to Polyfluoroalkyl Chemicals and Cholesterol, Body Weight, and Insulin Resistance in the General US Population. Environmental Health Perspectives. http://ehp03.niehs.nih.gov/article/fetchArticle.action?articleURI=info:doi/10.1289/ehp.0901165

[33] Do Perfluoroakyl Compounds Impair Human Semen Quality? Environmental Health Perspectives. http://ehp03.niehs.nih.gov/article/fetchArticle.action?articleURI=info:doi/10.1289/ehp.0800517

[34] Maternal levels of perfluorinated chemicals and subfecundity. Human reproduction. http://www.oxfordjournals.org/eshre/press-release/freepdf/den490.pdf

fluorinated compounds were also found in children jackets and mittens (see description above).

3.1.2.11 Night clothes (2005) – Austrian Standards Institute

In 2005, the Austrian Standards Institute tested 20 different night clothes – bedsheets, bedding, pyjamas, and nightshirts made of either cotton, cotton/polyester, cotton/modal, polyester, or silk. All 20 products were tested according to the Oeko-Tex Standard requirements. The analysis showed that:

- Two samples contained formaldehyde. One sample had a high content of formaldehyde of 121 ppm.
- Two samples contained one or more allergenouss colorants.
- Eight of the tested samples would not fulfil an Oeko-Tek 100 certification. (Öti, 2005)

3.1.2.12 Toxic childrenswear (2004) – Greenpeace

In 2004, Greenpeace tested 19 different pieces of textiles – all of them childrenswear and all of them Disney textiles. The textiles were bought in 19 different countries all over the world: 11 from European countries, the rest from Canada, the USA, Mexico, the Philippines, New Zealand, Argentina, China, and Thailand. The textiles were analysed for the content of phthalates (reprotoxic), alkylphenol ethoxylates (hormone-dirupting), organostannic compounds (suspected as human endocrine disrupters), lead (toxic, permanent lowering of IQ), cadmium (toxic and carcinogenic), and formaldehyde (carcinogenic and sensitizing).

The test showed that:

- All of the tested textiles contained phthalates. The sum of all phthalates ranged from 1.4 ppm to 320,000 ppm (i.e. 32 % by weight). The textiles with the very content of phthalates suggest that they have been printed with PVC-based plastisol prints.
- Alkylphenolethoxylates were found in all of the tested textiles in concentrations between 34 and 1700 ppm.
- Organostannic compounds were found in 10 of the 17 tested textiles in concentrations between 4 and 474 μg/kg (as a sum of all organostannic compounds).
- Lead was found in all of the 19 tested textiles in concentrations between 0.14 and 2600 μg/kg.
- Cadmium was found in 14 of the 19 tested textiles in concentrations between 0.0069 and 38 ppm (mg/kg).
- Formaldehyde was found in 8 of the 15 textiles tested in concentrations between 23 ppm and 1100 ppm. (Greenpeace, 2004).

3.1.3 Shoes

3.1.3.1 Environmental toxicants in leather shoes (2009) – SSNC

The Swedish Society for Nature Conservation (2009a) has tested 21 pair of leather shoes from all over the world for the content of different heavy metals and organic compounds. Most of the chemical compounds studied can be assumed to originate from the tanning, preservation, or dyeing of the leather.

Metals in various concentrations were found in all the shoes that were analysed. The report concludes that although there may be no immediate risk to the wearer of the shoes, they may pose a long-term health risk to humans

and the environment as shoes end up as waste and the metals and semi-metals they contain will eventually leach out and enter the natural environment.

Extremely high levels of trivalent chromium were found in the shoes. Chromium tanning accounts for some 80-85% of all tanning globally. When leather shoes and waste are incinerated or dumped in landfills, the most common and least toxic form of chromium, trivalent chromium, may oxidise into the highly toxic and carcinogenic hexavalent form. Highly toxic metals, such as arsenic, lead, and mercury, were also found in some shoes at concentrations higher than the levels found in untanned raw hide.

Organic compounds (such as chlorinated paraffins, azodyes, ortho-phenylphenol etc.) hazardous to health and the environment were detected in some of the shoes.

Two shoes contained azodyes, capable of forming carcinogenic amines.

A high level of the bactericide/fungicide 2,4,6-trichlorophenol was found in one shoe bought in Sweden. This compound is not easily degradable in natural environmental systems. It is also bioaccumulative, highly toxic and is presumed to disrupt the body's production of thyroid and sex hormones.

The highly allergenic compound dimethylfumarate, a mould inhibitor, was found in a Swedish shoe in a concentration corresponding to the threshold limit value set by the European Union on May 1, 2009.

Low concentrations of formaldehyde, a highly allergenic and possibly carcinogenic compound, were detected in some shoes.

3.1.3.2 Hazardous chemicals in plastic shoes (2009) – SSNC and Danish EPA

Both the Danish EPA and the Swedish Society for Nature Conservation have tested plastic shoes for content of hazardous chemicals. The Danish EPA (No. 103, 2009) has tested plastic clogs for the content of phthalates in the report "Two-year-old children's exposure to chemical substances" (in Danish) and the Swedish Society for Nature Conservation (2009b) has tested a long range of plastic shoes for the content of phthalates, tin organic compounds, PAHs, and heavy metals.

The survey from the Danish EPA

The Danish EPA investigated five different types of plastic clogs – the originals and different copies – and found phthalates in three of the five tested plastic clogs: One plastic clog containing 0.08 % DEHP (di-2-ethylhexyl phthalate), one containing 2.5 % DBP (dibutyl phthalate), and one containing 0.09 % DIBP (diisobutyl phthalate) and 1.6 % DEHP. Furthermore, the migration of the three phthalates to sweat was analyzed. This showed a migration of DBP and DIBP, but no migration of DEHP was detected.

A risk assessment was carried out in the report and the conclusion was that:

- The migration of DIBP from the plastic clog was not a risk in itself, but contributed to the total exposure of endocrine disrupting chemicals that two-year-old children are exposed to through different consumer products. The total exposure of endocrine disrupting chemicals constitutes a clear risk for two-year-old children.

- The migration of DBP from the plastic clog was in itself so high that use of the clog 4 hours a day (with bare feet) constitutes a risk of endocrine disrupting effects of the two-year-old children.

The Danish EPA plans to initiate another survey of phthalates in plastic shoes during 2010.

The survey from the Swedish Society for Nature Conservation
The Swedish Society for Nature Conservation tested 27 different pairs of plastic shoes from all over the world for different hazardous chemicals. 18 of the shoes were tested for content of different phthalates. The analyses showed that 17 of the 18 shoes that were tested contained one or more of the tested phthalates. The phthalate DEHP was present in various amounts in all 17 of these products. The highest content, 23.2%, was found in a pair of flip-flops from South Africa.

The analyses that were conducted also showed that several shoes contained PAH (polyaromatic hydrocarbons), tin organic compounds, and heavy metals. Two pairs of shoes contained mercury (highest level 0.1 ppm), and several contained lead (highest level 2220 ppm) and cadmium (highest level 117 ppm). 5 of the 27 pair of shoes had a content of lead over 100 ppm, which is the limit value of lead in products according to Danish legislation.

The study shows that the content of chemicals is not linked to where the shoes are manufactured or purchased. Neither is it possible to draw any conclusions regarding the chemical content based on the price of the product.

The report concludes that the results in the report indicate the need for tighter legislation at international level, at EU level, and at domestic level, leading to the phasing out of hazardous chemicals in products.

3.1.4 Shoe care products/impregnating agents

3.1.4.1 Fluorinated compounds in impregnating agents (2008) – Danish EPA

Many different types of proofing sprays are sold directly to the consumers as agents for after-treatment of different types of textiles especially in order to obtain a water- and dirt-repellent effect.

In recent years, it has been observed internationally and in Denmark that in certain cases, spray products for proofing of textiles result in acute respiratory illness and similar acute poisoning symptoms. During the period from 1991 to 2007, 84 cases of varying degrees of poisoning in connection with the use of textile proofing were identified in Denmark. It has not been possible to find any unambiguous reason for the cases of poisoning on the basis of the information about the compounds. Therefore, the Danish EPA initiated this project in order to investigate textile proofing sprays on the Danish market.

The survey concludes that most ascertained cases of poisoning that arise when textile proofing has been used involve products that are based on fluorocarbon compounds. It was not possible to determine the exact chemical structure of the fluorocarbon compounds that exist in textile proofing agents. The survey concludes that exposure to nonpolymerised or partly polymerised fluorocarbon compounds in rather high concentrations is possible.

Furthermore, the survey stresses that the use of textile proofing agents sprayed with propellant results in a considerable exposure to fine (< 1 μm) and ultra fine aerosols (nanoaerosols) (< 100 nm). The toxicological effect from inhaling nanoaerosols is not known yet. Existing information in the field cannot document that small aerosols in themselves are harmful. Aerosols can be carriers of (re)active chemical substances, e.g. fluorocarbon monomers but the importance is not known as the chemical structure of the substances could not be detected or procured in this project. (Danish EPA No. 98, 2008).

3.1.4.2 Hydrogenated carbons in shoe care products (2005) – Danish EPA

In 2004, different shoe care products were investigated by the Danish EPA. Organic solvents (hydrogenated carbons) were present in a large amount in all types of shoe care products (except the more solid products like grease and wax).

The exposure scenarios showed that there is a potential health risk in the form of irritation of the respiratory tract and effects on the nervous system when using products that contain large amounts of white spirits. Furthermore, the survey concluded that it cannot be ruled out that there may be effects in the form of irritation to the respiratory tract and effects on the central nervous system when using products that contain other solvents. (Danish EPA No. 52, 2005).

3.2 Toys

3.2.1 Test of toys on the German market (2009) – Öko-test

In 2009, the German test magazine Öko-test tested a wide range of different toys like hand puppets, plastic animals, noisy toys, railway systems, rocking horses, and toy buggies. The test showed that:

- Three out of nine hand puppets contained the carcinogenic colour aniline, and several of the hand puppets contained other colours that can release aniline. Halogenated organic carbons were found in 4 out of 9 hand puppets.
- A high content of PAHs (polycyclic aromatic hydrocarbons) was found in almost all of the 13 plastic animals tested. Chlorinated hydrocarbons, nonylphenol, organostannic compounds (e.g. dibutyltin), bisphenol A, brominated flame retardants like TBBPA and DecaBDE, as well as phthalates were found in many of the plastic animals.
- Chlorinated hydrocarbons and phthalates were found in some of the rocking horses.
- A high content of PAHs (polycyclic aromatic hydrocarbons) was found in 2 of 6 toy buggies. Furthermore, chlorinated hydrocarbons and phthalates were found in half of the toy buggies. (Öko-test 12, 2009)

3.2.2 Balloons (2009) – Öko-test

Öko-test tested 21 different types of balloons for the content of the carcinogenic nitrosamines and other nitrosable substances, and 2-mercaptobenzothiazol (2-MBT) and latex-proteins that can cause contact allergy. The results showed that:

- 12 of the balloons contained traces of nitrosamines and/or other nitrosable substances. 9 of the balloons contained either elevated levels or strongly elevated levels of nitrosamines and/or other nitrosable substances.
- 3 of the balloons contained the allergenic substance 2-MBT.
- 15 of the balloons contained latex-proteins, and 6 of the balloons contained only traces of latex-proteins. (Öko-test 2a, 2009)

3.2.3 PAHs in outdoor toys (2008) – Öko-test

Öko-test has tested different kinds of outdoor toys and found Polycyclic Aromatic Hydrocarbons (PAHs) that are known for their carcinogenic, mutagenic, and teratogenic properties in amounts between 1,000 and 10,000 μg/kg (1-10 ppm). In four outdoor toys the amount was higher than 10,000 μg/kg. (Öko-test 4, 2008).

3.2.4 Bindeez pearls (2007) – Danish Information Centre on Environment and Health

In 2007, the Bindeez pearls were withdrawn from the market all over the world as there were cases of children that fell down unconscious because they swallowed the pearls. The pearls turned out to contain a large amount of the chemical 1,4-butanediol which is considered as mutagenic. (Danish Information Centre on Environment and Health, 2007a).

3.2.5 Wooden toys (2005) – Danish EPA

In 2004, the Danish EPA investigated different surface treated wooden toys. The toys chosen for analysis and migration analysis were toys that small children (0-3 years of age) could put into their mouth. The analysis showed a long range of chemical substances and many of these substances were classified as hazardous to health – some of them are even classified as carcinogenic.

2-butoxyethanol that is harmful by inhalation, in contact with skin and if swallowed was found in concentrations that resulted in a daily burden closest to the tolerable daily intake. Therefore, one specific toy could perhaps cause health concern because of the amount of 2-butoxyethanol migrating from the wooden toy.

In general, the conclusion from this study is that none of the examined pieces of wooden toys is considered to pose a health risk to children mouthing the toys when the evaluation is based on individual substances.

However, during the use of the toy the child is exposed to several substances released simultaneously from the toy. The effects from the exposure to several chemicals at the same time are unknown. This means that a potential effect cannot be entirely be refused. (Danish EPA No. 60, 2005).

3.2.6 Formaldehyde in children tents (2004) – Danish EPA

In 2003, tents and tunnels for children (also to be used for indoor play) were investigated by the Danish EPA. The release of chemical substances from the tents and tunnels was analysed at room temperature and at elevated temperature.

A total of 46 substances or groups of substances was identified in the analyses. For most of the substances, the concentration declines with time as it would be expected. For some of the products, however, a higher concentration has been determined for certain substances after 28 days than after 10 days. This was the case for formaldehyde, dimethylformamide, xylenes and acetone.

The survey concludes that several of the substances, which are present in the tents and tunnels for children, are under suspicion of having carcinogenic, teratogenic, mutagenic, and allergic effects. Formaldehyde is present in one product in a concentration above the indoor limit value while two of the other products are close to the value. In a supplementary three days test of the emission of formaldehyde, no concentrations above the limit values were detected. As for the other substances, the emitted quantities are relatively small. None of these substances are present in concentrations, which will cause a potential health risk for children to play with the tested products. (Danish EPA No. 46, 2004).

3.2.7 Test of toys on the European market (2004) – Danish Information Centre on Environment and Health

The Danish Information Centre on Environment and Health tested 81 different toys together with the Danish Consumer Council. The toys were from 10 different European countries, but a large part from the Danish market (22 toys). The tested toys were popular toys (in 2004. The screening of the toys showed that almost all of the toys contain chemicals substances that are problematic to either health or the environment. Substances that are endocrine disrupting, carcinogenic, sensitizing, and problematic for the environment were found. The results of the test were that:

- Antimony, barium, chromium, lead, nickel, and cupper were found in the tested toys.
- 31 different toys were tested for the content of volatile organic compounds (VOCs). In all 114 different, VOCs were found! Of these 48 are classified as either problematic for health or the environment – for example cyclohexane, toluene, chloroform, chlorinated phenol, and limonene.
- 35 different toys were tested for the content of phthalates. DBP, DEHP, and DINP were found in the tested toys. In one case, the content of DINP was 400,000 ppm corresponding to 40% (w/w).
- Three of six toys were tested positive for the degassing of formaldehyde. The largest amount found was 115 ppm in a dress up set.
- Four of seven toys were tested positive for the content of brome and phosphor which indicates a content of brominated and phosphinated flame retardants. (Danish Technological Institute, 2004).

3.3 Electronics

3.3.1 Hazardous substances in games console components (2008) – Greenpeace

In 2008, Greenpeace tested for different hazardous substances in three different games consoles: Microsoft Xbox, Sony Playstation 3, and Nintendo Wii. The three games consoles were dismantled and a wide selection of the internal and external materials and components was analysed at the Greenpeace laboratory and at two independent laboratories. The games consoles were analysed for lead, cadmium, mercury, hexavalent chromium, certain brominated flame retardants, PVC, phthalates, and beryllium-containing alloys. The analysis showed that:

- All three consoles appeared to comply with the EU RoHS directive as the heavy metals lead, chromium (VI), cadmium, and mercury were not found in concentrations above the legal limits in all the tested components.
- However, just over half of all the analysed components were found to contain bromine at over 1% of the total composition of the material in almost all cases. Highest concentration of bromine in a component was found to be 13.8%. This indicates a widespread use of brominated flame retardants by all three manufactures. The specific type of flame retardants was not investigated further.
- PVC was identified in a number of flexible materials. Very high levels of phthalates were found in components from two of the consoles (10.6% and 27.5% of the total weight of the materials). Two of the phthalates (DEHP and DINP) not permitted in toys or childcare articles (in case of DINP only for products that can be placed in the mouth) were found in these very high levels.
- Two of the consoles contained beryllium-containing alloys (up to almost 2%) that are known carcinogens and can cause beryllium sensitisation and lead to a chronic beryllium disease (an incurable lung disease).

Greenpeace concludes it is clear that the producers have focused on reducing specific dangerous materials in specific components, but that there is still a clear room for improvement in order to meet the pledges of the producers on specific hazardous chemicals and materials. (Greenpeace, 2008).

3.3.2 PAHs in hair dryers and heart rate monitors (2008) – Öko-test

Öko-test has tested the grip of hair dryers and heart rate monitors (wrist watches) and found Polycyclic Aromatic Hydrocarbons (PAHs) that are known for their carcinogenic, mutagenic, and teratogenic properties in amounts between 1,000 and 10,000 μg/kg (1-10 ppm). In one hair dryer and in 3 heart rate monitors the amount was higher than 10,000 μg/kg. (Öko-test 4, 2008).

3.3.3 Hazardous substances in iPhones (2007) – Greenpeace

In 2007, Greenpeace tested Apples iPhone, as Apple has announced in May 2007 that their new products would be free from brominated flame retardants and PVC by the end of 2008. The iPhone was carefully deconstructed and a selection of 18 internal and external materials and components was

subsequently forwarded to an independent laboratory for analysis of chemical composition. The IPhone was analysed for lead, cadmium, mercury, hexavalent chromium, certain brominated flame retardants, PVC, phthalates, and other hazardous substances. The analysis showed that:

- All of the tested components appeared to comply with the EU RoHS directive as the heavy metals lead, chromium (VI), cadmium, and mercury were not found in concentrations above the legal limits in all the tested components.
- However, just over half of all the analysed components were found to contain bromine. In three cases, in concentrations above 1% of the total composition of the material. Highest concentration of bromine in a component was found to be above 10%. This indicates a widespread use of brominated flame retardants but none of the non-permitted brominated flame retardants according to the RoHS Directive was identified.
- The presence of antimony in four of the components raised additional concerns. Despite its well recognised toxicity, antimony (often used to enhance brominated flame retardant formulations) is not currently regulated under RoHS.
- A high level of chlorine and four different phthalates (which are not permitted in toys) were found in a total concentration of over 1.5%, suggesting use of PVC, in the headphone cables. (Greenpeace, 2007)

3.3.4 Toxic chemicals in computers (2006) – Greenpeace

In 2006, Greenpeace tested five different brands of labtop computer purchased in Europe for the content of hazardous substances. 40 different components from each of the five labtop computers were analysed for one or more of the following hazardous substances: lead, cadmium, mercury, hexavalent chromium, certain brominated flame retardants, and PVC. The analysis showed that:

- Lead was only identified in one of the labtop computers – in three out of 44 tested materials or components. Highest surface concentration was 13% lead.
- Chromium was identified in a number of components from all labtops. However, chromium VI was not identified in any of the five computer models.
- Bromine (an indicator of the possible presence of brominated compounds used as brominated flame retardants) was detected in about a quarter of the materials tested, at surface concentrations ranging from 0.19 to 9.4% by weight.
- The brominated flame retardants found were TBBPA and certain PBDEs. Highest concentrations were 0.165% of decaBDE, 0.204% of nonaBDE, and 0.262% of TBBPA.
- PVC was found in the coating of internal wires within three labtops. (Greenpeace, 2006)

3.4 Personal Protection Equipment

3.4.1 Working gloves (2009) – Öko-test

In 2009, the German test magazine Öko-test tested twenty different pairs of working gloves for the content of different hazardous substances like PVC,

halogenated organic compounds, heavy metals, PAHs, and phthalates. The results showed that 4 of 20 pairs contained PVC and these four pairs also contained a large amount of phthalates – either the phthalates forbidden in children toys or other types of phthalates. 14 of 20 pairs contained halogenated organic compounds – two of them contained triclosan. 11 of 20 pairs contained chromium, but it is not mentioned whether this is found as the allergenic chromium (VI). Finally, dibutyltin was found in three of the working gloves. (Öko-test 2b, 2009).

3.4.2 Children ski helmets (2006) – Austrian Standards Institute

In 2005, the Austrian Standards Institute tested the interlining of 15 different children ski helmets. The interlinings were made of fabric and foam. All 15 products were tested according to the Oeko-Tex Standard requirements. The analysis showed that:

- Three samples contained allergenous colorants.
- Four samples did not fulfil the requirements of the release of heavy metals. Lead and nickel were released in too high amounts (in one and four samples respectively).
- The results indicated that five helmets contained forbidden cleavable azo colorants.
- Eight of the tested samples would not fulfil an Oeko-Tek 100 certification. (Öti, 2006)

3.5 Construction products

3.5.1 Hazardous substances in wood preservatives (2009) – Ökotest

In 2009, the German consumer magazine Ökotest has tested the content of hazardous chemical substances in wood preservatives for both indoor and outdoor use. Of course, the solvent based wood preservatives were all containing volatile organic compounds (VOC), whereas the water based wood preservatives only contained trace amounts of VOCs. Some of both the solvent based and water based products contained aromatic organic solvents that can damage the nervous system.

Furthermore, both the solvent based and water based wood preservative products contained several allergenic/sensitizing ingredients such as cobalt, the anti-skinning agent 2-butanone oxime (which are also suspected as carcinogenic), isothiazolinone and/or formaldehyde releasers. Content of allergenic substances is of course a problem when the wood preservatives are applied but also if the substances are released to the indoor environment after they have been applied indoors. (Ökotest 4, 2009).

3.5.2 Phthalates in do-it-your-self products (2009) – Danish Information Centre for Environment and Health

In 2009, the Danish Information Centre for Environment and Health investigated different do-it-your-self products of plastic. Cables, cords, cable trays, drain pipes, and floors of vinyl were investigated for the content of PVC. Of all 89 investigated products, only three products did not contain PVC. All cables and cords contained phthalates as well as all floors of vinyl (but it was not investigated which phthalates and in which concentrations).

The phthalates contribute to the total exposure of phthalates that consumers are exposed to through the indoor environment. (Danish Information Centre for Environment and Health, 2009b).

3.5.3 Hazardous substances in floorings (2008) – Ökotest

In 2008, Öko-test tested PVC floorings from 14 different producers. The floorings were analysed for the presence of dibutyltin (DBT), tributyltin (TBT), other organostannic compounds, PAHs, phthalates, and heavy metals.

The test showed that 11 of the 14 floorings contained elevated (> 25 μg/kg) or strongly elevated (>μg/kg) amounts of DBT, TBT, or other organostannic compounds. DBT and TBT are pesticides which are used to prevent pest attack in the textiles. The compounds are also suspected as human endocrine disrupters. Five of the 14 floorings contained PAHs and other 7 floorings contained traces of PAHs. All of the 14 floorings contained phthalates in strongly elevated amounts (> 10,000 ppm = 1%), and 13 of the 14 floorings contained the phthalates that are restricted in toys in strongly elevated amounts. This is problematic for the indoor environment as the phthalates in several investigations of indoor climate have been found in problematic amounts in house dust.

Finally, the test showed that 3 of the 14 floorings contained cadmium, lead, and/or nickel. (Öko-test 1, 2008).

3.5.4 Phthalates in grout (2008) – Danish Information Centre on Environment and Health

In 2008, the Danish Information Centre on Environment and Health tested acrylic grout products that can be bought as do-it-your-self products. Eight out of nine products contained phthalates. The phthalates DEHP, DINP, and DIBP were measured in concentration up to 0.2 %, 10.1 %, and 3.9 % respectively. (Danish Information Centre on Environment and Health, 2008).

3.5.5 Phthalates in air fresheners (2007) – NRDC

In 2007, the American organisation National Resources Defense Council examined 14 different air fresheners. Twelve of the 14 air fresheners contained phthalates like DEP, DIHP, and DBP. The phthalates are probably added as part of the solvents in the perfumes. (NRDC, 2007).

3.5.6 Silicone based grout (2007) – Öko-test

Öko-test tested 20 silicone based grouts used for sanitary purposes. The test showed that:

- 15 of the grouts had a strongly elevated content of either tributyltin (TBT) and/or dibutyltin (DBT), i.e. concentrations above 2500 μg/kg. In four of the grouts the DBT content was elevated corresponding to concentrations between 250 and 2500 μg/kg. DBT

and TBT are pesticides which are used to prevent pest attack. The compounds are also suspected as human endocrine disrupters.
- 12 of the grouts used the sensitising dichloroisothiazolinone as fungicide (preservative).
- Four of the grouts contained between 1,000 and 10,000 ppm in total of the phthalates that are restricted in toys (i.e. DEHP, DBP, BBP, DINP, DIDP, and DNOP). (Öko-test 1, 2007).

3.5.7 Indoor paint (2007) – Öko-test

Öko-test tested 25 different white indoor wall-paints that are water based. The paints were tested for the content of formaldehyde, formaldehyde releasers (can cause allergic responses), volatile organic compounds (VOC), and the preservatives isothiazolinones (can cause allergic responses). The test showed that:

- Eight of the paints contained formaldehyde and/or formaldehyde releasers that can cause allergic responses and seven others only traces of formaldehyde and/or formaldehyde releasers.
- 21 of the paints contained the preservatives isothiazolinones.
- Seven paints contained either high amounts or traces of different VOCs. In three of these paints the perfume limonene was found. Limonene is also a substance that can cause allergic responses. (Öko-test 3, 2007)

3.5.8 Lacquers (2007) – Öko-test

Öko-test tested 23 different coloured lacquers for indoor use as well as indoor/outdoor use – 12 were solvent based and 11 were water based. The test showed that:

- Two of the solvent based lacquers had a strongly elevated content of VOCs (volatile organic compounds) i.e. more than 440 g/liter. Nine of the solvent based lacquers had an elevated content of VOCs of more than 330 g/liter. All of the water based lacquers only contained traces of VOCs.
- Problematic organic compounds like limonene, terpenes, aromatic compounds, and naphthalene were found in all of the solvent based lacquers. Six of the solvent based lacquers contained more than 1,000 ppm of aromatic compounds. Problematic organic compounds like limonene, glycols, and butoxyethanol were found in six of the 11 water based lacquers.
- Of other problematic substances, cobalt was found in all of the solvent based lacquers and butanonoxim, which is considered as carcinogenic, was found in 10 of the solvent based lacquers. Finally, lead was found in one of the solvent based lacquers. In comparison, only three of the 11 water based lacquers contained cobalt. One of the water based lacqers also contained formaldehyde (allergenic and carcinogenic) and formaldehyde releasers. (Öko-test 4, 2007).

3.5.9 Construction products (2007) – German Federal Environment Agency

The German Federal Environment Agency has made a study with the purpose to set environment and health requirements for construction

products. In this study 50 construction products were tested in emission test chambers: 7 acrylic and 6 silicone sealants, 6 paste-like synthetic resin plasters, 13 wood based products, 4 adhesives, 5 lacquers, 6 wall paints, and 3 further construction products. VOC emissions were tested on the 1st, 3rd, 10th, and 28th day. The results showed that all of the 50 tested construction products emitted VOCs – and all but 5 of the 50 tested products still emitted VOCs on the 28th day – even though the VOC emission was lower. (Umwelt Bundes Amt, 2007)

3.5.10 Indoor climate (2006) – Danish EPA

Most of the previous reports on consumer products published by the Danish EPA conclude that the release of chemicals from one single product does not give rise to concern, but the collective burden of chemicals from all products used indoor e.g. in the bed room, in the family room, the kitchen, or the children's room, may be a problem. Therefore, the Danish EPA investigated this concern in 2005.

The potential indoor concentrations of eight selected volatile chemicals (phenol, formaldehyde, acetaldehyde, benzene, toluene, xylenes, styrene, limonene) were estimated in three model rooms: a hall/utility room, a kitchen/family room, and a children's room. The survey concluded that the highest concentrations in a home are likely to occur in the children's room. The reason is that the children's room normally is smaller than most other rooms in the home and it contains many products which may release chemicals to the air.

The worst case calculations show that the total burden of phenol, acetaldehyde, toluene, and limonene in a children's room may be close to the highest tolerable daily burden for children. The calculations also show that the concentrations of formaldehyde and xylenes in a children's room easily will be higher than the tolerable daily intake.

Furthermore, the daily intake of DEHP, brominated flame retardants, and perfluoroalkylated compounds (PFAS) via dust in the homes was investigated. Brominated flame retardants and PFAS do not seem to pose a risk but if a small child eats some dust when crawling on the floor and subsequently put their fingers in their mouth, then the content of DEHP in the dust in our homes results in a daily intake that is very close to the tolerable daily intake of DEHP if the intake of DEHP with the food is added. (Danish EPA No. 75, 2006).

3.6 Other relevant examples/"horizontal category"

3.6.1 Endocrine disrupting substances that two-year-old children are exposed to (2009) – Danish EPA

Most of the previous reports on consumer products published by the Danish EPA conclude that the release of chemicals from one single product does not give rise to concern but the collective burden of chemicals from all products that children are exposed to may possess a problem. Therefore, the Danish EPA in 2008 initiated a project with the purpose to investigate the sum of endocrine disrupting chemicals that two-year-old children are exposed to via consumer products.

As new research has shown that a dose-addition approach can be used for assessing the risk of exposure to phthalates and other antiandrogene[35] substances, this approach was used in the risk assessment in the project. In other words, it is assumed that if two different substances both have the same effect on humans (in this case blocking the action of androgens (the hormones responsible for male characteristics)), the dose or the exposure to these types of chemicals can be added.

The project listed different exposures that former have been measured for different types of consumer products that two-year-old children are exposed to. Exposure to endocrine disrupting chemicals like DEHP, DBP, DINP, DIBP, BBP, PCB's, parabens, and bisphenol A through the food and the indoor climate was also added.

The conclusion of the project was that there definitely is a health risk involved when looking at the worst case exposure to endocrine disrupting chemicals for two-year-old children. Some single exposures are critical in this respect: For example exposure to phthalates in plastic clogs, exposure to PCB's through the indoor climate and food, exposure to DEHP through indoor climate and food, and exposure to parabens through cosmetic products. (Danish EPA No. 103, 2009).

[35] An antiandrogen is a substance that blocks the action of androgens, the hormones responsible for male characteristics.

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