Chemical requirements for toys

bmask
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This study explores the toy area in depth when it comes to chemical requirements and tries to give examples of requirements that could be introduced in order to protect children from harmful health effects. This has been done by a review and a discussion of the available scientific literature on the 'necessary or needed' levels of requirements of specific chemicals to ensure the safety of children when using toys. Chemical risk assessments for individual substances have not been performed in this project. The suggested 'necessary or needed' levels of specific chemicals in toys are based on existing chemical risk assessments on different specific chemicals.

The report is divided into different subjects/groups of chemicals, and for each subject/group of chemicals first the existing legislation in the Toy Safety Directive is described as well as the normative requirements in the EN 71 series, and finally different literature has been presented and discussed for each subject/group of chemicals. The chemicals and groups of chemicals discussed in this report (chapter 3) are:

1. SVHCs including CMRs, PBTs, vPvBs and others (e.g. EDCs)
    - SVHCs in general
    - PAHs
    - BPA
    - Phthalates and other plasticisers
    - Nickel
    - Formaldehyde
    - Phenol
2. Elements
    - Lead
    - Cadmium
    - Antimony
    - Arsenic
    - Mercury
    - Barium
3. Sensitisers – fragrances
    - Fragrances
    - Isothiazolinones
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    - Sensitisers in general
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    - Diantimoy trioxide

    - Flame retardants in general
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6. Monomers
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8. Preservatives and biocides
9. N-nitrosamines and N-nitrosatable substances
10. Other substances
    - Substances classified as very toxic, toxic, harmful, corrosive, irritative, etc.
    - PFOS/PFOA
11. Nanomaterials
12. Use of Food Contact Materials Regulation for toys

The suggested chemical requirements are listed in one long table in chapter 5 of the report (see Table 25).

The suggested requirements (Table 25 in chapter 5) are a substantial expansion of the chemical requirements in the new Toy Safety Directive. However, the chemical requirements listed represent the "gaps" in the existing legislation that should be closed from a risk assessment perspective.

It has not been a purpose of this study to discuss in which context the proposed chemical requirements for toys should be made – i.e. whether the chemical requirements could be introduced in a new version of the Toy Safety Directive or whether the chemical requirements could be included in another legal framework for chemicals in articles/products. Different options for this were discussed in the previous studies commissioned by The Consumer Council at the Austrian Standards Institute.

In this report the requirements (limit values) have been suggested without looking at the specific materials or kind of toys. Of course some of the requirements may only be relevant for certain types of materials. E.g. phthalates and other plasticisers are only relevant for plastic materials. This subject does, however, deserve much more discussion and description but it was not possible to go to this level of detail in this study.

Finally, it should be mentioned that it was not possible in this study to go into detail with every relevant type of chemical/every relevant substance. This study has focused on the substances being discussed most intensively.

1 Introduction

The current regulatory framework in the European Union to protect consumers from chemicals contained in consumer articles has been found insufficient in previous review studies commissioned by The Consumer Council at the Austrian Standards Institute.

In this introduction, a summary of these studies will be presented and their conclusions will be compared to the European Commission's future intentions for chemicals in products (see chapter 1.1 "Chemical requirements for consumer products").

The area of toys is an example of consumer products where chemical requirements are actually set, but are judged still to be too inadequate by various organisations (see chapter 1.2 "Chemical requirements for toys"). This study explores the toy area in depth when it comes to chemical requirements and tries to give examples of requirements that could be introduced in order to protect children from harmful health effects.

1.1 Chemical requirements for consumer products

The current regulatory framework in the European Union to protect consumers from chemicals contained in consumer articles has been found insufficient in two former review studies commissioned by The Consumer Council at the Austrian Standards Institute (ASI) and funded by the Austrian Ministry for Labour, Social Affairs and Consumer Protection: "Chemical requirements for consumer products" – Part I and Part II (Poulsen et al., 2010; Poulsen and Strandesen, 2011).

1.1.1 Summary of the two former ASI Consumer Council studies (part I and II)

The aims of the two former studies prepared for the ASI Consumer Council (Part I and II) were to (ANEC Position Paper, 2011):

- Review the chemical requirements in selected product legislation (19 different in all). Some of them were:
  - General Product Safety Directive
  - REACH
  - Toy Safety Directive
  - Personal Protective Equipment Directive
  - RoHS
  - Food Contact Materials legislation
  - Packaging and Packaging Waste Directive
  - Ecodesign requirements for Energy-related Products Directive
- Identify and discuss the gaps in this European legal framework.
- Review in greater detail the provisions of REACH with respect to consumer products/articles.
- Make recommendations for addressing chemicals in products in a consistent manner through changes in the European regulatory framework.

The two studies revealed the following common deficiencies in the selected consumer products regulation:

1. **In general few chemical requirements in consumer product regulation**
   When it comes to chemical restrictions in the European consumer products regulation, they are either non-existent or limited to a few chemicals or general statements. Of the 19 reviewed legislations the Food Contact Materials regulation is the only regulation relating to articles which establishes a positive list system.
   The Toy Safety Directive is not sufficiently ambitious (e.g. high content of CMR substances is allowed and several other categories of dangerous substances are not even mentioned).
   In REACH consumer articles are hardly addressed.
2. **Use of weak phrases instead of specific limit values**
   Weak phrases such as 'must be safe' are often used. This is a problem since companies have difficulties in understanding how they should secure compliance.
3. **Ad hoc based regulation**
   Meaning that chemicals are only regulated when they have proven to be problematic. The reverse approach – i.e. the use of positive lists – is encouraged.
4. **Only a small number of products/chemicals covered by regulations**
   Existing regulation only covers a small amount of the products/chemicals on the market. This is partly due to the fact that creating/amending regulations is a time-consuming task.
5. **Insufficient market surveillance of consumer products**
   A more efficient market surveillance system is needed – i.e. a system that not only checks for compliance, but also reports back to decision makers how to amend the regulations.
6. **Multiple exposures not considered in all cases**
   The Medical Device Directive considers multiple exposures and to some extent also the Food Contact Materials Regulation. However, multiple exposures are not considered in the rest of selected regulations. This creates a significant underestimation of the risk associated with the amount of chemicals in the different products.
7. **Combination effects are not considered**
   Combination effects are not considered, however, this issue is even more complex than multiple exposures since it requires the knowledge of how chemicals interact with each other. This information is not available.
8. **Lack of information on chemicals in consumer products**
   Today we only have profound knowledge of very few of the more than 110,000 chemicals used in today's manufacturing practices. This will slowly change as REACH is implemented, but for many years to come our toxicological knowledge of the majority of chemicals is limited.
9. **Nanosubstances are currently not regulated properly**
   A large number of challenges are related to the use and regulation of nanosubstances, among these is the lack of suitable measurement methods and proper toxicological evaluations. This makes it difficult to regulate nanosubstances in a proper manner.
10. **Limitations in the regulatory frame**
    A major limitation in the regulatory framework is the general lack of comitology procedures that allow for a quick and easy amendment of requirements in the different Directives. Only the new Toy Safety Directive and the revised RoHS Directive make use of comitology procedures, however only in certain areas. For example, the Toy Safety Directive has a comitology procedure in place but only for toys intended to use by children below the age of 36 months and for mouthed toys. When a comitology procedure is not in place, the amendment of the Directive becomes a long and tedious process.

The aforementioned studies demonstrated that the current European legal framework concerning chemicals in products is insufficient. There is thus a lack of insurance for a high level of safety to consumers and the environment. These studies concluded that the adoption of a new regulatory framework for chemicals in consumer products is necessary.

The options for the regulatory framework were discussed and the following possibilities were discussed:

a. Expand/revise existing product directives to (adequately) cover chemicals in all relevant consumer products.
b. Introduce specific chemical legislation for every sector following the RoHS model with legislation targeted the sector of the electronic products sector.
c. Adopt a horizontal directive for chemicals in products.
d. Extend REACH to address chemicals in consumer products in a comprehensive way.
e. Extend the Energy-Related Products (ERP) Directive to include generic and specific chemical restrictions, in principle, for all product groups.

It was concluded that the option of expanding the ERP Directive to cover restrictions for chemicals in all products represented the best possibility for combining a horizontal approach for chemicals 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 anyway be the case for any option chosen. The other framework suggestions discussed would either require an entire new Directive/Regulation or major changes in existing Directives, having no comitology procedures in place. Both of these aspects would result in very lengthy procedures.

The main conclusions were therefore to:

- Generally strengthen the chemical requirements in product legislation as chemical requirements are few or in some cases non-existent.
- Use a horizontal approach for setting chemical requirements, i.e. generic chemical requirements, by the use of, for example, positive lists, and at the same time, allow for exemptions if a risk assessment conducted by a scientific committee, e.g. SCHER, considers the use of a specific substance in a specific product/material for safe.
- Introduce a comitology procedure in all product legislations so it will be possible to quickly adopt new chemical requirements or alter existing limit values when new information is available.
- Strengthen the market surveillance of consumer products.

1.1.2 Future intentions for chemicals in products

The European Commission has made a draft proposal for a General Union Environmental Action Programme to 2020 called “Living well, within the limits of our planet”. This programme is based on the precautionary principle and preventive action. One of the priority objectives listed is “Priority objective 3: To safeguard the EU citizens from environmental–related pressures and risks to health and wellbeing”. Under this priority objective no. 3 the following statements are listed (European Commission, 2012a):

- “Horizontal chemicals legislation (REACH and CLP) provides baseline protection for human health and the environment…

However, there is still uncertainty about the impacts on human health and the environment from combined effects of different chemicals (mixtures), nanomaterials, chemicals that interfere with the endocrine (hormone) system (endocrine disruptors) and chemicals in products… The EU will further develop and implement approaches to address combination effects of chemicals and safety concerns related to endocrine disruptors and set out a comprehensive approach for minimising adverse effects of hazardous substances, including chemicals in products".

- "In order to safeguard the EU citizens from environmental-related pressures and risks to health and wellbeing, the programme shall ensure that by 2020" (six points are listed – one of them is):
    - "the combination effects of chemicals and safety concerns related to endocrine disruptors are effectively addressed, and risks for the environment and health associated with the use of hazardous substances, including chemicals in products, are assessed and minimised".

According to this draft proposal, it is the intention of the European Commission to minimise the adverse effects of chemicals in products. In order to reach the intentions described in this document, actions need to be taken to make sure that the chemical requirements in consumer products in general are strengthened.

In June 2013, the European Parliament, European Council and European Commission reached a provisional agreement on the EU's 7th Environment Action Programme (7EAP) which confirms the need to take action on chemicals in products, including imported products (Chemical Watch, June 2013).

1.2 Chemical requirements for toys

This project is focusing on one area of consumer products – namely toys. The focus is to look at which chemical requirements should be set for toys to ensure that children are not exposed to dangerous chemicals. The area of toys has been selected as this is a product group where chemical requirements are already set, but these have been judged to be inadequate.

1.2.1 Hazardous chemicals found in toys

An American article about toxic chemicals found in toys sums up the problem very well (Becker et al., 2010):

> "There are two major reasons why toys contain toxic chemicals: lack of regulation and violation of existing regulations".

Several reports describe problematic chemicals found in toys. Some of these are mentioned below. Common for the reports mentioned is that they all come to the conclusion that the number of hazardous chemicals used in toys (or in products for children) is large.

Kalberlah et al., 2011

In a report from the German Federal Environment Agency (Kalberlah et al., 2011), a list of substances of concern in toys has been made. The list was prepared by use of national statistics, test reports, international reports, own studies and personal communication with qualified staff from laboratories. The list counts in all 70 different substances or groups of substances. Substances of concern are defined as substances classified as:

- CMR (category 1A, 1B and 2)
- Very toxic
- Respiratory and skin sensitisers
- Endocrine disruptors
- PBT and vPvB
- Persistent
- Bio-accumulative
- Dangerous for the environment

The report compared the list of substances of concern in toys with substances being regulated in toys (old Toy Safety Directive (88/378/EEC) and new Toy Safety Directive (2009/48/EC), REACH restrictions from Annex XVII, the German Consumer Goods Ordinance and the EN 71 series of standards).

The report states that 33 of the 70 substances of concern are regulated in toys (new Toy Safety Directive, the toy standards (EN 71-3 (1994) and 71-9 (2007), REACH and the German Consumer Goods Ordinance). Some of the non-regulated substances mentioned are:

- Dyes/colours, e.g. p-Anisidin and several disperse dyes
- UV-stabilisers, e.g. benzophenone
- Other phthalates currently not regulated, e.g. DIBP, DEP
- Several solvents, e.g. cyclohexanone, dichlormethane, 2-ethoxyethanol, formamide, methanol, tetrachlorethylene, triclhorethylene, phenol, toluene, xylene
- Nonylphenol and octylphenol
- PAH

The German study therefore concludes that many other substances of concern that can be found in toys are not adequately regulated.

Swedish Chemicals Agency, 2012

A report from the Swedish Chemicals Agency (2012) has, by use of an extensive literature survey, compiled a long list of chemicals that have been identified in toys (according to published literature). The report concludes that thousands of substances have been identified with possible connections to toys, i.e. that the substances are used in the production processes, the raw material production or are added to the toys in order to give certain properties (e.g. colours, fragrances, flame retardants, etc.). 388 of these substances are classified according to the CLP Regulation.

The study shows that the majority of the classified substances according to the CLP Regulation are related to chemicals used during production (i.e. process chemicals), such as monomers for polymer production and vulcanization chemicals. Process chemicals may be traced in the end product (the toys) and pose a risk to the users. Some substances are also related to raw material production, e.g. pesticides used in agriculture. A minor part of the identified

chemicals (149 of the identified 388 chemicals) is, however, used in order to give properties to the material in the product and can therefore be found in the final product – the toys. These substances relate to the following functions:

- Preservatives and biocides, e.g. triclosan, pentachlorphenol
- Colorants (pigments and dyestuffs), e.g. disperse dyes
- Plasticizers, e.g. benzylbutyl phthalate, diallyl phthalate
- UV and heat stabilizers, e.g. ethylene glycol, methenamine
- Viscosity controlling agents, e.g. phenyl glycidal ether, cyclohexanone
- Flame retardants, e.g. antimony trioxide, TCEP (tris(2-chloroethyl) phosphate), tri-o-cresyl phosphate
- Fragrances, e.g. citral, xylene musk
- Anti corrosives, e.g. cyclohexanone
- Solvents, e.g. 2-phenoxyethanol, phenol, acetamide, isopropyl alcohol, 2-butoxyethanol,

The authors' recommendation to industry is to ask for information in the supply chain of toys on which chemicals that have been used to provide the functionalities of the product and where the most toxic chemicals can be expected: biocides/preservatives, colouring agents, stabilizers, solvents, fragrances, plasticizers and anti corrosives.

The report concludes that there are several data gaps in the survey for the majority of the substances identified and those need to be further compiled and assessed in order to minimise the potential risks from chemicals in toys (Swedish Chemicals Agency, 2012).

US EPA, 2013

The US EPA has in 2013 released information on more than 7,600 chemicals and their uses in the so-called CDR database (Chemical Data Reporting). According to the US Toxic Substances Control Act (TSCA), companies that manufacture or import chemicals in production volumes above 25,000 lb (about 11,440 kg) are required to provide information on chemicals used in children's and other consumer products. It is therefore possible, by use of this database, to get information on the number of chemicals that are used in children's products in the US (as a search can be performed specific for substances that are used in products intended for children). According to this CDR database (updated April 4 2013), 539 different chemicals are used in children's products (such as toys and other products for children) (US EPA, 2013).

The database lists the chemicals used in products intended for children by chemical name and CAS number. There is no information about the type or function of chemical (i.e. solvent, plasticiser, etc.) and there is no information about the hazardous properties of the substances. It has not been possible to go through all 539 chemicals in this database in order to check which hazardous chemicals that are used in products intended for children, but are not already being regulated through the Toy Safety Directive.

RAPEX, 2012

According to the latest RAPEX annual report (RAPEX, 2012), toys are the area where second most notifications regarding risks to consumers have been notified. In 2012, toys represented 19% of all 2,278 notifications (clothing and textiles represented the largest part of the notifications in 2012 with 34%).

According to the 2012 annual report, 58% of all notifications have China (including Hong Kong) as the manufacturing country of origin. The reason for the notifications is mostly due to injuries (25% of the notifications), but chemical risks are the reason for the second highest number of notifications (18% of all notifications). However, these notifications on toys are probably mainly related to non-compliance with existing thresholds and not based on risk assessments from Member States.

A similar picture seems to continue according to the RAPEX statistics prepared for January, February, March and April, 2013.

1.2.2 Critique of the new Toy Safety Directive

The old Toy Safety Directive (Directive 88/378/EEC) has been replaced by the new Toy Safety Directive (Directive 2009/48/EC), and the chemical requirements of the new Directive – which have been expanded in comparison with the old one – entered into force on July 20, 2013.

In the project "Chemical requirements for consumer products" – Part I (Poulsen et al., 2010), the Toys Safety Directive was discussed. Toys are actually one of the consumer products where several chemical requirements are actually set, but the area is still being discussed intensely by several consumer organisations for not being strict enough (even with the new chemical requirements set in the new Toy Safety Directive).

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. Aspects such as the followings are addressed by BfR (BfR No. 29, 2008; BfR No. 51, 2009):

- Unsafe toys are often found on the market, despite the fact that the manufacturers must confirm their compliance with the safety requirements by using the CE mark (see the RAPEX notifications above).
- The migration limits for certain elements have been raised in the new Toy Safety Directive compared to the old Toy Safety Directive.
- Allergenic substances are not sufficiently addressed.
- BfR questions why the rules that exist for FCM (Food Contact Materials) have not been transferred to toys – e.g. release of CMR substances must not be detectable.

Furthermore, Germany stated in 2010 – a year after the new Toys Safety Directive was adopted – that Germany will lobby for a tightening of limits for chemicals before the rules become effective (20 July 2013 for the new chemical requirements). In January 2011, Germany asked the Commission for permission to maintain their more stringent current requirements on five elements (lead, arsenic, mercury, barium and antimony) as well as for nitrosamines and nitrosatable substances released from toy material. Germany asked for permission to retain their requirements beyond the date of entry into force for the chemical requirements (i.e. 20 July 2013 for Annex II part III to the new Toy Safety Directive). The Commission accepted the German request only partly (for lead and barium) and only temporarily (until 20 July 2013). However, the Commission accepted the German request on nitrosamines and nitrosatable substances without a deadline. This means that

Germany is allowed to continuing using their more strict requirements on nitrosamines and nitrosatable substances in toys, but not on lead and barium (Decision 2012/160). This means that Germany, now after July 2013, refers partly to the existing European limits in the new Toy Safety Directive and partly to German legal provisions (on nitrosamines and nitrosatable substances).

Germany wants to strengthen restrictions on heavy metals, allergenic substances and carcinogenic, mutagenic and toxic to reproduction (CMR) substances. The Federal Risk Assessment Institute (BfR) has repeatedly warned of loopholes in the new rules (as mentioned above). In 2010 Germany's product testing group, Stiftung Warentest, revealed that two thirds of a sample of 50 toys tested by the organisation contained high concentrations of chemicals such as formaldehyde and heavy metals. Seven products should have been withdrawn from the market even though all tested products contained the CE label that stands for compliance with existing EU product safety rules (ENDS Europe, 2010).

Even the European Parliament has discussed the chemical requirements of the new Toy Safety Directive. In December 2010, the European Parliament debated the new Toy Safety Directive[1]. The following issues were raised (European Parliament Debate, 2010):

- New expert opinions have concluded that the strictest limit values for heavy metals are not strict enough, given the latest scientific knowledge. We need to change the limit values in the legislation.
- Latest information on PAHs may make it necessary to amend the limit values. This calls for a rectification of the legislation.
- It is important that CMR substances are reduced to a minimum in children's toys.
- Market supervision is another problem. Market supervision should ensure that only toys that truly satisfy the safety standards reach the market. This is not always the case.
- The latest RAPEX reports also underline problems concerning market surveillance for toys. There are still a large number of toys entering the EU market that pose a high risk to the most vulnerable consumers.
- A European safety mark that is truly reliable and monitored by third parties should be introduced.

Three years after the new Toy Safety Directive was adopted ANEC (The European consumer voice in standardisation) and BEUC (The European Consumer's Organisation) made a position paper with the title: "EU Subgroup on chemicals in toys fails its mission". In this critical review they criticise the following aspects of the new Toy Safety Directive (ANEC/BEUC, 2012c):

- The directive lacks a comitology procedure which would allow the adoption or modification of limits for all kinds of toys and all kinds of substances.
- Requirements for CMR substances are not strict enough.
- Requirements for allergenic fragrances are deficient as in some cases only labelling is required.
- Sensitizers other than allergenic fragrances are not covered.

[1] In July 2010 SCHER published a scientific opinion on the "Evaluation of the migration limits for chemical elements in toys" (SCHER Opinion, 2010a). This opinion started the European Parliament debate in December 2010.

- Some of the limits for elements have been increased and are questionable.
- Endocrine disrupting chemicals are not addressed.
- Persistent, bio-accumulative and toxic chemicals (PBT) as well as very persistent and very bio-accumulative (vPvB) chemicals are substances of very high concern and should have been prohibited.
- Chemicals falling into other classes of dangerous substances such as very toxic, toxic, harmful, corrosive, irritant or non-classified (or not yet classified), which pose health hazards, are not covered or only in broad terms by the "toys must be safe" phrase.
- Materials used in toys for children under 3 years should follow the same principles of the legislation concerning plastic materials in contact with food, i.e. only approved substances should be allowed to be used.

ANEC and BEUC conclude that after 2 years of operation of the European Commission's subgroup on chemicals in toys, the subgroup has failed its mission: "Very little progress has been made and it is unlikely that things will change to the better. From the date of its full implementation in July 2013 the revised Toy Safety Directive will still permit the use of many dangerous substances, such as carcinogenic, allergenic and hormonal disrupting substances, despite the potential risks to children's health" (ANEC/BEUC, 2012c).

1.2.3 Summary of the former ASI Consumer Council study (part III)

The first two ASI Consumer Council studies "Chemical requirements for consumer products" Part I and II were followed by a third study – Part III (Strandesen and Poulsen, 2012). The purpose with this study was a first attempt to propose chemical requirements for eight different consumer products areas (e.g. food contact materials, packaging materials, clothing, and products for children). As several product areas were covered there was no in-depth investigation of each area, but more general suggestions were made.

In this former ASI Consumer Council study (Part III), the area "products for children" was evaluated and the following changes (see Table 1) were suggested as an expansion of the Toy Safety Directive. In general, it was suggested that the Toy Safety Directive was expanded to cover all products which are intended to come into contact with children, i.e. also including products such as child care products.

Furthermore, it was once again emphasised that the following elements should be used to strengthen the product regulation in general:

- Introduce a comitology procedure in all product legislations.
- Strengthen the market surveillance of consumer products.
- Generally strengthen the chemical requirements in product legislation.

Table 1: Additional chemical requirements to be included in the Toys Safety Directive – suggestion made in the former ASI Consumer Council study (Part III) (Reference: Strandesen and Poulsen, 2012).

Former suggested additional chemical requirements to be included in the Toys Safety Directive (TSD)	
Based on the Poulsen et al. (2010), BfR No. 29 (2008) and Danish national regulation regarding phthalates in toys (DK Statutory Order No. 855, 2009).	
Coverage	1) The TSD should be expanded to cover products which are intended to come into contact with children, thus also including products such as child care products (diapers, high chairs, etc.). The TSD should change name to the 'Products for Children Directive'.
The entire product	2) The content allowed limits of CMR substances should be lowered to 0.01%. 3) Substances, that are classified as very toxic, toxic or endocrine disrupters must not be used. 4) Allergenes should not be allowed. The content level should be discussed further. Maybe a reduction of the 100 ppm level is needed (at least for the most extreme sensitizers). 5) Migration levels for lead should be lowered again (as lead is a non-threshold chemical). 6) Potential nickel content shall comply with the restriction on nickel in REACH Appendix XVII (restriction of the use of nickel in jewellery and personal articles that come into contact with the skin), but should cover all hand-held products for children. 7) The allowed content level of PAHs should be lowered in line with the German restriction dossier, i.e. 0.2 mg/kg. 8) It should not be allowed to use phthalates (defined as esters of o-phthalic acid) as substance or as constituents in chemical products – in the manufacture of products for children in concentrations above 0.05 % by weight. 9) The flame retardants TCEP, TCPP and TDCP should not be present in detectable levels in products for children. Finally, the suggestions for flame retardants in general could be used as well (see section on flame retardants).
Potential further restrictions	10) The regulation (or selected elements from the regulation) for food contact materials could be applied to 'products for children' as well (for products for children under the age of 36 months and products, which are to be placed in the mouth). 11) Requirements for specific materials mentioned elsewhere could be applied to 'products for children' as well.
Comitology procedure	A comitology procedure should be expanded to cover all products for children and not just for product for children under the age of 3 or for mouthed products.
Surveillance system	Ensure that adequate inspection and control measures are carried out. Random tests should be an integrated part of the system. The point of the surveillance system is of course to gather information on chemicals which need to be adjusted in the legislation (limit values, new substances, etc.). For example, new entries in the Candidate list could automatically be evaluated for their appropriateness to be restricted in this area.

2 Purpose and methodology

2.1 Purpose of this study

The purpose of this study is to go into further details regarding the specific requirements needed for toys to make sure that children are not exposed to chemicals in a manner that causes health concerns. This has been done by a review and a discussion of the available scientific literature on the necessary or 'needed' levels of requirements of specific chemicals to ensure the safety of children when using toys.

It has not been a purpose of this study to discuss in which context the proposed chemical requirements for toys should be made – i.e. whether the chemical requirements could be introduced in a new version of the Toy Safety Directive or whether the chemical requirements could be included in another legal framework for chemicals in articles/products. Different options for this were discussed in the previous studies (see section 1.1.1 "Summary of the two former ASI Consumer Council studies (part I and II)", including an expansion of REACH, an expansion of the existing directive, introduction of a sector specific legislation, introduction of a horizontal directive for chemicals in products, as well as the suggestion that seemed most promising: expansion of the Energy-Related Products (ERP) Directive to include generic and specific chemical restrictions, in principle, for all product groups. These aspects are only covered very briefly in chapter 4 "General discussion".

2.2 Methodology used

This study has been performed as a desk-top study meaning that a comprehensive search was made for relevant literature which discusses the issues of strengthening the chemical requirements for toys or specific groups of chemicals relevant for toys (such as e.g. phthalates, elements, allergenic substances, etc.).

This search resulted in a list of more than 80 documents discussing the area of chemicals, or use of specific groups of chemicals, in toys or in consumer products in general. It has not been possible to review all these documents in this study, but the most important documents have been included in the review. The documents have been selected so they cover different chemical groups and different chemical aspects with respect to toys. Furthermore, the choice of documents to review has been discussed with the supervisor of this project: Dr. Franz Fiala, from The Consumer Council at the Austrian Standards Institute.

In short, the methodology used in this report has been to gather existing information regarding 'necessary or needed' levels of specific chemicals in toys in order to ensure the safety of children when using them. Chemical risk assessments for individual substances have not been performed in this project. The suggested 'necessary or needed' levels of specific chemicals in toys are based on existing chemical risk assessments on different specific chemicals. It

has not been a task in this study to verify the existing chemical risk assessments.

The report is divided into different subjects/groups of chemicals, and for each subject/group of chemicals first the existing legislation in the Toy Safety Directive is described as well as the normative requirements in the EN 71 series, and finally different literature has been presented and discussed for each subject/group of chemicals. This was done with the intention of using this information to make a final list of chemical requirements that could be used as legal requirements for toys in the future. The result of this report is therefore a compilation of different views and aspects when it comes to setting chemical requirements for specific chemicals found in toys.

3 Review: Chemical requirements

This review is a compilation of different literature/discussions of different chemicals/groups of chemicals. Relevant discussions and opinions have been listed for each chemical/group of chemicals. Based on the literature, a conclusion has been made for each chemical/group of chemicals. The conclusion contains the following aspects:

- Which type of limit value should apply (e.g. migration or content-based)?
- Which limit value should be used for the chemical/group of chemicals?
- Which test method should be used?

This review part is divided in the following sections:

1. SVHCs[2] including CMRs[3], PBTs[4], vPvBs[5] and others (e.g. EDCs[6])
2. Elements (heavy metals)
3. Sensitisers - Fragrances
4. Flame retardants
5. Colourants and primary aromatic amines
6. Monomers (migration)
7. Solvents (migration and inhalation)
8. Preservatives and biocides
9. N-nitrosamines and N-nitrosatable substances
10. Other substances
11. Nanomaterials
12. Use of FCM legislation for toys

Each of the 12 sections may be divided in different sub-sections, e.g. one sub-section for each element. For each section (and sub-section) the current or envisaged legal requirements as well as normative requirements in the EN 71 series are described initially. This description is then followed by review of relevant literature and finally a conclusion of which limit values that could/should be used for the chemical/group of chemicals.

3.1 SVHCs including CMRs, PBTs, vPvBs and others (e.g. EDCs)

3.1.1 Generic SVHCs including CMRs, PBTs, vPvBs and others (e.g. EDCs)

A common aspect for all SVHCs (including CMRs, PBTs, vPvBs and others (e.g. EDCs)) is that they are substances with critical effects either on health (CMR and EDC) or on the environment (PBT, vPvB). SVHCs are substances that cover all groups of substances (CMR, EDC, PBT and vPvB) by the definition in REACH. SVHC (Substances of Very High Concern) are

[2] SVHCs = Substances of Very High Concern as defined by the REACH system
[3] CMRs = Substances that are Carcinogenic, Mutagenic and toxic to Reproduction
[4] PBTs = Persistent, Bio-accumulative and Toxic substances
[5] vPvBs = very persistent and very bio-accumulative substances
[6] EDCs = Endocrine Disrupting Chemicals

defined in article 57 of the REACH Regulation No 1907/2006, as substances that are:

- Carcinogenic, mutagenic or toxic to reproduction (CMR), meeting the criteria for classification in category 1A or 1B in accordance with the CLP Regulation No. 1272/2008.
- Persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to the criteria in Annex XIII of the REACH Regulation.
- Identified, on a case-by-case basis based on scientific evidence, as causing probable serious effects to human health or the environment of an equivalent level of concern as those above (e.g. endocrine disrupters (EDCs)).

According to the old Toy Safety Directive, none of these groups of substances are regulated in any way other than by the general statement that 'toys must not present a health hazard'. However, in the new Toy Safety Directive **CMR substances** are regulated (entered into force July 20, 2013) in the way described in the section below on CMRs.

3.1.1.1 CMRs

According to the new Toy Safety Directive, **CMR substances** of category 1A, 1B or 2 under the CLP Regulation (Regulation 1272/2008) are not allowed in toys if the concentration is the same, or exceeds, the concentration set for classification of mixtures containing these substances. 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%
- Category 2 carcinogens and mutagens: 1.0%
- Category 2 reproductive toxicants: 3.0%
- For reproductive effects on, or via lactation: 0.3%

These concentration thresholds are used in general, but if substance specific values exist, these thresholds should apply instead of the general thresholds. The PAH benzo[a]pyrene has, for example, a specific value for category 1B carcinogenicity of $\geq 0.01\%$, whereas other PAHs have no specific concentration limits.

However, it should be noted that the above concentration limits on CMR substances do not apply until June 1, 2015. According to the new Toy Safety Directive annex II, appendix B, the classification of mixtures is carried out according to Directive 67/548/EEC and Directive 1999/45/EC until May 31, 2015, as the classification of mixtures according to the CLP Regulation do not enter fully into force before this date. In practice this means that the threshold for substances toxic for reproduction category 2 is 5% for the time being and not 3% (as it will be from June 1, 2015). Furthermore, the threshold for reproductive effects relating to lactation does not exist in the old classification, packaging and labelling directives.

However, these CMR substances may anyway be used as components in toys even when over the aforementioned 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), which has already been permitted for use in stainless steel). A decision may be taken if the use of the substance has been evaluated as safe in toys and if the substance is not restricted for use in consumer articles according to REACH. Furthermore, a decision may be taken to permit the substance and its use, if there are no suitable alternatives. However, this later aspect regarding no suitable alternatives applies only in the case of CMR category 1A and 1B (not category 2).

Furthermore, according to Annex II (point III.7) of the new Toys Safety Directive, the restrictions on the CMR substances

1. "do not apply to materials that comply with the specific limit values set out in Appendix C" (none set yet)
2. "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".

Point 1 above is problematic because it suggests that even if just a few limits have been incorporated in appendix C, the general CMR exclusion does not apply anymore – or at least one could interpret the text like this. Another interpretation would be that the generic limit does not apply for the substances with a limit in appendix C. This is an aspect that should be made clearer in a future revision of the Toy Safety Directive.

Point 2 above means that materials which comply with the requirements in the Regulation No. 1935/2004 for food contact materials do not have to comply with the CMR requirements – at least until specific limit values have been set out in Appendix C. This is also problematic as it is only for plastic materials that somewhat comprehensive rules have been established (and rules regarding CMR substances). In fact, this means that compliance with the FCM Regulation does not rule out the possibility to use CMR substances.

Moreover, a **specific CMR** substance – benzene – is regulated in toys through REACH Regulation No. 1907/2006 Annex XVII entry No. 5. The free state of benzene must not exceed 0.0005% or 5 mg/kg in toys. Benzene is classified as Carc 1A and Muta 1B according to the CLP Classification, but no specific concentration limit is given for benzene in the CLP Regulation.

There are no generic requirements concerning CMRs in the EN 71 series of standards.

<u>BfR No. 51, 2009</u>

BfR states in this opinion that the number of cases of cancer in children is increasing and therefore they ask for urgent action to minimise, as much as possible, exposure to CMR substances. BfR maintains the opinion that the ALARA principle (as low as reasonably achievable) should be applied to CMR substances.

BfR recommends that regulations of CMR substances in toys should in general refer to migration rather than to content, as it is the case for plastic materials and articles intended to come in contact with food. For these materials, it is required that the migration of CMR substances is not

detectable (< 0.01 mg/kg). BfR therefore suggests that the Regulation for Food Contact Materials should be assumed for all types of toy materials and without age limit in order to minimise children's exposure to CMR substances. According to BfR, this is technologically feasible and already best practise.

SCHER opinion, 2010b

SCHER is of the opinion that non-threshold carcinogens (categories 1A and 1B according to CLP Regulation) should not be present in toys as intentionally added compounds. For chemicals of a non-threshold mechanism, it is virtually impossible to set safe levels (SCHER opinion, 2010b).

However, this is in contradiction to an earlier opinion from SCHER (SCHER, 2007) where SCHER states the following: "The SCHER does not accept the procedure to define action limits for CMR and very toxic compounds. Such compounds should not be present in toys and need to be determined directly in the toys using appropriate extraction procedures and suitably sensitive chemical - analytic methods". This earlier opinion from SCHER advocates an elimination of all CMR substances (and not just category 1A and 1B) and with a content-based level of detection.

In the new Toy Safety Directive, the presence of CMR substances in toys is limited to a maximum concentration corresponding to the limits established for the classification as CMR in mixtures. Derogation to this limit of content is accepted only when CMR substances are present in inaccessible parts of toys. SCHER is of the opinion that this approach causes problems due to the fact that classification limits for mixtures (chemical liquids) are applied to articles (toys). Chemical mixtures are uniform in their concentration, but articles are not necessarily. For example:

- The percentage composition refers to the toy as a whole or a specific part of the toy. However, a CMR substance present in a specific part of the toy may not be homogeneously distributed so that the local concentration could be higher in that specific part and possibly above the limit.

SCHER was asked if it is possible to set, e.g. a general migration limit of 10% of the concentration limit for each CMR substance. SCHER rejected this possibility with the following arguments:

- SCHER questions the scientific basis of the general 10% "rule" and says that "Limits are cut of values, defined for a practical approach to be used for regulatory purposes".
- SCHER argues that the 10 fold difference with respect to limits for CMR categories (category 1A and 1B (0.1% and 0.3% respectively) versus category 2 (1.0% and 3% respectively)) has no scientific foundation either.
- SCHER states that for non-threshold CMRs the Toy Safety Directive limits are wrong as these substances should not be present at all in toys (however, this statement contradicts their earlier statement regarding an elimination of all CMRs).
- SCHER states that for other CMRs (threshold CMRs) the Toy Safety Directive limits are wrong because they are not derived from a case-by-case risk assessment, but based on the hazard-based classification limits approach.

SCHER is of the opinion that the presence of CMR category 2, when characterized by a threshold mechanism, can be accepted only by a case-by-case evaluation. This evaluation should be based on available toxicological data (to derive a TDI[7]) compared with exposure data in order to identify possible risks.

SCHER recommends that a risk-based approach is used for the CMR substances instead of the hazard-based classification limits approach. This means that specific acceptable levels of exposure should be calculated for each CMR substance. This risk-based approach should be based on identification of exposure levels through appropriate migrations tests. Migration due to sucking is not the only source of exposure. Sucking and chewing can result in ingestion of small particles, thus CMR substances could be absorbed in dust particles which could be ingested. Migration in sweat could also be relevant if the toy is in contact with the skin, and finally, inhalation cannot be excluded.

SCHER is of the opinion that the method to measure the migration of chemicals (EN 71-9 (2007), EN 71-10 (2005) and EN 71-11 (2005)) is not reliable. SCHER is among other things criticising the fact that the variation of the data obtained from the different studies by the different participating laboratories cannot be estimated. According to SCHER, this does not permit evaluation of the uncertainties of the limit values and action limits. SCHER therefore recommends the following aspects concerning migration tests:

- Different chemicals may be present in different areas of the toy. SCHER therefore recommends that when toy materials are sampled for migration analysis, they should be representative of all parts of the toy.
- Dynamic migration testing should be used (i.e. ensuring adequate mixing of the sample with the extraction fluid – head over heals extraction). SCHER recommends that the method should be appropriately described in the standard methods.
- SCHER does not find the use of water as simulant for saliva, sweat and gastric juice justified. SCHER is of the opinion that artificial saliva should be used – and as toy particles may be ingested as well, thus a combined exposure should be estimated by determining the migration of the chemical in artificial saliva as well as in artificial gastric juice. SCHER refers to fortified saliva described in a JRC report (2001 EUR 19826 EN).
- Migration studies are carried out at 20 °C, but it has been shown that e.g. phthalates migration increases with increasing temperature. SCHER therefore recommends that the tests should be carried out at 37 °C.
- SCHER is of the opinion that for simulation of sucking/chewing, replenishment of artificial saliva is required. SCHER recommends that 4 x 30 minutes migration from a toy sample should be determined (with recovery periods of at least 12 hours between each migration test) and the average migration rate is calculated.

SCHER was asked if the migration limits set out in the Food Contact Materials Regulation are appropriate to ensure that the use of such materials in toys poses no risk to the health of children. As of today, if materials apply with the Food Contact Materials Regulation (No. 1935/2004), they do not have to apply with the CMR requirements – at least until specific limit values

[7] Tolerable Daily Intake

have been set out in Appendix C. SCHER is of the opinion that the Food Contact Materials Regulation generally cannot be used to assess the risk for children from exposures to CMR in toys, as it has been done in the new Toy Safety Directive. SCHER is of the opinion that a case by case adaption would be necessary. The reasons for this are that, for example:

- Specific migration limits are currently established only for plastics, ceramics, regenerated cellulose and some individual substances (vinyl chloride, nitrosamines, and certain epoxy derivatives).
- The migration tests used in the Food Contact Materials Regulation would never be representative for toys in general because of:
    - Migration tests are performed under static conditions. This does not simulate mouthing or chewing for toys.
    - The simulants used are distilled water, 3% acetic acid, 10% ethanol and olive oil. They represent food categories and not children's saliva, sweat or gastric juice.
    - The specific migration limit values used are based on toxicological evaluations related only to the oral route. Sensitisation aspects for dermal contact are not considered.

ANEC position on SCHER opinion (ANEC position, 2010b)

ANEC has made a position paper (ANEC position, 2010b) on the above SCHER opinion (SCHER opinion, 2010b). ANEC states that the positions taken by SCHER concerning the alternative approach (case by case risk-based approach) are somewhat unclear and contradictory. ANEC concludes that the SCHER opinion seems to imply that the risk assessment approach should be used for CMR category 2 chemicals (when a threshold mechanism exists) whereas CMR substances of category 1A and 1B should be generally excluded.

ANEC disagrees with SCHER on the point that a case by case risk assessment of CMR substances in toys is needed. This may be desirable from a scientific perspective, but impossible to carry out in a reasonable time frame and may take decades and is therefore unacceptable from a consumer protection perspective.

ANEC is of the opinion that the use of the general CMR limit values in the new Toy Safety Directive is a step forward in regulating chemicals in products. It is, however, questionable to use the limits established for the classification of mixtures for the purpose of setting thresholds of chemicals in products such as toys. On this point, ANEC agrees with SCHER. ANEC hence advocates for a general exclusion of CMR substances, which are not based on the limits for classification in the CLP Regulation. ANEC suggests instead using a migration limit value of 0.01 mg/kg (10 ppb) for all CMR substances in any toy or at the very least for toys intended to be used by children up to 3 years of age or to be mouthed.

Furthermore, ANEC agrees with SCHER on the point that the Food Contact Materials Regulation is, as of now, not suited for the purpose of regulating chemicals in toys. However, ANEC is of the opinion that the requirements for plastic materials could be used as a starting point for developing a set of criteria applicable for toys for children below the age of 36 months and toys intended to be placed in the mouth. ANEC advocates for the principles used in the Food Contact Materials Regulation:

- Only approved materials are allowed to be used.

- Non-approved materials may be used only under restrictive conditions (functional barrier, no CMRs) and only if the migration into food simulant does not exceed 0.01 mg/kg (10 ppb).
- An overall migration limit of 60 mg/kg is defined to ensure the inertness of plastic materials.
- However, other aspects need to be discussed further in order to use the principles for toys of Food Contact Materials Regulation. For example, the specific migration limits should be based on a fraction of the TDI value (instead of the entire TDI value), and not related to adults of 60 kg but to the weight of children instead.

Overall ANEC proposes the following:

- CMR substances of all categories (category 1A, 1B and 2) should be eliminated from toys (accessible parts) following the ALARA (as low as reasonably achievable) and precautionary principle.
- Non-volatile CMR substances (all categories) should generally not be detectable at a dynamic migration limit of 0.01 mg/kg (10 ppb).
- Equivalent approaches should be used for volatile CMR substances and the dermal contact route.
- Exemptions may be granted, but only on the basis of a full risk assessment and a positive opinion by SCHER.
- Suitable screening methods need to be developed.
- The use of legislation for food contact materials – in particular for plastics materials – should be further discussed.

Finally, ANEC is disagreeing with the claim from SCHER that it is unlikely that water is a good simulant for saliva. ANEC states that no evidence is provided that any other simulant is better suited and yields results which are more in line with what can be achieved with real saliva.

ANEC proposal, 2011b

In this proposal from ANEC, they describe how a general CMR requirement for toys could be made in the new Toy Safety Directive for these products used by children below the age of 36 months and toys intended to be placed in the mouth. This is instead of the existing requirements using the classification limits as content based limit values. Whether or not a migration limit or a content based limit should be used depends on the exposure. For solid toy material where the risk of ingestion is very low, the exposure limit should be based on migration, whereas the limit value for liquid and powder-like toys should be based on content where there is a risk of ingestion of some of the material of the toy. These aspects cover the contact route of mouthing, but special considerations must be given to the contact routes inhalation and skin contact which need to be discussed further.

ANEC suggests the following general requirements for CMR substances in toys for children below the age of 36 months and in toys intended to be placed in the mouth:

Contact route mouthing:

- For solid toy materials: CMR substances should be restricted by a migration limit and should not be detectable by migration (CMR ≤ 0.01 mg/l saliva simulant in accordance with EN 71-10 (2005) with dynamic migration at 36 °C).
- For powder-like toy materials: CMR substances should be restricted by content and should not be detectable (CMR < 0.01 mg/kg toy material).
- For liquid toy materials: CMR substances should be restricted by content and should not be detectable (CMR < 0.01 mg/kg toy material).

Contact route inhalation:

- For volatile organic compounds, a different method must be chosen. E.g. by limiting CMR substances that evaporate from the toys at level of detection. Methods need to be validated.

Contact route skin contact:

- To some extent skin contact is also covered by the suggested approaches for mouthing. For exposure through skin contact with solid toy materials with extensive skin contact, additional measures might be needed.

ANEC/BEUC, 2012c

ANEC and BEUC describe in a joint position paper that the requirements for CMR substances in the new Toy Safety Directive are not strict enough to protect children's health because of the inadequate thresholds which are based on the classification of mixtures according to the CLP Regulation (no. 1272/2008). They call for the generic ban of CMR substances (as described in the ANEC proposal (2011b) above) in toys intended for use by children below the age of 36 months or in other toys intended to be placed in the mouth, using a low detection level of 0.01 mg/kg based on a dynamic migration test. Stricter limits for certain CMR substances should be used where required.

ANEC and BEUC state that instead of adopting a generic ban, the Commission suggests to ban (a few) individual CMR substances. According to ANEC and BEUC this is not acceptable and the two organisations call for a revision of the new Toy Safety Directive. The revision should include and introduce a comitology procedure which would allow the adoption or modification of limits for all kinds of toys and all kinds of substances (and not just as today for allergenic fragrances, elements and for toys intended for use by children below the age of 36 months or in other toys intended to be placed in the mouth (ANEC/BEUC, 2012c).

Nordic Ecolabelling, 2012

In the Nordic Ecolabelling of toys, there is a general requirement for additives used in plastics, rubber, dyes, pigments, auxiliary chemicals, adhesives, glues, paper, cardboard, chemical products in wood-based materials including those used for wood and metal surface treatment, that substances classified as CMR in category 1A, 1B and 2 (i.e. labelled with either H350, H350i, H351, H340, H341, H360 and H361) are not allowed to be used in ecolabelled toys. For some materials/chemicals, the requirement is valid for the chemical mixture

and for other chemicals the requirement is valid for the constituent substances, however there is an overall limit value of CMR substances of 0.1% by weight (Nordic Ecolabelling, 2012).

3.1.1.2 EDCs

There are no general legal requirements in the new Toy Safety Directive on EDCs and neither any generic requirements concerning EDCs in the EN 71 series of standards. Legal requirements exist for specific EDCs (certain phthalates), but this is discussed later in section 3.1.4 “Phthalates”.

The European Commission has suggested that a classification scheme similar to CMRs should be set up. The criteria to identify EDCs should be based on categories similar to those used for CMRs (Chemical Watch, December 2012). An overview of the Commission proposal on a strategy for EDCs (from November 2012) is described below.

Community Strategy for EDCs (European Commission, 2012b)

In this document from the European Commission (2012b), possible elements for the definition, identification and categorisation of EDCs are being discussed. It should be noted that this discussion is in its infancy – the Commission proposal contains the initial thoughts on the criteria for EDCs.

The proposed categories are:

- Category 1A: Known endocrine disruptors
- Category 1B: Presumed endocrine disruptors
- Category 2: Suspected endocrine disruptors
- Category 3: Potential endocrine disruptors

Category 1 substances would include substances that are known to have caused adverse effects in humans. It is suggested that this category is sub-divided with proof of evidence for substances in 1a from human studies and 1b based on the result of animal studies. Category 2 would include substances for which there is some evidence for endocrine disrupting-mediate effects from humans or experimental animals and where the evidence is not sufficiently convincing to place the substance in category 1. For category 3 substances there would be some in vitro/in silico evidence indicating a potential for endocrine disruption mediated adverse effect, but the evidence would not be sufficiently convincing to place the substance in category 1 or 2.

The paper also briefly discusses further issues that should be considered when drawing up criteria for EDCs. However, most of these subject are not discussed but merely listed as being important and in need of future debate:

- Definition of the endocrine system (organs and mechanisms involved)
- Potential routes of exposure
- Potential definition for adverse effects on human health and the environment
- Mode of action
- Proof of causality
- Data that is apt for consideration
- Potency
- Lead toxicity
- Severity

- Irreversibility
- Specificity
- Step by step procedure to categorise substances

Danish survey on the exposure of 2 year-olds to endocrine disruptors, 2009

The Danish EPA conducted a survey from 2008 to 2009, on the cumulative exposure of 2 year-olds to endocrine disrupting chemicals such as phthalates, PCBs, parabens, bisphenol A, etc. The report concluded that when looking at toys alone, there is no risk of endocrine disrupting effects in 2 year-olds. However, when looking at the cumulative risk, i.e. exposures from other sources than toys and exposure from other endocrine disrupting chemicals with the same target effect, a risk of effects on the endocrine system can occur. The report therefore concludes that there is a need to reduce the total exposure to endocrine disrupting chemicals, but no specific limit values were suggested (Danish EPA, 2009).

Kortenkamp et al., 2011

Kortenkamp et al. have in a report called ”State of the art assessment of endocrine disrupters”, summarised the knowledge on endocrine disruptors. In this report it is stated that extensive laboratory studies support the notion that the exposure of certain chemicals contribute to endocrine disorders in humans and wildlife. Exposure during critical periods of developments can cause irreversible and delayed effects that do not become evident until later in life. hese toxicological properties justify consideration of endocrine disrupting chemicals (EDCs) as substances of concern, equivalent to CMRs as well as to persistent, Bioaccumulative and toxic chemicals.

The report describes that one of the concerns of EDCs is their low dose effects, meaning that EDCs elicit effects at doses much lower than normally used in regulatory testing. This means that the current risk assessment paradigm needs modification or has become obsolete. Another of the concerns of EDCs is that there is good evidence that several EDCs can work together to produce combined effects. Especially when exposure is to multiple chemicals simultaneously which are capable of affecting the same endpoint, combination effects can occur at doses where each chemical individually does not present any detectable effects. From a regulatory point of view, it is therefore of great importance to have information about the spectrum of EDCs that are present in relevant exposure scenarios. This information is currently fragmentary and this lack of information makes it likely that the full extent of risks associated with EDCs might be underestimated.

UNEP & WHO, 2012

A group of scientific experts has presented a report for UNEP and WHO with information and key concerns for policy-makers about endocrine disruptors. The experts list the following key concerns for endocrine disruptors:

- Human and wildlife health depends on the ability to reproduce and develop normally. This is not possible without a healthy endocrine system.
- Many endocrine-related diseases and disorders are on the rise (e.g. low semen quality in men, genital malformations, endocrine-related cancers (breast cancer, testicular cancer etc.), type 2 diabetes, neurobehavioural disorders).

- Close to 800 chemicals are known or suspected to be capable of interfering with hormone receptors, hormone synthesis or hormone conversion. However, only a small fraction of these chemicals has been investigated in tests.
- Human and wildlife populations all over the world are exposed to EDCs.
- The speed with which the increases in disease incidence have occurred in recent decades rules out genetic factors as the sole plausible explanation.
- Significant knowledge gaps exist as to associations between exposures to EDCs and other endocrine diseases.
- The most sensitive window of exposure to EDCs is during critical periods of development, such as during foetal development and puberty.
- Worldwide there has been a failure to adequately address the underlying environmental causes of trends in endocrine diseases and disorders.
- Internationally agreed and validated test methods for the identification of EDCs capture only a limited range of the known spectrum of endocrine disrupting effects. This increases the likelihood that harmful effects in humans and wildlife are being overlooked.
- Disease risk to EDCs may be significantly underestimated.
- An important focus should be on reducing exposures by a variety of mechanisms. Government actions to reduce exposures, while limited, have proven to be effective in specific cases.
- Despite substantial advances in our understanding of EDCs, uncertainties and knowledge gaps still exist and they are too important to ignore.
- Children can have higher exposures to EDCs because of their hand-to-mouth activities. Humans and wildlife are exposed to complex mixtures of EDCs consisting of hundreds of EDCs at low concentrations.
- Animal studies show that exposures to mixtures of EDCs produce additive effects. These additive effects occur even when each chemical is present at low levels not shown to produce effects individually. This means that many chemicals, each at levels without individual effect, could act together to cause health problems.
- Examination of one endocrine disruptor at a time is likely to underestimate the combined risk from simultaneous exposure to multiple endocrine disruptors.
- Many sources of EDCs are not known because of a lack of chemical constituent declarations in products, materials and goods.

Vandenberg et al., 2012

In this article, Vandenberg et al. have reviewed more than 800 articles concerning EDCs. The authors present more than 100 examples that clearly show that low-dose effects and non-monotonic dose-response curves are common in studies of hormones and EDCs. Low-dose effects are defined as those effects that occur in the range of human exposures (i.e. low exposures) or effects observed at doses below those used for traditional toxicological studies. If chemicals have a linear dose-response curve, then it is possible to use the information on the test carried out at higher doses to extrapolate and comment on the expected effects at lower doses. However, the problem with

most EDCs (which has been illustrated in this article) is that the dose-response curve is not linear, but non-monotonic which means that the effects of low doses cannot be predicted by the effects observed at high doses (or the doses used in traditional testing). In addition, the authors conclude that the finding that chemicals having adverse effects on animals and humans in the range of environmental exposures clearly indicate that low doses cannot be ignored. The authors therefore suggest that before new chemicals are developed, a wider range of doses, extending into the low-dose range, should be fully tested.

European Parliament, 2012

Åsa Westlund has prepared a draft report on the protection of public health from endocrine disrupters for the Committee on the Environment, Public Health and Food Safety, European Parliament (European Parliament, 2012). In this report, Westlund describes that the increased incidence of hormone-related disorders and illnesses in humans needs to be taken very seriously and therefore stresses the importance of rapidly adopting measures that will increase protection for the most vulnerable groups. Westlund expresses the following views:

- Endocrine disruptors should be regarded as substances for which it is not possible to set a limit value at which effects may occur ("non-threshold" substances) and that any exposure to such substances may entail a risk.
- The most important thing to do is to restrict the use of endocrine disruptors in products aimed at specific target groups, such as skin care products, textiles and toys.
- The Commission should review the existing legislation and propose new legislation in the areas of cosmetics, furniture, electronic goods, building products, toys, textiles, food and packaging so as to protect people from substances with endocrine-disrupting properties.
- The Commission should, as soon as possible, submit proposals for comprehensive criteria together with testing and information requirements for chemicals on the commercial market and for the EU legislation to make clear what is regarded as a substance with endocrine-disrupting properties.
- The Commission should consider the introduction of "endocrine disruptor" as a regulatory hazard class.
- The Commission should, in all relevant EU legislation, introduce appropriate testing requirements and testing methods for EDCs to take better account of endocrine disruptors and their possible low-dosage effects and non-linear dose-response relationships.

ANEC/BEUC, 2012c

ANEC and BEUC (2012c) describe in a joint position paper that the endocrine disrupting chemicals need to be addressed in toys. Currently EDCs are neglected in the new Toy Safety Directive. ANEC and BEUC call for implementation of a suitable comitology procedure that would allow for the adoption or modification of the limits for all kinds of toys and all kinds of substances in a fast and flexible way (without having to change the whole piece of legislation) and not only for toys intended for use by children below the age of 36 months or toys intended to be placed in the mouth. ANEC and BEUC hope for development of horizontal criteria for EDCs (ANEC/BEUC, 2012c).

WECF, 2012

In a position paper from WECF (Women in Europe for a Common Future), WECF criticises the new Toy Safety Directive for not being strict enough, i.e. not sufficiently protecting children from exposure to dangerous chemicals. Amongst other things WECF states that endocrine disruptors should be banned from toys as they, even at low doses, can trigger long-term health consequences for exposed children (WECF, 2012).

Berlaymont Declaration on EDCs, 2013

Close to 100 different scientists have signed the so-called "2013 Berlaymont Declaration on Endocrine Disruptors" in 2013. In this declaration, the following statements are listed:

- We are concerned that the prevalence of endocrine-related diseases is higher than it has ever been. The disease burden continues to increase in the EU and globally.
- Evidence is strengthening that environmental factors, including chemical exposure, play a role in these phenomena.
- Animal experiments and some human health studies have shown that exposure to endocrine disruptors during developmental periods can cause irreversible harm that becomes apparent long after these exposures took place.
- Existing EU chemicals regulation are entirely inadequate for identifying EDCs, and internationally validated test methods that have been available for years have not been implemented.
- Some proposals for regulating EDCs from EU Member States are not sufficiently protective, do not follow the best available science, and place commercial interests above the protection of human and wildlife health.
- Certain EDCs have toxicological properties that preclude the definition of thresholds below which exposures can be deemed safe.
- We call on the European Commission to implement a regulatory regime for EDCs that is based on sound scientific principles.

National considerations on bans of EDCs

According to news from ENDS Europe, France is considering pushing for an EU-wide ban on toys and educational tools that contain the most worrying endocrine disruptive chemicals (EDCs). The ban would apply to children below the age of 14, but it is not specifically mentioned which EDCs are to be included and with which limit values (ENDS Europe, 2012).

Furthermore, the Danish Consumer Council has in April 2013 launched an online-petition to ban EDCs in all consumer goods EU-wide. If successful, the petition will be delivered to the European Commission[8].

Nordic Ecolabelling, 2012

In the Nordic Ecolabelling of toys, there is a more or less general requirement stating that substances considered as endocrine disruptors listed as category I

[8] http://www.wecf.eu/english/articles/2013/03/danish_petition_edcs_eu_wide.php
http://taenk.dk/ban-endocrine-disrupting-chemicals-in-consumer-products

or II according to the EU Commission priority list of potential EDCs from 2000 must not be added to the toys (plastic materials, rubber, chemical products used in wood-based materials, chemical products used for surface treatment of wood and metal, and glue). The limit value is for some materials set to 100 ppm (Nordic Ecolabelling, 2012).

3.1.1.3 PBTs and vPvBs

PBTs and vPvBs are substances with critical environmental effects. PBTs are persistent, bio-accumulative and toxic substances and vPvBs are very persistent and very bio-accumulative substances.

There are no general legal requirements in the new Toy Safety Directive on PBTs and vPvBs and neither any generic requirements concerning PBT and vPvBs in the EN 71 series of standards.

ANEC/BEUC, 2012c

In a joint position paper, ANEC and BEUC describe that substances which are PBTs and/or vPvBs are substances of very high concern and should be prohibited in toys. ANEC and BEUC therefore call for a ban of this type of chemicals in toys. This is only possible by changing the Toy Safety Directive for all kinds of toys (ANEC/BEUC, 2012c).

WECF, 2012

In a WECF position paper (Women in Europe for a Common Future), WECF states that substances with PBT and vPvB properties should be banned from toys,
as they, even at low doses, can trigger long term health consequences for exposed children (WECF, 2012).

Nordic Ecolabelling, 2012

In the Nordic Ecolabelling of toys, there is a more or less general requirement stating that substances which meet the criteria for PBTs and vPvBs must not be added to the toys (plastic materials, rubber, chemical products used in wood-based materials, chemical products used for surface treatment of wood and metal, and glue). The limit value is for some materials set to 100 ppm (Nordic Ecolabelling, 2012).

3.1.1.4 Conclusion generic SVHCs including CMRs, PBTs, vPvBs and others (e.g. EDCs)

Previously SCHER (2007) was of the opinion that no CMRs should be used at all and had in mind using a test method ensuring the absence of CMR substances with a low level of detection (LOD). However, the recent opinion of SCHER (SCHER opinion, 2010b) is that non-threshold carcinogens (i.e. category 1A and 1B according to CLP Regulation) should not be present in toys as intentionally added compounds as it is impossible to set safe levels. However, SCHER does not propose any specific limit value and opens up for individual risk assessments of category 2 substances in order to establish correct limit values, but only for substances characterised by a threshold mechanism. BfR on the other hand proposes to use a general limit value of < 0.01 mg/kg for all CMR substances, measured as migration corresponding to no detectable migration of CMR substances (BfR No. 51, 2009). ANEC

agrees with BfR on this generic approach but proposes that either a migration or a content based limit value is used depending on the toy material type (migration for solid toy materials and content based for powder-like and liquid toy material where ingestion is possible).

It is suggested to use a generic approach for all substances (category 1A, 1B and 2) and instead open up for exemptions which may be granted (as suggested by ANEC), but only on the basis of a full risk assessment and a positive opinion by SCHER. Nickel is an example of an exemption of the general CMR requirement in the new Toy Safety Directive as nickel has been assessed to be safe for use in metal toys.

Full knowledge of the toxicological effects of EDCs and identification of all substances with endocrine disrupting effects are still lacking. This is the main problem with using a general requirement for EDCs because we simply lack knowledge of which substances that have endocrine disrupting properties and can today only base requirements on EDCs on existing priority lists of problematic EDC substances. It has been suspected that at least some EDCs may act in a non-threshold fashion such as genotoxic carcinogens or have adverse effect at very low levels "low-dose effects") and additive effects may play a big role, i.e. any exposure will add to an already existing internal load. EDCs should therefore be restricted as quickly as possible. Several scientists also state in the 2013 Berlaymont Declaration on EDCs that the current chemicals regulation on EDCs is entirely inadequate both regarding identification of EDCs and regulation of EDCs in our society.

PBT and vPvB substances are mainly an environmental issue but could end up being a human health problem when the substances are accumulated in the animals that we end up eating. ANEC and BEUC call for a general ban of substances with PBT and vPvB properties (ANEC/BEUC, 2012c) and this type of substances must generally not be added to toy materials according to the Nordic Ecolabelling of toys. The limit value is for some materials set at 100 ppm (Nordic Ecolabelling, 2012).

It should be discussed whether this generic requirement on SVHCs including CMRs, PBTs, vPvBs and others (e.g. EDCs) should be valid only for toys for children below the age of 36 months or for all toys. This requires an in-depth discussion which is not made in this report. In this report it is suggested to make the requirement for all toys based on a precautionary principle. Often children below the age of 36 months also play with toys intended for children above the age of 36 months.

Type of limit value

BfR recommends that in general the regulation for CMR substances in toys should not apply to the content but instead to migration since only migration is relevant to exposure. ANEC has a more varied approach. ANEC has, in their proposal for how to restrict CMR substances in toys (ANEC proposal, 2011b), reflected on the type of limit values which should be used. ANEC suggests using a migration based limit value for solid toy material (where ingestion is limited) and a content based limit value for powder-like and liquid toy material where ingestion is possible. Furthermore, another approach should be used for volatile CMRs.

The total exposure of CMRs/EDCs to children is the added exposures through ingestion (or mouthing), skin contact and inhalation. In order to account for all exposures, all exposure routes must be taken into account but mouthing is by far the most important one for most substances regarding toys. The easiest way to restrict the use of CMRs/EDCs would be to restrict by content. However, this may be too restrictive for solid toy materials, where ingestion is limited and where migration may be small. An example is nickel in stainless steel which has been assessed to be safe. One way is therefore to do as ANEC proposes, i.e. restrict in different ways depending on the toy material or the nature of the substances (volatile or non-volatile). Another way is simply to restrict by content or migration and make exceptions where a risk assessment shows no risk. Restricting solely by content may, as mentioned, be too restrictive for solid toy materials whereas restricting solely by migration may overlook exposure situations where children ingest some of the liquid or powder-like toys. Another option could therefore be to use both options, i.e. combining the generally content based limit for non-threshold substances (as suggested by SCHER) with a general migration based limit for substances included in solid materials. This could be supplemented with a content based limit for threshold and non-threshold substances for powder and liquids.

It is suggested to use the approach as described by ANEC (ANEC proposal, 2011b), i.e. restrict in different ways depending on the toy material or the nature of the substances (volatile or non-volatile). It is suggested that this approach is used for CMRs as well as EDCs. Of course this can only work on EDCs already being identified. The main problem with using a general requirement for EDCs is, however, that we simply lack knowledge of which substances that have endocrine disrupting properties. Therefore, as soon as EDCs are identified they should of course be restricted (or at least EDCs of the proposed category 1A and 1B in the proposal from the European Commission (2012b)).

PBTs and vPvBs are different in the sense that direct exposure is irrelevant. Here the main concern is that persistent substances are spread in the environment. These substances therefore call for a content based limit.

A general aspect for all SVHCs is that for many substances there is no harmonised classification yet. According to the Classification & Labelling Inventory database by ECHA, only about 4,500 substances (September 2013) have a harmonised classification. A suggestion is therefore to use the classification of substances notified to ECHA in cases where no harmonised classification exists. The ECHA C&L Inventory database contains (September 2013) notified classifications of about 115,000 substances. This approach would be the most conservative approach as it will ensure that if just one company has notified a classification of e.g. Carc. 1A to ECHA, the substance should be regarded as carcinogenic (1A) until a harmonised classification is in place. This approach of course needs further discussion and will not be further elaborated in this report.

For EDCs the main problem is, however, that identification and categorisation with respect to classification are lacking. EDCs can of course not be restricted before they are identified. However, a system should be in place to ensure that EDCs are restricted as soon as they are known to be EDCs (i.e. the proposed category 1A and 1B).

Limit values

SCHER and BfR state that non-threshold substances should not be present in toys. Therefore, the general limit value should be non-detectable as also suggested by BfR and ANEC. Non-detectable of course depends on the test method and on the substance and may be lowered in the future. It is suggested to use the general limit value of 0.01 mg/kg, as mentioned by BfR and ANEC.

It may, however, be problematic in practise to use a content based limit. Many substances may disturb the analysis in contrast to a migration based testing method where only the migrating substances in the simulant will be present. Such aspects of course also need to be considered and more discussions are therefore called for on this issue. When using a content based limit value, the limit value will probably have to be somewhat higher compared to the migration based limit value. However, this needs to be discussed further.

It is suggested to use this low general limit value (0.01 mg/kg) for migration to restrict all CMRs and EDCs, as some of the substances are non-threshold substances (i.e. do not have a lower limit value for being dangerous). This should also allow accounting for possible cumulative effects (several substances with effects on same target organ).

Of course there is the general problem of not all substances having a harmonised classification as listed above. Either the notified classification (ECHA C&L Inventory database) should be used or the substances should be restricted as soon as a classification as CMR or EDC is in place.

As suggested by ANEC, exemptions should be allowed (as it has been done for nickel in the new Toy Safety Directive). However, this should only be on the basis of a full risk assessment and a positive opinion by SCHER. It is suggested to use the limit value (non-detectable, i.e. 0.01 mg/kg) for migration. However, the limit values for content and evaporation need to be discussed further, taking into account the aspects discussed above.

For PBTs and vPvBs the limit value does not have to be that strict as the direct exposure is irrelevant – here the main concern is that the persistent substances are spread in the environment. For PBTs and vPvBs it is therefore suggested to use a content based limit value of 0.1 % (as used in the REACH system for SVHCs).

Test methods

No specific test method has been described concerning content based testing.

Concerning the test method for migration, ANEC emphasises that a dynamic migration should be used, and SCHER emphasises that artificial saliva and a temperature of 37 °C should be used as well as a method where replenishment of artificial saliva is required. ANEC is, however, questioning some of the test options mentioned by SCHER, e.g. using artificial saliva instead of water. The exact test method therefore needs to be discussed further. It is suggested to use a test method based on the dynamic migration contained in EN 71-10 (2005) with some improvements called for by organisations such as SCHER and ANEC.

Suggestion: Generic SVHCs including CMRs, PBTs, vPvBs and others (e.g. EDCs)

The following suggestions for chemical requirements are made for SVHCs including CMRs, PBTs, vPvBs and others (e.g. EDCs).

Table 2: Suggested chemical requirements regarding SVHCs including CMRs, PBTs, vPvBs and others (e.g. EDCs) in toys

SVHCs including: **CMRs** **PBTs** **vPvBs** **and others (e.g. EDCs)** **(all materials)**	**Type of limit value:** Migration or content based limit values depending on the toy material and the nature of the substances: Non-volatile substances: • Dry, brittle, powder-like or pliable: Content based • Liquid or sticky: Content based • Solid: Migration based Volatile substances: • All toys: Evaporation based **Limit value CMRs (category 1A, 1B and 2) and EDCs (proposed category 1A and 1B):** Migration based limit value: Must not be detectable, i.e. 0.01 mg/kg (10 ppb) in all toys. Content and evaporation based limit value: Need to be discussed. Exemptions can be made, but only on the basis of a full risk assessment and a positive opinion by SCHER. **Limit value PBTs and vPvBs:** PBTs and vPvBs must not be present in all toys in a content above 0.1 %. **Test method:** Content: None suggested. Dependant on the substance. Migration: Must be further discussed, but based on the dynamic migration test method contained in EN 71-10 (2005) with some improvements called for by organisations such as SCHER and ANEC.

3.1.2 PAHs

PAHs are short for polyaromatic hydrocarbons. PAHs are a group of organic contaminants that form from the incomplete combustion of hydrocarbons, such as coal and gasoline. Numerous PAHs are carcinogenic and are classified as CMR. PAHs usually refer to a substance mixture of over one hundred individual compounds. Examples of PAHs are naphthalene, anthracene, benzo[e]pyrene, benzo[a]pyrene. PAHs can be part of toys made of rubber or elastomers (BfR No. 051, 2009).

There is no specific requirement regarding PAHs in the new Toy Safety Directive. PAHs are covered by the general requirement on CMR substances

(as described above in section 3.1.1 "Generic SVHCs including CMRs, PBTs, vPvBs and others (e.g. EDCs)"). However, the general CMR requirement only applies to PAHs that are classified as CMRs.

There are no requirements concerning PAHs in the EN 71 series of standards.

According to news from Chemical Watch (August 2013), the EU has confirmed its intention to add a restriction to REACH covering the presence of PAHs in articles supplied to the general public. This is the first example of the so-called "fast track" restriction procedure, outlined in Article 68.2 of REACH which can be applied to CMR substances coming into contact with consumers. Germany first requested that the Commission proposes a restriction for PAHs using the fast track procedure in the summer of 2010, but the process has taken time because it is the first case of its kind and the initial German request was not supported by the industry. The initial German proposals are discussed in more details below as Germany initially suggested a lower limit value compared to the limit value included in this proposed regulation on PAHs.

The proposed regulation which has been adopted at the most recent REACH Committee in June 2013 will be added to entry no. 50 concerning PAHs in REACH Annex XVII. The proposed regulation states that

- Toys, including activity toys, and childcare articles, shall not be placed on the market, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonable foreseeable conditions of use, contain more than 0.5 mg/kg (0.00005% by weight) of any of the listed PAHs.
- For other consumer articles the limit value should be 1 mg/kg (0.0001% by weight) instead, of any of the listed PAHs.
- The listed PAHs are the eight PAHs that already are restricted in REACH Annex XVII entry no. 50 in tyres[9].
- The restriction above should not be valid until 2 years after the date of entry into force.

The Council and the European Parliament have until 12 October 2013 to reach an opinion on the proposal or to adopt it. Publication in the Official Journal would happen as soon as possible after the date of adoption.

<u>BfR No. 51, 2009</u>

In this opinion, BfR states that cases of cancer in children are increasing and therefore asks for urgent action to minimise, as much as possible, the exposure to CMR substances. BfR has in this opinion applied the regulations on CMR substances to the new Toy Safety Directive when it comes to PAHs and has assessed it with regard to their health risk. BfR concludes that the currently valid levels neither protect children's health adequately, nor do they meet the requirement on exposure minimisation for CMR substances. BfR maintains the opinion that the ALARA principle (as low as reasonably achievable) should be applied to such substances. Studies of toys show that

[9] I.e. benzo[a]pyrene (BaP), benzo[e]pyrene (BeP), benzo[a]anthracene (BaA), chrysen (CHR), benzo[b]fluoranthene (BbFA), benzo[j]fluoranthene (BjFA), benzo[k]fluoranthene (BkFA), and dibenzo[a,h]anthracene (DBAhA).

the technologically possible levels of PAHs substances are clearly below the maximum levels permitted by the Toy Safety Directive.

BfR recommends that regulations of CMR substances in toys should in general rather refer to migration – not to content – as it is applied for plastic materials and articles intended to come into contact with food. For these materials, it is required that the migration of CMR substances is not detectable (< 0.01 mg/kg). BfR therefore suggests that the Regulation for Food Contact Materials should be applied to all types of toy materials and without age limit in order to minimise children's exposure to CMR substances. According to BfR this is technologically feasible and already best practise.

BfR No. 032, 2010

In this opinion BfR has performed a human health risk assessment for PAHs in consumer products. The risk assessment has focused on the potential carcinogenic risk following contact and uptake through the skin. BfR has evaluated chemical-analytical data on the PAH content of 5,300 consumer products (including toys). In 90% of these investigated products the sum of 6 PAHs[10] was below 1 mg/kg and PAHs (sum of 6 PAHs) were not detected in 84% of the products (limit of quantification was 0.2 mg/kg for all 6 PAHs). However, in some products very high PAH contents were found.

Based on this opinion from BfR the German Government handed over a request to the Commission of proposing a restriction for PAHs using the fast track procedure (article 68.2 of REACH). Germany recommended restricting the content of the 8 specific PAHs that are classified as carcinogenic in consumer products to a maximum of 0.2 mg/kg for each of the 8 PAHs. This limit value is based on the limit of quantification (LOQ) of the analytical test method used for the German GS (certified safety) mark. In addition, it is proposed that future technical progress is monitored and the limit value is adjusted to future (lower) analytical quantification limits as appropriate.

Of the 8 PAHs that BfR suggests a restriction of six are classified as Carc 1B and one as Carc 2, and two of these PAHs have a special concentration level of 0.01% meaning that the content of these PAHs are restricted in toys by the general CMR rule in a concentration of 0.01% (equivalent to 100 mg/kg).

Tests of PAHs in toys and childcare products

According to studies carried out by both Germany (BfR No. 025, 2009; BfR No. 032, 2010) and Denmark (Lassen et al., 2011), PAHs are found in several consumer products and toys. A Danish survey of 20 toys and childcare products found 16 specific PAHs in all 20 investigated products (detection limit was between 0.002 and 0.01 mg/kg for each of the 20 different PAHs), but in a maximum concentration of 100 mg/kg (calculated as a sum of the 16 PAHs). Germany has suggested a limit value of 0.2 mg/kg in consumer products for each of the 8 PAHs that are regulated within REACH (see above). Two of the investigated 20 products in the Danish study had a content of PAHs higher than this suggested German limit value. These two of the 20 products also had a content of PAHs higher than the proposed REACH Annex XVII restriction regulation of 0.5 mg/kg (Lassen et al., 2011).

[10] I.e. benzo[a]pyrene (BaP), benzo[a]anthracene (BaA), chrysen (CHR), benzo[b]fluoranthene (BbFA), benzo[k]fluoranthene (BkFA), and dibenzo[a,h]anthracene (DBAhA).

Oeko-Tex 100, 2013

Oeko-Tex 100 (the "Confidence in textiles" labelling) sets requirements for PAHs in their Oeko-Tex Standard 100. The requirements for baby products (Product Class I) are 0.5 mg/kg for benzo[a]pyrene and 5.0 mg/kg as a sum of all PAHs listed in their Appendix 5 (contains a list of 24 specific PAHs). The requirements for PAHs in textile products in direct contact with skin (Product Class II) are 1.0 mg/kg for benzo[a]pyrene and 10.0 mg/kg as a sum of all 24 PAHs listed in their Appendix 5 (Oeko-Tex 100, 2013).

According to the supplement to the Oeko-Tex Standard 100 (Oeko-Tex 100 Supplement, 2013), textile toys can also receive the Oeko-Tex mark by complying with the Oeko-Tex requirements. The requirements to toys are that all textile and non-textile components of textile toys must comply with at least the requirements of Product Class II as listed above. Articles for babies and toddlers under the age of 3 years must comply with the requirements for Product Class I as listed above.

In the testing procedure document (Oeko-Tex 100 Testing procedures, 2013), it is stated that the determination of the PAH content is performed by extraction of the textile material with an organic solvent. The extract is analysed after clean-up by GC-MS.

3.1.2.1 Conclusion PAHs

A risk assessment carried out by BfR shows that the general CMR restriction in the new Toy Safety Directive is not adequately protecting children from negative health effects from exposure to PAHs and that the limit value should be lowered accordingly.

Germany proposed a restriction for PAHs using the fast track procedure of REACH. The proposal was that each of the 8 PAHs classified as carcinogenic should be restricted to a content of 0.2 mg/kg as this corresponds to the quantification level/detection level. In addition, it is proposed that future technical progress is monitored and the limit value is adjusted to future (lower) analytical quantification limits as appropriate. This means that Germany advocates for a future lowering of the 0.2 mg/kg limit value, when lower detection limits are possible, as 0.2 mg/kg may not be stringent enough. Precisely where the "correct" limit value should be is not mentioned in the risk assessment carried out by BfR but the exposure levels and DMEL values calculated indicate that it is possible to argue for a lowering of the PAH limit value.

According to the Danish EPA report (Lassen et al., 2011), it is possible to lower the detection limit to 0.01 mg/kg (or even lower for some specific PAHs) for each of the PAHs. It is, however, not known whether the test method has been validated.

In the conversion into a REACH restriction proposal, the Member States have reached an agreement on a limit value of 0.5 mg/kg for each of the 8 PAHs, i.e. a proposal that is worse than what Germany had suggested (0.2 mg/kg for each of the 8 PAHs).

In their large survey of PAHs in consumer products, BfR has illustrated that the limit value of 0.2 mg/kg should be possible to meet as PAHs (sum of 6 PAHs) were not detected in 84% of the about 5,300 investigated consumer products (limit of quantification was 0.2 mg/kg for all 6 PAHs).

In the Oeko-Tex Standard 100, the restriction is based on the content and the Oeko-Tex Standard 100 restricts in all 24 different PAHs and not just the 8 PAHs as suggested in the restriction proposal by BfR.

Type of limit value

BfR is suggesting a content based limit value for PAHs. The German proposal was therefore also based on a content based limit value and so is the REACH restriction proposal. It is therefore suggested to use a content based limit value for the PAHs.

Limit values

As mentioned above, the REACH restriction proposal of 0.5 mg/kg for each of the 8 PAHs is worse than what Germany originally had suggested (0.2 mg/kg for each of the 8 PAHs). BfR is even arguing in their opinion (BfR No. 032, 2010) that the limit value of 0.2 mg/kg should be lowered in the future as soon as lower analytical quantification limits have been established.

BfR has in their large survey of PAHs in consumer products illustrated that the limit value of 0.2 mg/kg should be possible to meet as PAHs (sum of 6 PAHs) were not detected in 84% of the about 5,300 investigated consumer products (limit of quantification was 0.2 mg/kg for all 6 PAHs).

For this reason, it is suggested to keep the original limit value as suggested by Germany of 0.2 mg/kg for each of the 8 PAHs.

Test methods

The test method used should be the test method as described in BfR No. 032 (2010), i.e. the test method used for the German GS (certified safety) mark. However, it is suggested as soon as validated test methods exist which could ensure a lower detection limit than 0.2 mg/kg for each of the 8 PAHs, this test method should be used instead.

Suggestion: PAHs

The following suggestions for chemical requirements are made for PAHs.

Table 3: Suggested chemical requirements regarding PAHs in toys

PAHs **(in rubber and elastomer materials)**	**Type of limit value:** Content based **Limit value:** 0.2 mg/kg as for each of the 8 carcinogenic PAHs in all toys. However, a lowering of the limit value should be possible when validated test methods with lower detection limit values exist in the future. **Test method:** Test method used for the German GS (certified safety) mark.

3.1.3 BPA

BPA (bisphenol A) is used as a building block for polycarbonate plastics and is often used in food and beverage storage. Polycarbonate plastic can also be used in toys. BPA is a known endocrine disrupting chemical and studies have shown that BPA can leach from polycarbonate plastic products. Furthermore, human epidemiological studies have revealed a correlation between BPA levels and disease (Rubin, 2011). However, according to Rubin (2011) much more investigation is needed to understand the potential adverse health effects of BPA exposure in humans.

BPA is not restricted in the old Toy Safety Directive but will be restricted with a 3.0% limit value (from June 1, 2015) as BPA is a Category 2 reproductive toxicant according to the CLP regulation. Until June 1, 2015 the limit value for BPA is 5%.

In EN 71-9 (2007) BPA is restricted by a migration limit of 0.1 mg/l simulant. EN 71-9 (2007) is not a harmonised standard and therefore has no legal status.

An inclusion of this limit value of 0.1 mg/l simulant in Appendix C of the new Toy Safety Directive is currently (September 2013) being discussed in the Expert Group on Toy Safety and its Subgroup "Chemicals". Appendix C (of Annex II) is a list of 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.

Swedish Chemicals Agency, 2012

The Swedish Government assigned the Swedish Chemicals Agency (KEMI) to conduct a survey of the extent to which BPA is included in and migrates from toys and childcare articles and, if required, to propose measures to reduce the exposure. Based on their results of the chemical analysis of BPA in toys and childcare articles, together with evidence from scientific research studies on BPA, the Swedish Chemicals Agency concludes that no risk could be identified when applying the REACH risk assessment method. The Swedish Chemicals Agency states that the reference dose they have used to estimate the risks is far below the TDI value, which is used by EFSA. The Swedish Chemicals Agency also states that the EU ban on BPA in feeding bottles has resulted in a considerable reduction of exposure of small children to BPA. At the present time the Swedish Chemicals Agency does therefore not propose any further restrictions to reduce the exposure of children to BPA in toys and childcare articles. However, they state that humans are still continuously exposed to BPA from, in many cases, unknown sources and it is essential to identify all sources where children may be exposed to BPA. The Swedish Chemicals Agency therefore considers it very important to actively monitor developments in the health risks of children after exposure to BPA (KEMI, 2012).

The Endocrine Society, 2012

In a newsletter on the website of the Endocrine Society, the Endocrine Society expresses disappointment in the FDA (US Food and Drug Administration) for neglecting key research and endocrine principles in deciding not to ban BPA in food packaging in spite of the fact that recent research demonstrates

its harmful effects to the endocrine system. The Endocrine Society is concerned that the available scientific data such as “low dose effects” is being “ignored” (The Endocrine Society, 2012).

FDA has derived a TDI value (the same approach as used by EFSA). However, this TDI value ignores (according to scientists) many scientific studies which have shown effects at much lower doses (“low dose effects”) (as described by e.g. Vandenberg et al. (2012)).

Digital Journal, 2012 & Chemical Watch, May 2013

According to news from Digital Journal, France is banning BPA in food contact materials. The ban will apply to food contact material for children under the age of three and pregnant and feeding mothers (warning label) and will enter into force on 1 October 2013. The rest of the ban will be rolled out for all other food contact packaging by 1 January 2015 (Digital Journal, 2012; Chemical Watch, May 2013).

Danish survey on the exposure of 2 year-olds to endocrine disruptors, 2009

The Danish EPA conducted a survey from 2008 to 2009 on the cumulative exposure of 2 year-olds to endocrine disrupting chemicals including BPA. BPA was examined in e.g. pacifiers made of polycarbonate plastics. The chemical analysis showed that BPA was present in five of five pacifiers made of polycarbonate plastics in concentrations ranging from 0.1-0.2%. However, in a migration test with use of artificial sweat and artificial saliva no detectable or a very low migration of BPA (0.0007%) was found (Danish EPA, 2009).

3.1.3.1 Conclusion BPA

Several sources show that BPA is an endocrine disrupting chemical. However, a risk assessment carried out by the Swedish Chemicals Agency shows that BPA does not present a risk in toys and childcare articles. On the other hand, the Chemicals Working Group of the Toy Safety Experts Group has proposed to adopt the EN 71-9 (2007) limit (which is based on the EFSA TDI derived value) and to incorporate it in Appendix C. Furthermore, France has banned the use of BPA in food contact materials intended for children under the age of three years.

Scientists do not agree on the risk assessment of BPA and EFSA has decided to come up with a new risk assessment of BPA later in 2013. The conclusion is therefore that there is an uncertainty of the risk of BPA and the risk of BPA is being heavily debated.

For this reason, no separate restriction is proposed for the time being in this report for BPA in toys. Instead, it is proposed that BPA is restricted by a more overall restriction covering the group of endocrine disrupting chemicals, CMRs, etc. See the section on general aspects in chapter 3.1.1 “Generic SVHCs including CMRs, PBTs, vPvBs”. Furthermore, it is recommended to review the situation after EFSA has made its new assessment.

3.1.4 Phthalates and other plasticisers

Certain phthalates are restricted in toys and childcare articles by the REACH Regulation No. 1907/2006 Annex XVII entry No. 51:

- The phthalates DEHP, DBP and BBP are not to be used in concentrations higher than 0.1% by weight of the plasticised material in toys and childcare articles.
- The phthalates DINP, DIDP and DNOP are not to be used in concentrations higher than 0.1% by weight of the plasticised material in toys and childcare articles which can be placed in the mouth by children.

Furthermore, certain phthalates are on the REACH's candidate list of SVHC[11] meaning that they are subject to an information requirement (article 33 of REACH) if the content in articles is higher than 0.1%. These 10 phthalates are: DEHP, DBP, BBP, DIPP, DIBP, DIHP, DHNUP, DPP, DMEP, DPP, N-pentyl-isopentylphtalate (as of 20 June 2013).

The Toy Safety Directive (2009/48/EC) does not contain specific limits for phthalates or other plasticisers. However, other phthalates may be restricted by the general CMR requirement in annex II, but the limit may be as high as 3% (for category 2 reproductive toxicants) or 5% until June 2015.

EN 71-9 (2007) contains some limited requirements regarding plasticisers. Requirements are set for the following plasticisers; however, EN 71-9 (2007) is not a harmonised standard and therefore has no legal status. The limit value set is the "action limit", i.e. the limit of the applicable method as specified in EN 71-11 (2005), which in case of these plasticisers is 0.03 mg/litre aqueous migrate.

- Triphenyl phosphate
- Tri-o-cresyl phosphate
- Tri-m-cresyl phosphate
- Tri-p-cresyl phosphate

<u>BfR opinion No. 004, 2011</u>
BfR has assessed the risk of the phthalate DPHP (di-2-propoylheptyl phthalate) used in toys. DPHP is not restricted by the REACH Annex XVII restriction and is not listed as a SVHC. DPHP has been found in toys in concentrations up to 48.2% by weight. BfR states that DPHP has been proven in experiments with animals to have a damaging effect on the thyroid and hypophysis. In a risk assessment where only the exposures to DPHP from toys were taken into account, BfR found no health risk. However, when exposure to DPHP from other sources was also taken into account, the safe intake dose calculated was sometimes exceeded. BfR therefore concludes that it is necessary to reduce the levels of DPHP to which children are exposed through toys. However, no suggestion for a specific limit value was recommended (BfR No. 004, 2011).

[11] Substances of Very High Concern

CEN/TC 52, 2002

A comprehensive assessment of plasticisers has been made by a group of toxicologists in the development of EN 71-9/10/11 regarding organic chemical compounds in toys. The CEN/TC 52 working group received a list of over 800 different organic chemicals potentially used in toys. This list was reviewed and the plasticisers were identified as well as their hazard. The work resulted in the following conclusions (CEN/TC 52, 2002):

- Tri-o-cresyl phosphate and tri-o-tolyl phosphate should not be intentionally used and should not be detected in toys on the basis of clear evidence of harmful effects in humans. Tri-o-cresyl phosphate ended up being restricted in EN 71-9 (2007) as well as tri-m-cresyl phosphate and tri-p-cresyl phosphate as all three substances are available together in commercial mixtures.
- 70% of all the 33 investigated plasticisers used in toys had no or insufficient data regarding their health properties. The CEN/TC 52 working group therefore recommended that the most of the plasticisers should be submitted to the Commission as a matter of high priority for the acquisition of appropriate toxicological information in order to perform risk assessment on these substances. Furthermore, the CEN/TC 52 working group recommended that until this information becomes available the plasticisers should not intentionally be used in toys.

Danish regulation on phthalates

Denmark has a stricter regulation on phthalates than the rest of the EU. According to Statutory Order No. 855 of 5.9.2009 concerning restriction of phthalates in toys and articles for toddlers, all phthalates are restricted in toys intended for children at the age of 0-36 months and in articles for toddlers that can be placed in the mouth (e.g. soothers, bibs, bathing equipments). Phthalates are defined as esters of o-phthalic acid. The content limit value is set at 0.05 % by weight, i.e. 500 ppm (DK Statutory Order No. 855, 2009).

Danish survey on the exposure of 2 year-olds to endocrine disruptors, 2009

The Danish EPA conducted a survey on the cumulative exposure of 2 year-olds to endocrine disrupting chemicals (incl. the phthalates DEHP, DINP, DBP, DIBP and BBP) from 2008 to 2009. The report concluded that when looking at toys alone there is no risk of endocrine disrupting effects in 2 year-olds. However, when looking at the cumulative risk, i.e. exposures from other sources than toys and exposure from other endocrine disrupting chemicals with the same target effect (antiandrogenic effects), a risk of effects in the endocrine system can occur. The report therefore concluded that there is a need to reduce the exposure to endocrine disrupting chemicals in general, but no specific limit values were suggested (Danish EPA, 2009).

Nordic Ecolabelling, 2012

In the Nordic Ecolabelling of toys, there is a kind of general requirement stating that phthalates must not be added to the toys (plastic materials, rubber, chemical products used in wood-based materials, chemical products used for surface treatment of wood and metal, adhesives and glue). The limit value is for some materials set at 100 ppm (Nordic Ecolabelling, 2012).

Oeko-Tex 100, 2013

Oeko-Tex Standard 100 (the "Confidence in textiles" labelling) sets requirements for phthalates (used for prints on textiles, for accessories made from plastics, coated articles and flexible foams). The requirement to phthalates is that the maximum sum of specific phthalates allowed is 0.1% (i.e. 1000 mg/kg) (Oeko-Tex 100, 2013). This applies to:

- Product Class I (for babies), where the following phthalates are not allowed: DINP, DEHP, DIDP, BBP, DBP, DIBP, DIHP, DHNUP, DHP, DMEP, and DPP.
- Product Class II (direct skin contact), III (no direct skin contact) and IV (decoration materials), where the following phthalates are not allowed: DEHP, BBP, DBP, DIBP, DIHP, DHNUP, DHP, DMEP, and DPP.

According to the supplement to the Oeko-Tex Standard 100 (Oeko-Tex 100 Supplement, 2013), textile toys can also receive the Oeko-Tex mark by complying with the Oeko-Tex requirements. The requirements to toys are that all textile and non-textile components of textile toys must comply with at least the requirements of Product Class II as listed above. Articles for babies and toddlers under the age of 3 must comply with the requirements for Product Class I as listed above.

In the testing procedure document (Oeko-Tex 100 Testing procedures, 2013), it is stated that the determination of phthalates is performed by extraction of the testing material with an organic solvent. The extract is analysed after clean-up by GC-MS.

3.1.4.1 Conclusion phthalates and other plasticisers

A Danish risk assessment on the cumulative risk of endocrine disrupters (including phthalates) concludes that there is a need to reduce the exposure to endocrine disrupting chemicals in 2 year-olds. For this reason it seems reasonable to restrict a general use of phthalates in toys in line with Denmark. Six phthalates are today restricted through Annex XVII of REACH. However, ten phthalates are on the REACH candidate list of SVHCs because of being toxic to reproduction. Not all phthalates are hence restricted by REACH, but some are subject to the information requirement (i.e. no restriction but only a requirement to inform the professional customer when the phthalates are contained in the products above 0.1%).

The CEN/TC 52 working group recommended in their report from 2002 that specific plasticisers should be restricted in toys. Some of these are today restricted via EN 71-9 (2007), which, however, is not a harmonised standard and therefore has no legal status. The CEN/TC 52 working group furthermore recommended that toxicological data should be found on all other plasticisers used in toys as data was lacking for 70% of the used plasticisers in toys, and that these plasticisers should not be used in toys until toxicological data was found and a risk assessment performed.

Type of limit value

Phthalates are not chemically bound in the plastic products and can thus migrate from the plastic products when present in the compounds. This supports a migration based limit value; however, as certain phthalates already are restricted by use of a content based limit value, it is therefore suggested to use a content based limit value in line with the existing phthalate limits. A content based limit value may furthermore be easier to verify.

Limit values

It is suggested to use the limit value as used in the Danish Statutory Order of 0.05% (500 mg/kg). The Danish Statutory Order uses this limit value for toys intended for use by children of the age of 0-36 months only as this age group has a higher exposure towards the substances because of their tendency to put toys in their mouth. Nordic Ecolabelling seems to use a lower limit value of 100 ppm; however this value is only specified for some materials.

It is suggested to use the same limit value for all toys irrespective of the age group the toys are intended for. An argument for this suggestion is that children below the age of three also play with toys intended for a higher age group, especially if they have older siblings. Furthermore, the survey from the Danish EPA (2009) on the cumulative exposure of 2 year-olds illustrated that there is a need to reduce the exposure to endocrine disrupting chemicals in general as it is the cumulative exposure of e.g. all the phthalates that is interesting.

DPHP, as assessed by BfR, is not restricted nor contained in the REACH candidate list of SVHCs. It is therefore suggested to restrict this phthalate as well in line with DINP, DIDP and DNOP in toys which can be placed in the mouth by children.

For these reasons, it is therefore suggested to restrict all phthalates (esters of o-phthalic acid) in toys for all ages with the limit value of 0.05%. It should of course be possible to allow for exemptions if a full risk assessment and a positive opinion by SCHER show that specific phthalates may not present a risk (when taking cumulative risks into consideration).

For other plasticisers there is in general a lack of information (as illustrated by the work carried out by the CEN/TC 52 working group in 2002). A few plasticisers are restricted in EN 71-9 (2007) (however, the standard is not harmonised). It is therefore suggested to use the approach as recommended by the CEN/TC 52 working group, i.e. restricting the use of all plasticisers in toys until a risk assessment has illustrated safe use.

Test methods

No specific test method has been described concerning content based testing.

Suggestion: Phthalates and other plasticisers

Table 4 summarises the suggestions for requirements for phthalates and other plasticisers.

Table 4: Suggested chemical requirements regarding phthalates and other plasticisers in toys

Phthalates and other plasticisers **(in plastic materials)**	**Type of limit value:** Content based **Limit value:** • No phthalates (esters of o-phthalic acid) are allowed in toys (for all ages). Limit value: 0.05% (500 ppm). • Exemptions may be granted but only on the basis of a full risk assessment and a positive opinion by SCHER. • It is only allowed to use other plasticisers that have been approved by SCHER on the basis of a full risk assessment (= positive list of other plasticisers that can be used in specific concentrations). **Test method:** None suggested. Dependant on the substance.

3.1.5 Nickel

Nickel is carcinogenic and is therefore in the new Toy Safety Directive restricted by the general CMR restriction as listed above. However, nickel is exempted from this general restriction, according to Appendix A in the new Toy Safety Directive, when used in stainless steel. This is because nickel in stainless steel has proven to be safe.

SCHER opinion, 2012

SCHER has assessed the risk to children's health by the presence of metallic nickel in toys (SCHER Nickel, 2012). According to SCHER, the carcinogenic effect of nickel is related to inhalation of nickel-containing dusts and fumes and not to dermal exposure. SCHER therefore concludes that the use of metallic nickel in toys (allowing the correct electrical function of toys) will result in a very low potential for exposure to nickel by oral and dermal intake and thus health risks are not expected.

This means that when it comes to the carcinogenic effect of the use of metallic nickel in toys, health risks are not expected. This is the reason why nickel has specifically been listed in Appendix A: "List of CMR substances and their permitted uses" of the Toy Safety Directive. Nickel is, according to Appendix A, permitted for use in stainless steel.

3.1.5.1 Conclusion nickel

Nickel in stainless steel is considered to be safe for use in toys. For this reason, no restriction will be made for nickel in this report, specifically concerning its carcinogenic effects. However, nickel is also a sensitiser, and should for this reason be restricted in toys. See section 3.3 on "Sensitisers – Fragrances".

3.1.6 Formaldehyde

Formaldehyde is used as a preservative and biocide primarily in "chemical" toys (e.g. modelling clay or similar) or in textiles. Formaldehyde is carcinogenic and allergenic. Formaldehyde is therefore in the new Toy Safety Directive restricted by the general CMR restriction as listed above. Formaldehyde is classified as Carc. 2 (suspected of causing cancer) and Skin Sens. 1, but has in November 2012 been reclassified by ECHA Committee for Risk Assessment (RAC) as Carc. 1B (and as Muta. 2), (ECHA RAC, 2012). This reclassification has not yet been updated in the CLP system. Being classified as Carc. 1B means that a concentration of 0.1% formaldehyde is allowed in toys.

In the EN 71-7 (2002) standard, the content of free formaldehyde is restricted in finger paints in concentrations of 0.1% (1000 mg/kg) and it is expected that the limit value will be kept in the new EN 71-7 standard (for the new Toy Safety Directive – sent to formal vote in July 2013). In comparison, free formaldehyde is restricted in cosmetic products in a concentration of 0.2% (Directive 76/768/EEC).

The EN 71-9 (2007) standard contains requirements on formaldehyde contained in textiles, paper, wood and as preservative and monomer. EN 71-9 (2007) is not a harmonised standard and therefore has no legal status. The requirements are:

- Accessible textile components of toys intended for children under 3 years of age shall not contain free and hydrolyzed formaldehyde in excess of 30 mg/kg when tested in accordance with EN ISO 14184-1.
- Accessible paper components of toys intended for children under 3 years of age shall not contain formaldehyde in excess of 30 mg/kg when tested in accordance with EN 645 and EN 1541.
- Accessible resin-bonded wood components of toys intended for children under 3 years of age shall not release formaldehyde in excess of 80 mg/kg when tested in accordance with EN 717-3.
- Migration of formaldehyde (as a monomer) shall not exceed the action limit of 2.5 mg/l simulant.
- Formaldehyde (free) (as a preservative) shall not exceed the limit of 0.05%.

In the chemicals working group of the Toy Safety Experts Group, there is a discussion going on to publish the EN 71-9 (2007) requirements in appendix C of the new Toy Safety Directive. There are some doubts about the test methods referred to in EN 71-9 (2007). But in principle there is an agreement that the content based requirement (0.1% in the future) should be complemented by an additional entry in appendix C regarding e.g. paper, textiles and wood, maybe including an inhalation based requirement using test chambers[12].

Nordic Ecolabelling, 2012

In the Nordic Ecolabelling of toys, there is a requirement stating that formaldehyde emissions from textiles and padding materials shall be less than 20 mg/kg. The test method listed is ISO 14184-1. Furthermore, the content of

[12] Information from Franz Fiala, The Consumer Council at the Austrian Standards Institute

free formaldehyde is restricted in wood (either by a content based limit value or by an emission limit value). The content based limit value is maximum 5 mg/100 g solids for MDF boards and 4 mg/10 g solids for all other boards. The emission based limit value is 0.09 mg formaldehyde/m^3 air for MDF boards and 0.07 mg/m^3 air for all other boards (Nordic Ecolabelling, 2012).

Oeko-Tex 100, 2013

Oeko-Tex Standard 100 (the "Confidence in textiles" labelling) sets a requirement for formaldehyde. The requirement is that formaldehyde must not be used in concentrations higher than listed below (Oeko-Tex 100, 2013):

- Product Class I (for babies), where the maximum allowed concentration should not be detectable, i.e. 16 mg/kg.
- Product Class II (direct skin contact), where the maximum allowed concentration is 75 mg/kg.
- Product Class III (no direct skin contact) and IV (decoration materials), where the maximum allowed concentration is 300 mg/kg.

According to the supplement to the Oeko-Tex Standard 100 (Oeko-Tex 100 Supplement, 2013), textile toys can also receive the Oeko-Tex mark by complying with the Oeko-Tex requirements. The requirements to toys are that all textile and non-textile components of textile toys must comply with at least the requirements of Product Class II as listed above. Articles for babies and toddlers under the age of 3 must comply with the requirements for Product Class I as listed above.

In the testing procedure document (Oeko-Tex 100 Testing procedures, 2013), it is stated that the determination of formaldehyde is performed as given by the Japanese law "Harmful Substance – Containing Household Products Control Law No. 112". According to this method, the content of free and partially releasable formaldehyde is integrally determined in an aqueous extract using the acetyl-acetone method by means of a spectrophotometer.

3.1.6.1 Conclusion formaldehyde

Today the content of formaldehyde is already limited in textiles, paper, wood, as preservative and monomer through EN 71-9. EN 71-9 (2007) is, however, not a harmonised standard and therefore has no legal status. The limit value (content based) in textiles and paper is set at 30 mg/kg (0.003%) and at 80 mg/kg (0.008%) for wood. The limit value as a preservative is set at 500 mg/kg (0.05%) whereas the suggested limit value in the EN 71-7 (draft 2013) standard put to the vote for finger paints is 0.1%.

It is therefore suggested to adopt the already existing EN 71-9 (2007) limit values as the legal limit values. The test methods need further discussion.

Suggestion: Formaldehyde

Table 5 summarises the suggestions for requirements for formaldehyde.

Table 5: Suggested chemical requirements regarding formaldehyde in toys

Formaldehyde **(in textiles, wood, paper, as preservative and monomer)**	**Type of limit value:** Dependant on the material **Limit value:** • Textiles: Accessible textile components of toys intended for children under 3 years of age shall not contain free and hydrolyzed formaldehyde in excess of 30 mg/kg when tested in accordance with EN ISO 14184-1. • Paper: Accessible paper components of toys intended for children under 3 years of age shall not contain formaldehyde in excess of 30 mg/kg when tested in accordance with EN 645 and EN 1541. • Wood: Accessible resin-bonded wood components of toys intended for children under 3 years of age shall not release formaldehyde in excess of 80 mg/kg when tested in accordance with EN 717-3. • Migration of formaldehyde (as a monomer) shall not exceed the action limit of 2.5 mg/l simulant. • Formaldehyde (free) (as a preservative) shall not exceed the limit of 0.05%. **Test method:** Use of existing test methods, but to be discussed further.

3.1.7 Phenol

Phenol is used, amongst others, in the production of plastics and dyes. The substance may therefore be contained in toys. BfR states in an opinion on phenol that migration tests from toys and utensils have shown migration of phenol from these products (BfR No. 038, 2009).

Phenol has a harmonised classification of Muta. 2 which means that phenol is indirectly restricted by the general CMR requirement in the new Toy Safety Directive. The content limit value of phenol is therefore 1.0% in toys.

Phenol is currently limited by the following migration limit values according to EN 71-9 (2007) and EN 71-11 (2005). It should, however, be noted that neither the EN 71-9 (2007) standard nor the EN 71-11 (2005) standard is harmonised and therefore has no legal status:

- As a monomer – 15 mg/l in aqueous migrate (migration limit value).
- As a preservative – action limit of 10 mg/kg in toy material (content based limit value).

SCHER opinion, 2007

In an opinion from SCHER (SCHER, 2007), it is stated that, based on the migration limit value set in EN 71-9 (2007) of 15 mg/l (as a monomer), the calculated margin of exposure is 48 and SCHER therefore concludes that its limit value has to be lowered at least by a factor of 2. This is based on a margin of exposure of 100 being considered to be sufficiently large.

BfR No. 038, 2009

In an opinion on limit values for phenol in food-contact articles and toys, BfR has stated that the existing limit value for phenol in toys is not adequate. BfR assumes that the existing TDI value for phenol of 1.5 mg/kg bw/day has been used to deduce the existing migration value of 15 mg/l for toys in EN 71-9 (2007). However, an EU assessment has shown that the TDI value for phenol is in the range where harmful effects still are observed in animals experiments (LOAEL of 1.8 mg/kg bw/day). BfR is therefore of the opinion that a reassessment of phenol is necessary (BfR No. 038, 2009).

BfR also states that the data on release or migration of phenol from consumer products is scarce so they cannot perform a realistic exposure assessment for consumers.

BfR therefore asked EFSA to re-evaluate the TDI for phenol.

EFSA, 2013

EFSA was asked by BfR to re-evaluate the TDI for phenol of 1.5 mg/kg bw/day. The EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) comprehensively reviewed the available toxicological studies, mainly those using an oral route of exposure. The conclusion of the CEF Panel was that the TDI value should be lowered. The CEP Panel set a TDI for phenol to 0.5 mg/kg bw/day by applying a standard uncertainty factor of 100 (for inter- and intra-species differences). The CEP Panel did not assess the hazards related to the possible oxidation products of phenol, e.g. quinones/hydroquinones. Therefore, the above TDI only covers phenol. The CEF Panel noted that exposure to phenol may occur via sources other than food contact materials, e.g. flavourings, smoke flavourings, traditionally smoked foods, floor waxes, cosmetics, disinfectants, etc., and noted that it may be relevant to take note of all these sources of exposure when restricting phenol.

3.1.7.1 Conclusion phenol

EFSA has re-evaluated the TDI value of phenol and came to the conclusion that the TDI value should be lowered to 0.5 mg/kg bw/day instead of the existing 1.5 mg/kg bw/day. Assuming that the existing limit values for phenol are based on the TDI value of 1.5 mg/kg bw/day, a lowering of the TDI value by a factor 3 therefore calls for a parallel lowering of the limit values for phenol in toys. In their opinion, EFSA points out that it may be relevant to take note of all other sources of exposure from e.g. food, food contact materials and cosmetics, when restricting phenol. This could call for yet another lowering of the limit values of phenol. This needs to be investigated further. The conclusion is, however, that the existing limit values for phenol should be lowered by (at least) a factor 3. Furthermore, the new limit values for phenol should be included in Appendix C according to article 46 of the new Toy Safety Directive so that the requirements get legal status.

The existing migration limit value of 15 mg/l in aqueous migrate is based on the former TDI value of 1.5 mg/kg bw/day. The TDI value translates into a value of 11.25 mg/child/day, when using a weight of a child of 7.5 kg as normally used (however, a weight of 10 kilos must have been used before to obtain the 15 mg/l). The limit for phenol should be set using 10% of the TDI value, i.e. resulting in 1.125 mg/child/day. As the migration test uses 100 ml of simulant this results in a value of 1.125 mg/100 ml of simulant or 11.25 mg/l

simulant. Using the same calculation with the new TDI value of 0.5 mg/child/day results in a limit value of 3.75 mg/l simulant.

The existing content based limit value of 10 mg/kg in the toy material for phenol as a preservative is an action limit value, which means that the limit value has been set based on the level of quantification. For this reason it is not suggested to change (or lower) this limit value for phenol used as a preservative.

The new limit values for phenol should therefore be:

- As a monomer – 4 mg/l in aqueous migrate.
- As a preservative – 10 mg/kg in toy material.

Suggestion: Phenol

Table 6 summarises the suggestions for requirements for phenol.

Table 6: Suggested chemical requirements regarding phenol in toys

Phenol	**Type of limit value:** Migration and content based **Limit value:** • As a monomer: 4 mg/l in aqueous migrate • As preservative: 10 mg/kg in toy material (content based) **Test method:** Use of existing test methods (in EN 71-9 (2007) and EN 71-11 (2005)).

3.2 Elements (heavy metals)

The chemical requirements of the Toy Safety Directive (Directive 2009/48/EC) entered into force on 20 July 2013. Until this date the chemical requirements of the old Toy Safety Directive (Directive 88/378/EEC) were still valid. There are some major differences from the former Directive to the new Toy Safety Directive when it comes to the elements:

- The old Toy Safety Directive included bioavailability limits which were "translated" into migration values for eight elements (antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium) in the old standard EN 71-3 (1994). Instead of only restricting eight elements, now 18 elements are restricted (see Table 7 below).
- Instead of only one migration value for the toy material, now three different migration limits per element are used dependant on the material:
    - Dry, brittle, powder-like or pliable toy material
    - Liquid or sticky toy material
    - Scraped-off toy material

The old Toy Safety Directive included bioavailability limits which were "translated" into migration values in the old standard EN 71-3 (1994) assuming that 8 mg of the material are ingested.

The new migration limit values are based on a report from RIVM (2008) where the migration limits have been calculated based on:

- A certain percentage of the TDI values (Tolerable Daily Intake) of the different elements (i.e. depending on the element either 5% or 10% of the TDI value is used as there are other sources of exposure than toys).
- The average weight of a child of an 8 months old baby (7.5 kg).
- Worst case values of toys being ingested by oral contact by the babies (i.e. 100 mg for powder-like material, 8 mg for scraped-off toy material and 400 mg for liquid material).

The RIVM report (2008) calculated different migration limit values based on 5, 10 or 20% of the TDI values and stated in the report that the actual choice of a percentage is a risk management decision and a political sensitive subject. In the new Toy Safety Directive it has been decided to use a migration limit value based on 5% of the TDI value for arsenic, cadmium, chromium VI, lead, mercury and organic tin. This is described in preamble 22 of the new Toy Safety Directive:

- "Limit values for arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, and which should therefore not be intentionally used in those parts of toys that are accessible to children, should be set at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee in order to ensure that only traces that are compatible with good manufacturing practice will be present."

For the rest of the elements, the migration limits are based on 10% of the TDI value.

The new Toy Safety Directive has been criticised for setting less strict migration limits when it comes to certain elements (such as antimony, arsenic, barium, lead and mercury). This will be discussed in more details below for each element. Table 7 shows the migration limit values in the new Toy Safety directive (Directive 2009/48/EC) compared to the former Toy Safety Directive (Directive 88/378/EEC).

Changes to the migration limits of cadmium have already been made (the amended limit values are included in Table 7 below and are based on 5% of a lower TDI value because of newer toxicology information on cadmium (Directive 2012/7/EU)).

Changes to the migration limits of barium have already been made by Regulation No 681 (2013). The amended limit values are included in included in Table 7 below and are based on 10% of a lower TDI value because of an update of the toxicological profile for barium.

Changes to the migration limits of lead are being discussed[13]. In April 2011 Member States in the Expert Group on Toy Safety agreed to follow a proposal of the Chemicals Subgroup to reduce the lead limit based on a benchmark dose limit proposed by EFSA, however, using a 10% allocation (the Subgroup had proposed 5% as listed in preamble 22 of the new Toy Safety Directive). This would have resulted in the following limits: 4 mg/kg in powder-like materials, 1 mg/kg in liquid materials and 47 mg/kg in scraped off materials. However, the industry raised concern claiming that several products

[13] Information from Franz Fiala, The Consumer Council at the Austrian Standards Institute

(writing instruments) using naturally contaminated materials (such as kaolin) would have to be withdrawn from the market. So the Commission was forced to initiate an impact assessment and to commission some studies in this regard (presented in May 2013). Hence, the whole process is delayed.

The methods of analysis for the elements are described in the new EN 71-3 (2013) which was adopted in June 2013.

Table 7: Migration limits for the elements in mg/kg (ppm)

Element	New TSD (2009/48/EC)			Old EN 71-3 (1994)
	Dry, brittle, powder-like or pliable toy material	Liquid or sticky toy material	Scraped-off toy material	Migration from all toy materials (except modelling clay and finger paints)
Aluminium	5,625	1,406	70,000	
Antimony	45	11.3	560	60
Arsenic	3.8	0.9	47	25
Barium	1,500	375	18,750	1,000
Boron	1,200	300	15,000	
Cadmium	1.3	0.3	17	75
Chromium (III)	37.5	9.4	460	60
Chromium (VI)	0.02	0.005	0.2	
Cobalt	10.5	2.6	130	
Copper	622.5	156	7,700	
Lead	13.5	3.4	160	90
Manganese	1,200	300	15,000	
Mercury	7.5	1.9	94	60
Nickel	75	18.8	930	
Selenium	37.5	9.4	460	500
Strontium	4,500	1,125	56,000	
Tin	15,000	3,750	180,000	
Organic tin	0.9	0.2	12	
Zinc	3,750	938	46,000	

SCHER opinion, 2010a

In this opinion paper, "Migration limits of chemical elements in toys", SCHER discussed the migration limits for the 18 elements in the new Toys Safety Directive and the prerequisites that RIVM used for the calculation of the migration limits. SCHER agrees that the total contribution of the elements from toys should not exceed 10% of the TDI value for the elements and SCHER agrees with the used default values for direct ingestion.

In the new Toy Safety Directive, either a value of 5% or 10% of the TDI value has been used dependant on the elements (5% has been used for arsenic, cadmium, chromium VI, lead, mercury and organic tin as it is listed in preamble 22 of the new Toy Safety Directive). However, SCHER does not support this differentiation and recommends the use of 10% value of the TDI for all chemical elements[14].

[14] But preamble no. 22 of the new Toy Safety Directive reflects the will of the legislator, which stands above any opinion of any scientific committee. So in principle preamble no. 22 suggests to use 50% of whatever any scientific committee finds appropriate.

ANEC position, 2010a

ANEC has made a position paper on the SCHER opinion on migration limits of chemical elements. In this position paper, ANEC strongly disagrees with SCHER that a 10% rather than 5% allocation of the TDI value should be used for certain elements. ANEC argues that the determination of the fraction of the TDI is entirely a political decision. There is no scientific basis for a 10% allocation (ANEC position, 2010a).

ANEC/BEUC position, 2012

In a joint position paper from ANEC and BEUC, these two organizations state that they, for many years, have been criticizing the limit values for heavy metals for being inappropriate to protect the safety of consumers. Furthermore, ANEC and BEUC generally state that safety cannot be compromised and in the case of children products which cannot be made safe, they might ultimately need to be removed from the market (ANEC/BEUC, 2012a).

Nordic Ecolabelling, 2012

In the Nordic Ecolabelling of toys, there is a more or less general requirement stating that pigments and additives based on lead (Pb), tin/pewter (Sn), cadmium (Cd), chrome VI (CrVI) and mercury (Hg) and their compounds (plastic materials, rubber, chemical products used in wood-based materials, and chemical products used for surface treatment of wood and metal) shall not be actively added to the toy material. The limit value is for some materials (plastics and rubber) set to 100 ppm (Nordic Ecolabelling, 2012).

Oeko-Tex 100, 2013

Oeko-Tex Standard 100 (the "Confidence in textiles" labelling) sets requirements for extractable heavy metals (10 different heavy metals) in textiles. Furthermore, there is a requirement for lead and cadmium for heavy metals in digested samples. In general, the limit values are much lower compared to the limit values in the new Toy Safety Directive. The limit values depend on the heavy metal and the Product Class (Oeko-Tex 100, 2013). The limit values are listed in Table 8.

According to the supplement to the Oeko-Tex Standard 100 (Oeko-Tex 100 Supplement, 2013), textile toys can also receive the Oeko-Tex mark by complying with the Oeko-Tex requirements. The requirements to toys are that all textile and non-textile components of textile toys must comply with at least the requirements of Product Class II as listed above. Articles for babies and toddlers under the age of 3 must comply with the requirements for Product Class I as listed above.

In the testing procedure document (Oeko-Tex 100 Testing procedures, 2013), it is stated that the determination of migration of heavy metals is performed by the use of artificial sweat solution according to ISO 105E04 (testing solution II). The analysis method for digested heavy metals is to use acids in order to get a clear solution. The total content of lead should be determined by the method stated in the American legislation for children's articles (CPSIA, Consumer Product Safety Improvement Act). The test for chromium (VI) is performed with the extract prepared by using the artificial acidic sweat solution.

Table 8: Migration limits for the heavy metals in Oeko-Tex 100 (in mg/kg (ppm))

Heavy metal/ Product Class	Extractable heavy metals			
	I (baby)	II (direct skin contact)	III (no skin contact)	IV (decoration materials)
Antimony	30	30	30	None
Arsenic	0.2	1	1	1
Cadmium	0.2	1	1	1
Chromium	1	2	2	2
Chromium (VI)	Under detection limit			
Cobalt	1	4	4	4
Copper	25	50	50	50
Lead	0.2	1	1	1
Mercury	0.02	0.02	0.02	0.02
Nickel	1	4	4	4
Heavy metal/ Product Class	**Heavy metals in digested sample**			
	I (baby)	II (direct skin contact)	III (no skin contact)	IV (decoration materials)
Cadmium	50	100	100	100
Lead	90	90	90	90

3.2.1 Lead

Table 7 above illustrates that the new migration limit for lead in scraped-off toy material has been raised to 160 mg/kg compared to the migration limit in the old Toys Safety Directive of 90 mg/kg (88/378/EEC). This has been criticised by different organisations and changes to this migration limit are also being discussed at EU level at the moment. As mentioned at the beginning of section 3.2 “Elements (heavy metals)” there have been discussions of lowering the lead limits to: 4 mg/kg in powder-like materials, 1 mg/kg in liquid materials and 47 mg/kg in scraped off materials based on a benchmark dose limit proposed by EFSA. However, the industry raised concern and the entire process has been delayed as an impact assessment and studies in this regard have been initiated (May 2013).

<u>BfR opinion No.048, 2009</u>

BfR states in an opinion paper that a safe threshold value for the effects of lead on the central nervous system cannot be defined. BfR is therefore of the opinion that the lead intake of children should be reduced as much as possible and that toys should not release lead at all (BfR No. 048, 2009).

<u>EFSA, 2010</u>

The EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) has evaluated the safety of lead in food. The CONTAM Panel identified developmental neurotoxicity in young children and cardiovascular effects and nephrotoxicity in adults as the critical effects for the risk assessment. The BMDL[15] derived from blood lead levels in µg/L (corresponding dietary intake

[15] BMDL = The lower bound of a 95% confidence interval on a benchmark dose (BMD) corresponding to a 1% risk of a decline of the IQ by 1 point (the IQ is the critical endpoint for neurodevelopmental effects).

values in µg/kg bw/day) was for developmental neurotoxicity in young children $BMDL_{01}$ 12 µg/L (or 0.50 µg/kg bw/day).

The CONTAM Panel concluded that the current PTWI[16] of 25 µg/kg bw is no longer appropriate as there is no evidence for a threshold for critical lead-induced effects. In adults, children and infants the margins of exposures were such that the possibility of an effect from lead in some consumers, particularly in children from 1-7 years of age, cannot be excluded. Protection of children against the potential risk of neurodevelopmental effects would be protective for all other adverse effects of lead, in all populations.

SCHER opinion, 2010a

In this opinion "Migration limits of chemical elements in toys", SCHER states that a TDI for lead cannot be derived on the basis of a non-threshold effect of lead. It seems that SCHER supports the EFSA opinion, i.e. they agree with the benchmark dose level $BMDL_{01}$ value of 0.50 µg/kg bw/day for neurodevelopmental effects (SCHER opinion, 2010a).

ANEC position, 2010a

ANEC has made a position paper on the SCHER opinion on migration limits of chemical elements. In this position paper, ANEC is referring to the $BMDL_{01}$ intake level of 0.50 µg/kg bw/day deduced by EFSA and calls for a parallel reduction in migration level based on this BMDL level (ANEC position, 2010a).

ANEC therefore calls for a reduction in the current migration level for scraped-off toy material to at least 22 mg/kg (based on the $BMDL_{01}$ intake level of 0.50 µg/kg bw/day (as deduced by EFSA) and a 5% allocation). Similar ANEC calls for a similar adjustment of the other migration limit values (ANEC position, 2010a). ANEC therefore calls for the following migration limit values:

- Dry, brittle, powder-like or pliable toy material: 1.9 mg/kg
- Liquid or sticky toy material: 0.49 mg/kg
- Scraped-off toy material: 22.9 mg/kg

Furthermore, ANEC states that a child might play with all three categories of toys (scraped-off toy material, powder-like, liquid/sticky) for which migration limits have been set and that therefore a further lowering of the migration limits is needed. Lead limits should be reduced as far as technically feasible following the ALARA principle (ANEC position, 2010a).

BfR opinion No. 034, 2012

The new Toy Safety Directive permits a higher intake of lead from toys compared to the old directive. BfR is of the opinion that this allowed higher intake values for lead are not acceptable for both health and preventive reasons. For lead, the ALARA principle (As Low As Reasonably Achievable) should be applied when defining limit values, as no limit value can be determined for which a health risk can be reasonably excluded. Furthermore, the intake of lead from food alone reaches already a critical level.

[16] Provisional Tolerable Weekly Intake

3.2.1.1 Conclusion lead

It is suggested to reduce the migration limit values to the values based on the EFSA $BMDL_{01}$ value of 0.50 µg/kg bw/day using a 5% allocation as stated in preamble no. 22 of the new Toy Safety Directive, as the migration limit values for lead are inadequate. As EFSA has already pointed out the current TDI value is inadequate. This means that the suggested migration limit values for lead are:

- Dry, brittle, powder-like or pliable toy material: 1.9 mg/kg
- Liquid or sticky toy material: 0.49 mg/kg
- Scraped-off toy material: 22.9 mg/kg

3.2.2 Cadmium

Table 7 above illustrates that the new migration limit for cadmium in scraped-off toy material has been lowered compared to the migration limit set in EN 71-3 (1994) of 75 mg/kg. First the cadmium migration limit value for scraped-off toy material was set to be 23 mg/kg (Directive 2009/48/EC). However, different opinions by BfR and SCHER have resulted in even lower migration limit values for cadmium (17 mg/kg for scraped-off toy materials) in amendments to the directive (see the descriptions below).

BfR opinion No.048, 2009

BfR states in an opinion on cadmium that the cadmium intake of children through food alone can exceed the tolerable weekly intake (TWI). For this reason BfR demands that the tolerable intake levels of cadmium through toys, i.e. the migration limit values of cadmium in toys are lowered considerable. As a first step BfR calls for a promptly adjustment of the migration limits for cadmium which refers to the lowering of the revised TWI value by EFSA to 2.5 µg/kg body weight per week (or 0.36 µg/kg body weight per day). Furthermore, BfR states that the toy materials should only contribute to a maximum of 5% of the EFSA TWI (BfR No. 048, 2009).

SCHER opinion, 2010a

In this opinion paper "Migration limits of chemical elements in toys", SCHER discusses among other things the TDI value used for setting the migration limit for cadmium in the new Toys Safety Directive. SCHER is of the opinion that a lower TDI value for cadmium should be used for setting migration limits for cadmium (0.36 µg/kg body weight per day instead of the 0.5 µg/kg body weight per day used originally in the new Toy Safety Directive) (SCHER opinion, 2010a).

ANEC position, 2010a

ANEC has made a position paper on the SCHER opinion on migration limits of chemical elements. In this position paper ANEC states that they agree with the proposal by SCHER regarding the use of a lower TDI value for cadmium (0.36 µg/kg body weight per day). However, ANEC points out that the EFSA CONTAM panel noted that the mean dietary exposures in European countries are close to or slightly exceeding the TWI value of 2.5 µg/kg body weight per week and that subgroups such as children may exceed the TWI by about a 2-fold. ANEC therefore suggests using a 5% TDI-allocation instead of the 10% allocation as suggested by SCHER. In addition, ANEC considers

that a child might play with all 3 categories of toys for which limits have been set and that therefore a further lowering of the limits is needed (ANEC position, 2010a).

Directive 2012/7/EU, 2012
The migration limits for cadmium has been lowered following advice of scientific committees. The cadmium migration limits have been lowered by between 26-40% depending on the specific migration limit with the use of 5% of the new and revised TWI value from EFSA of 2.5 µg/kg body weight per week (or 0.36 µg/kg body weight per day) (Directive 2012/7/EU).

3.2.2.1 Conclusion cadmium

Cadmium is one of the metals where a lowering of the migration limit values already has been performed since adaption of the new Toy Safety Directive. These changed limit values will therefore be kept.

3.2.3 Antimony

As illustrated in Table 7, the migration limit for scraped-off toy material for antimony has been raised from 60 mg/kg in EN 71-3 (1994) to 560 mg/kg in the new Toys Safety Directive.

BfR opinion No. 034, 2012
The new Toys Safety Directive permits higher intake of inorganic antimony (which is classified as carcinogenic) from toys compared to the old directive. BfR is of the opinion that this allowed higher intake value is not acceptable for both health and preventive reasons. BfR is of the opinion that the limit allowed in the old directive should be left unchanged in the new Toy Safety Directive as experience shows that manufacturers easily can comply with these lower limit values.

SCHER opinion, 2010
SCHER has in an opinion (SCHER Diantimony Trioxide, 2010) performed a risk assessment of the flame retardant diantimony trioxide in toys. The risk assessment has been performed on the basis of the health effects of antimony. They use a TDI value of 6 µg/kg bw/day. Assuming 8 mg ingestion of toys per day, 10 kg bw of a child, and using 10% of the TDI value, SCHER derives to the fact that the maximum daily intake will be reached if the antimony content in the toy is above 750 mg/kg[17] (in fact, the maximum allowed migration or content assuming 100% migration).

This value of 750 mg antimony/kg toy material differs from the value of 560 mg/kg in the new Toy Safety Directive with a factor of 1.33 corresponding to the fact that the value in the new Toy Safety Directive is based on a weight of a child of 7.5 kg and SCHER uses 10 kg.

SCHER states that no measured data is available to assess migration of antimony into saliva from mouthing the toy. Due to this uncertainty, SCHER

[17] 10% of 0.006 mg/kg bw/day x 10 kg bw / 0.000008 kg toy material = 750 mg/kg toy material

reduces the maximum concentration of antimony in toys by a factor of 5, which results in the maximum concentration of 750 mg/kg / 5 = 150 mg antimony/kg toy.

This concentration of 150 mg/kg SCHER uses to calculate the antimony intake from other types of toys: liquid or sticky material and brittle material. SCHER assumes an ingestion of 400 mg/day for liquid or sticky material and 100 mg/day for brittle material. This results in the following values:

- Liquid or sticky material: 400 mg/day x 150 mg/kg (ng/mg) / 10 kg bw = 6000 ng/kg bw/day = 6 µg/kg bw/day
- Brittle material: 100 mg/day x 150 mg/kg (ng/mg) / 10 kg bw = 1500 ng/kg bw/day = 1.5 µg/kg bw/day

Both of these values of 6 and 1.5 µg/kg bw/day are higher than 10% of the TDI value, i.e. 0.6 µg/kg bw/day. SCHER therefore concludes that the TDI value (or 10% of the TDI) is exceeded by a factor of 10 and 2.5 respectively. On the basis of this, SCHER recommends further reduction of the maximum limit of antimony in toys by a factor 10, i.e. to 15 mg/kg.

SCHER concludes that antimony in toys does not pose a risk to the health of children when used in a concentration of 15 mg/kg (calculated as antimony)[18]. This is based on a risk assessment with insufficient information and based on the fact that the exposure from toys should not be higher than 10% of the TDI value. An assumption of 100% migration and absorption has been made which overestimates the exposure as diantimony trioxide is rather insoluble.

Furthermore, SCHER notes that the carcinogenic effect of diantimony trioxide is considered a particle effect and therefore the carcinogenicity does not apply to dermal and oral exposure. Consequently, the CMR requirements from the Toy Safety Directive do not apply to toys because normally children are not exposed to particles of diantimony trioxide via toys.

Interpretation of SCHER opinion (2010)

Please note that the SCHER opinion is difficult to follow so the author of this report may have misinterpreted the conclusions above. However, assuming that the above conclusions are correct and interpreted correctly, the calculations made by SCHER could be interpreted as described below.

SCHER concludes that the ingestion of 400 mg liquid or sticky toy material containing 150 mg antimony/kg toy material will result in an exposure that is 10 times higher than 10% of the TDI value. This SCHER conclusion therefore suggests that the limit value for liquid or sticky toy material for antimony should be 15 mg/kg (150/10).

SCHER concludes that the ingestion of 100 mg brittle toy material containing 150 mg antimony/kg toy material will result in an exposure that is 2.5 times higher than 10% of the TDI value. This therefore suggests that the limit value for brittle toy material for antimony should be 60 mg/kg (150/2.5).

SCHER calculates that the ingestion of 8 mg toy material (this must be assumed to be scraped-off toy material) containing 750 mg antimony/kg will

[18] This value is not stated directly, but it is stated that use of diantimony trioxide concentrations of up to 18 mg/kg does not pose a risk to the health of children. This value corresponds to 14.75 mg/kg of antimony.

reach 10% of the TDI value. This SCHER conclusion therefore suggests that the limit value for scraped-off toy material for antimony should be 750 mg/kg.

To sum up the SCHER opinion could be interpreted as they suggest the following limit values (but it is not stated directly in the opinion):

- Liquid or sticky toy material – 15 mg/kg (calculated as antimony)
- Brittle material – 60 mg/kg (calculated as antimony)
- Scraped-off toy material – 750 mg/kg (calculated as antimony)

These limits are vey close to the limit values used in the new Toy Safety Directive of 11.3 mg/kg (liquid/sticky material), 45 mg/kg (brittle material) and 560 (scraped-off material). The only difference is a factor of 1.33 corresponding to SCHER using 10 kg for the body weight of a child where 7.5 kg has been used in the new Toy Safety Directive.

3.2.3.1 Conclusion antimony

The deduced limit values from the SCHER opinion and the limit values set in the new Toy Safety Directive are identical except for the fact that they are based on different body weights of a child. It is therefore suggested to leave the migration limit values for antimony unchanged.

3.2.4 Arsenic

As illustrated in Table 7, the migration limit for scraped-off toy material for arsenic has been raised from 25 mg/kg in the old Toy Safety Directive to 47 mg/kg in the new Toys Safety Directive.

EFSA, 2009

The EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) has assessed the risks to human health related to the presence of arsenic in food (EFSA, 2009). The CONTAM Panel concluded that the provisional tolerable weekly intake (PTWI) of 15 µg/kg bw (i.e. 2.1 µg/kg bw/day) established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) is no longer appropriate as data had shown that inorganic arsenic causes cancer of the lung and urinary bladder in addition to skin and that a range of adverse effects had been reported at exposures lower than those reviewed by the JECFA.

EFSA identified the range of benchmark dose lower confidence limit ($BMDL_{01}$) values between 0.3 and 8 µg/kg bw/day for cancers of the lung, skin and bladder, as well as skin lesions. EFSA concludes that the estimated dietary exposures to inorganic arsenic for average and high level consumers in Europe are within the range of the $BMDL_{01}$ values identified and therefore there is little or no margin of exposure and the possibility of a risk to some consumers cannot be excluded.

EFSA does not suggest which value to use but the lowest $BMDL_{01}$ values listed were for lung cancer (0.34-0.69 µg/kg bw/day).

SCHER opinion, 2010a

In this opinion paper "Migration limits of chemical elements in toys" SCHER discusses the TDI value for arsenic. SCHER states that the TDI of 1.0 µg/kg bw/day used in the new Toy Safety Directive was established by RIVM based on the Provisional Tolerable Weekly Intake (PTWI) established by JECFA. Since then, a range of adverse health effects has been reported at exposures lower than the PTWI. SCHER describes the EFSA opinion on arsenic, and SCHER notes that EFSA did not derive the TDI but used a risk-based value. SCHER cites conclusions of arsenic showing a non-linear dose response regarding cancer. SCHER concludes that the existing legal limit value for drinking water of 1.0 µg/kg bw/day does not increase tumour incidence and therefore the value can be used as a pragmatic TDI value. SCHER does therefore not agree with EFSA (of using a lower value than 1.0 µg/kg bw/day) and recommends using 10% of the TDI value of 1.0 µg/kg bw/day, i.e. 0.1 µg/kg bw/day for exposure of children via toys (SCHER opinion, 2010a).

ANEC position, 2010a

ANEC has made a position paper on the SCHER opinion on migration limits of chemical elements. In this position paper ANEC states that they disagree with SCHER that advocates for use of a TDI of 1 µg/kg body weight/day and a 10% TDI allocation. This would mean an increase of the value used in the new Toy Safety Directive (here a 5% TDI allocation has been used). ANEC does not find this acceptable. On the contrary ANEC argues that a lower TDI value should be used as suggested by the EFSA CONTAM panel. ANEC argues for using an average of $BMDL_{01}$ intake level 0.5 µg/kg body weight/day of the listed values in the EFSA opinion (0.34-0.69 µg/kg bw/day).

Using this value would (by use of 5% TDI allocation) give a reduction of the migration limit for scraped-off toy material to 24 mg/kg, which is in line with the migration limit value for arsenic from the old Toy Safety Directive. ANEC proposes that the other two migration limits should be reduced accordingly (ANEC position, 2010a).

In addition, ANEC considers that a child might play with all 3 categories of toys for which limits have been set and that therefore a further lowering of the limits is needed (ANEC position, 2010a).

BfR opinion No. 034, 2012

For arsenic the new Toy Safety Directive permits higher intake from toys compared to the old directive. BfR is of the opinion that these allowed higher intake values for arsenic are not acceptable for both health and preventive reasons. For arsenic the ALARA principle (As Low As Reasonably Achievable) should be applied when defining limit values as no limit value can be determined for which a health risk can reasonably be excluded. Furthermore, for arsenic the intake from food alone reaches a critical level.

3.2.4.1 Conclusion arsenic

BfR and ANEC are both of the opinion that the migration limit value of arsenic should not be raised. It is suggested to use the suggested migration limit value for scraped-off toy material which ANEC argues for using (use of lower TDI value as suggested by EFSA and use of a 5% TDI allocation). Furthermore ANEC proposes to reduce the other two migration limit values accordingly. This will result in the following limit values for arsenic:

- Scraped-off toy material: 24 mg/kg
- Liquid or sticky toy material: 0.9 x 24/47 mg/kg = 0.6 mg/kg
- Dry, brittle, powder-like or pliable toy material: 3.8 x 24/47 mg/kg = 1.9 mg/kg

3.2.5 Mercury

As illustrated in Table 7, the migration limit for scraped-off toy material for mercury has been raised from 60 mg/kg in the old Toy Safety Directive to 94 mg/kg in the new Toys Safety Directive.

BfR opinion No. 034, 2012
The new Toys Safety Directive permits higher intake of mercury from toys compared to the old directive. BfR is of the opinion that this allowed higher intake value is not acceptable for both health and preventive reasons. BfR is of the opinion that the limit allowed in the old directive should be left unchanged in the new Toy Safety Directive as experience shows that manufacturers easily can comply with these lower limit values.

3.2.5.1 Conclusions mercury

No scientific opinions on mercury discussing the limit values of mercury have been identified. It is therefore suggested to keep the migration limit values as listed in the new Toy Safety Directive.

3.2.6 Barium

As described at the beginning of chapter 3.2 “Elements (heavy metals)”, the migration limit for scraped-off toy material for barium has been raised from 1,000 mg/kg in the old Toy Safety Directive to 56,000 mg/kg in the new Toys Safety Directive. However, this was in July 2013 lowered to 18,750 mg/kg according to Regulation No 681 (2013) based on a TDI value of 0.2 mg/kg bw/day. This is still significantly higher compared to the value in the old Toy Safety Directive.

WHO, 2004
WHO has in their background document “Barium in drinking water” for development of WHO guidelines for drinking water quality used a NOAEL value of 0.21 mg/kg bw/day (WHO, 2004). This NOAEL is divided with 10 (uncertainty factor for intraspecies variation) in order to derive to the used TDI value for drinking water for barium. WHO therefore uses a TDI value of 0.021 mg/kg bw/day for establishing their limit for barium in drinking water (WHO, 2008).

Hence WHO is already in 2004, using a TDI value that is 10 times lower than the TDI value used in July 2013 (Regulation No 681, 2013) for lowering of the barium limit values in the new Toy Safety Directive.

ANEC proposal, 2011a

ANEC is according to their proposal (ANEC proposal, 2011a) of the opinion that the barium migration limit values in the new Toy Safety Directive are too high. The TDI value used in the RIVM report, which has been the basis for the migration limit values in the new Toy Safety Directive, was 0.6 mg/kg body weight per day. This limit value has in 2007, after the finalisation of the RIVM report, been reduced by a factor of 3 by ATSDR taking into account the uncertainty of the data base. The new TDI value should hence be 0.2 mg/kg body weight per day. ANEC points out, however, that WHO, ILO and UNEP have published a Concise International Chemical Assessment Document (CICAD) on barium in 2001 that concludes on a TDI value of 0.02 mg/kg bw/day, i.e. a factor of 30 lower than the TDI value used by RIVM – and the same TDI value of 0.02 mg/kg bw/day is already used by WHO for setting limit values for barium in drinking water (WHO, 2004; WHO, 2008). Furthermore, ANEC states that in the Food Contact Materials legislation a limit value of 0.0166 mg/kg body weight per day is used in Commission Regulation on plastic materials and articles intended to come into contact with food (Regulation 10/2011), i.e. roughly the same value as used by WHO. ANEC therefore proposes that the barium limit values in the new Toy Safety Directive should be reduced by a factor 30 (compared to the first announced barium limit values and reduced by a factor of 10 compared to the changed barium limit values (Regulation No 681, 2013)) to:

- 1867 mg/kg for scraped-off toy material
- 37 mg/kg for liquid or sticky toy material, and
- 150 mg/kg for dry, brittle, powder-like or pliable toy material.

SCHER opinion Barium, 2012

In this opinion SCHER revises and summarises literature data with the aim of deriving the most appropriate TDI for barium exposure. SCHER concludes that they support the TDI value concluded by ASTDR (2007) after the finalisation of the RIVM report, i.e. using a TDI value of 0.2 mg barium/kg body weight per day. They point out that the lower TDI value set by WHO (also mentioned above) is based on human data, but SCHER does not consider the data appropriate because of e.g. absence of dose-response relationship (no effects were seen at the highest dose tested). SCHER therefore concludes to use a 10% allocation of the TDI value of 0.2 mg/kg body weight per day.

This corresponds to the changes that can be found in the Regulation No 681 (2013). According to this Regulation the new limits for barium are lowered to 18,750 mg/kg, which is still significantly higher compared to the value in the old Toy Safety Directive of 1000 mg/kg.

BfR opinion No. 034, 2012

The new Toys Safety Directive permits higher intake of barium from toys compared to the old directive. BfR is of the opinion that this allowed higher intake value is not acceptable for both health and preventive reasons. BfR is of the opinion that the limit allowed in the old directive should be left unchanged in the new Toy Safety Directive, as experience shows that with good manufacturing practice it has been easily possible for manufacturers to comply with this lower limit value.

3.2.6.1 Conclusion barium

ANEC has made a proposal of lowering the migration limit values in the new Toy Safety Directive by a factor 30 (corresponding to a factor 10 to the adopted barium limit values in July 2013) (Regulation No 681, 2013). This is based on a lower TDI-value. This will result in a migration limit value for scraped-off toy material of 1867 mg/kg, i.e. close to old migration limit value of 1000 mg/kg in the old Toy Safety Directive.

BfR is, however, of the opinion that the limit value allowed in the old directive (1000 mg/kg) should be left unchanged.

As described above different scientific committees disagree about the TDI value (a factor of 10 in difference). In this report it is suggested to use the most conservative assessment, i.e. the TDI value of 0.02 mg/kg bw/day as used by WHO for setting drinking water limit value for barium and as suggested by ANEC. The suggested migration limit values for barium are therefore:

- Scraped-off toy material: 1867 mg/kg
- Liquid or sticky toy material: 37 mg/kg
- Dry, brittle, powder-like or pliable toy material: 150 mg/kg

3.2.7 Conclusion elements

As illustrated by the opinions and proposals listed above, the main concern from different organisations regarding the elements has been the increase in the migration limits from the old to the new Toy Safety Directive for some of them (antimony, arsenic, barium, chromium, lead and mercury). The argumentation has been toxicological (based on new information on lower TDI-values), but also practical: why increase the migration limit values when the former lower migration limit values actually could be met by the industry?

One aspect is to lower the TDI values if newer information exists that proves that a lowering of the TDI value is necessary. This is of course the correct thing to do. Another aspect is the percentage allocation of the TDI value. As children are exposed to the elements through other sources than toys (other consumer products and food), it is of course relevant only to allocate a certain percentage of the TDI value to the exposure from toys. It is, however, a political decision whether a 5% or 10% or higher/lower allocation of the TDI value should be used. SCHER argues that a 10% allocation should be used for all elements (SCHER opinion, 2010a). ANEC argues that the determination of the fraction of the TDI is a political decision entirely and that there is no scientific basis for a 10% allocation (ANEC position, 2010a). However, according to preamble 22 of the new Toy Safety Directive the EU has decided that for arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, the levels used should be half of those considered safe according to the criteria of the relevant Scientific Committee, i.e. a 5% allocation should be used for these elements.

Another argument also raised by ANEC (ANEC position, 2010a) is that children might play with all 3 categories of toys for which limits have been set. This is another argument for a further lowering of the limits. However, this is yet again a political decision.

Type of limit value

The restrictions on the elements are based on migration limit values in the EN 71-3 (1994) standard for the old Toy Safety Directive. The new Toy Safety Directive is also based on migration limit values (three different types of migration values). This seems to be the most correct way to set limit values in contrast to e.g. a content based limit value as the elements only to a certain extent are available for exposure, if they are migrating out of the toys, when children are sucking on the toys or holding the toys in their hands.

Limit values

It is suggested to use the limit values established in the new Toy Safety Directive except for the elements that have been discussed and commented by different scientific committees (arsenic, barium, and lead). For these elements it is suggested to lower the limit values (based on lowering of the TDI or BMDL values). For barium, where new limit values have been adopted (July 2013), it is suggested to use the limit values based on WHO which are a factor of 10 lower compared to the adopted changes in the limit values for barium (Regulation No 681, 2013).

Furthermore, it is suggested that the other two migration limit values (for dry, brittle, powder-like or pliable toy material and liquid or sticky toy material) are lowered proportionally.

The suggested limit values can therefore be summarised as listed in Table 9. Changes compared to the new Toy Safety Directive are marked with grey shading.

Table 9: Suggested migration limits for the elements in mg/kg (ppm). Changes compared to the new Toy Safety Directive (as amended) are marked with grey shading.

Element	Dry, brittle, powder-like or pliable toy material	Liquid or sticky toy material	Scraped-off toy material
Aluminium	5,625	1,406	70,000
Antimony	45	11.3	560
Arsenic	1.9	0.6	24
Barium	150	37	1,867
Boron	1,200	300	15,000
Cadmium	1.3	0.3	17
Chromium (III)	37.5	9.4	460
Chromium (VI)	0.02	0.005	0.2
Cobalt	10.5	2.6	130
Copper	622.5	156	7,700
Lead	1.9	0.49	22.9
Manganese	1,200	300	15,000
Mercury	7.5	1.9	94
Nickel	75	18.8	930
Selenium	37.5	9.4	460
Strontium	4,500	1,125	56,000
Tin	15,000	3,750	180,000
Organic tin	0.9	0.2	12
Zinc	3,750	938	46,000

Test methods

The new standard EN 71-3 was published in June 2013. This standard was prepared by the Technical Committee CEN/TC 52 “Safety of toys”. The

standard and the testing method for migration of elements were intensely debated in CEN TC 52 “Safety of toys”. According to the foreword to the British Standard (CEN/TC 52/WG 5, 2013), part of the work on the standard involved an inter-laboratory collaborative trial of the testing methods. This produced significant variations in the measurement of uncertainty values for certain elements and materials. This may have been due to the poor application of the methods by some laboratories or weaknesses in description of the methods or a combination of both. This is the reason for the intense debate during the preparation of the standard. Certain areas for improvement were identified but not completed within the mandated time frames. For this reason an immediate revision process of the standard has been launched and two amendments have already been planned (CEN/TC 52/WG 5, 2013). Furthermore, request for funding for a complete revision of the EN 71-3 (2013) has been submitted to the European Commission.

Suggestion: Elements

The following suggestions for chemical requirements are made for elements.

Table 10: Suggested chemical requirements regarding elements in toys

Elements

(in all materials)

Type of limit value: Migration limit values split in three depending on the toy material:

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

Limit value: Migration limit values for all toys as listed in the table below. Changes compared to the new Toy Safety Directive are marked with grey shading.

Element	Dry, brittle, powder-like or pliable toy material	Liquid or sticky toy material	Scraped-off toy material
Aluminium	5,625	1,406	70,000
Antimony	45	11.3	560
Arsenic	1.9	0.6	24
Barium	150	37	1867
Boron	1,200	300	15,000
Cadmium	1.3	0.3	17
Chromium (III)	37.5	9.4	460
Chromium (VI)	0.02	0.005	0.2
Cobalt	10.5	2.6	130
Copper	622.5	156	7,700
Lead	1.9	0.49	22.9
Manganese	1,200	300	15,000
Mercury	7.5	1.9	94
Nickel	75	18.8	930
Selenium	37.5	9.4	460
Strontium	4,500	1,125	56,000
Tin	15,000	3,750	180,000
Organic tin	0.9	0.2	12
Zinc	3,750	938	46,000

Test method: As described in EN 71-3 (2013), but improvements need to be made in order to ensure better reproducibility (as described in CEN/TC 52).

3.3 Sensitisers – Fragrances

3.3.1 Fragrances

The old Toy Safety Directive did not have any requirement regarding fragrances. The new Toy Safety Directive (2009/48/EC) sets requirements for a number of fragrances. 55 different fragrances are not allowed to be used in toys; however, traces below 100 ppm are allowed if a presence is technically unavoidable under good manufacturing practice. For 11 other fragrances no limits are set, but a labelling requirement is made: if the concentration in toys of one or more of these 11 fragrances exceeds 100 ppm, the names of the fragrances should be stated on the toy, on an affixed label, on the packaging or in any accompanying leaflet.

An exemption is made for olfactory board games, cosmetic kits and gustative games: 26 of the fragrances are allowed in these toys (no limit value set) if they are clearly labelled on the packaging including a warning "Contains fragrances that may cause allergy". These 26 fragrances are fragrances no. 41 to 55 (see Table 11) and all 11 fragrances with labelling requirements (no. 1-11 at the end of Table 11). These 26 fragrances correspond to the fragrances that are to be labelled according to the Cosmetics Regulation.

Table 11 below is a list of the fragrances restricted in toys. In comparison the restrictions in the Cosmetic Products Regulation (No 1223/2009) for these fragrances are listed.

Table 11: List of the fragrance restricted in the new Toy Safety Directive and comparison with the restriction of the fragrances in the Cosmetic Products Regulation

No.	Fragrance	CAS No.	Cosmetic Products Regulation (No 1223/2009)
	Restricted fragrances		
1	Alanroot oil (Inula helenium)	97676-35-2	Prohibited acc. to Annex II
2	Allylisothiocyanate	57-06-7	Prohibited acc. to Annex II
3	Benzyl cyanide	140-29-4	Prohibited acc. to Annex II
4	4 tert-Butylphenol	98-54-4	Prohibited acc. to Annex II
5	Chenopodium oil	8006-99-3	Prohibited acc. to Annex II
6	Cyclamen alcohol	4756-19-8	Prohibited acc. to Annex II
7	Diethyl maleate	141-05-9	Prohibited acc. to Annex II
8	Dihydrocoumarin	119-84-6	Prohibited acc. to Annex II
9	2,4-Dihydroxy-3-methylbenzaldehyde	6248-20-0	Prohibited acc. to Annex II
10	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5	Prohibited acc. to Annex II
11	4,6-Dimethyl-8-tert-butylcoumarin	17874-34-9	Prohibited acc. to Annex II
12	Dimethyl citraconate	617-54-9	Prohibited acc. to Annex II
13	7,11-Dimethyl-4.6,10-dodecatrien-3-one	26651-96-7	Prohibited acc. to Annex II
14	6,10-Dimethyl-3.5,9-undecatrien-2-one	141-10-6	Prohibited acc. to Annex II
15	Diphenylamine	122-39-4	Prohibited acc. to Annex II
16	Ethyl acrylate	140-88-5	Prohibited acc. to Annex II
17	Fig leaf, fresh and preparations	68916-52-9	Prohibited acc. to Annex II
18	trans-2-Heptenal	18829-55-5	Prohibited acc. to Annex II
19	trans-2-Hexenal diethyl acetal	67746-30-9	Prohibited acc. to Annex II
20	trans-2-Hexenal dimethyl acetal	18318-83-7	Prohibited acc. to Annex II
21	Hydroabietyl alcohol	13393-93-6	Prohibited acc. to Annex II
22	4-Ethoxy-phenol	622-62-8	Prohibited acc. to Annex II
23	6-lsopropyl-2-decahydronaphthalenol	34131-99-2	Prohibited acc. to Annex II
24	7-Methoxycoumarin	531-59-9	Prohibited acc. to Annex II

No.	Fragrance	CAS No.	Cosmetic Products Regulation (No 1223/2009)
25	4-Methoxyphenol	150-76-5	Restricted acc. to Annex III Limit value 0.02%, only for professional use
26	4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4	Prohibited acc. to Annex II
27	1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8	Prohibited acc. to Annex II
28	Methyl trans-2-butenoate	623-43-8	Prohibited acc. to Annex II
29	6-Methylcoumarin	92-48-8	Restricted acc. to Annex III Limit value 0.003%, oral products
30	7-Methylcoumarin	2445-83-2	Prohibited acc. to Annex II
31	5-Methyl-2,3-hexanedione	13706-86-0	Prohibited acc. to Annex II
32	Costus root oil (Saussurea lappa Clarke)	8023-88-9	Prohibited acc. to Annex II
33	7-Ethoxy-4-methylcoumarin	87-05-8	Prohibited acc. to Annex II
34	Hexahydrocoumarin	700-82-3	Prohibited acc. to Annex II
35	Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch)	8007-00-9	Prohibited acc. to Annex II
36	2-Pentylidene-cyclohexanone	25677-40-1	Prohibited acc. to Annex II
37	3.6,10-Trimethyl-3.5,9-undecatrien-2-one	1117-41-5	Prohibited acc. to Annex II
38	Verbena oil (Lippia citriodora Kunth)	8024-12-2	Prohibited acc. to Annex II
39	Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)	83-66-9	Prohibited acc. to Annex II
40	4-Phenyl-3-buten-2-one	122-57-6	Prohibited acc. to Annex II
41	Amyl cinnamal	122-40-7	Annex III: Labelling req. if above 0.001%/0.01%
42	Amylcinnamyl alcohol	101-85-9	Annex III: Labelling req. if above 0.001%/0.01%
43	Benzyl alcohol	100-51-6	Annex III: Labelling req. if above 0.001%/0.01% Restricted acc. to Annex V Limit value 1.0%
44	Benzyl salicylate	118-58-1	Annex III: Labelling req. if above 0.001%/0.01%
45	Cinnamyl alcohol	104-54-1	Annex III: Labelling req. if above 0.001%/0.01%
46	Cinnamal	104-55-2	Annex III: Labelling req. if above 0.001%/0.01%
47	Citral	5392-40-5	Annex III: Labelling req. if above 0.001%/0.01%
48	Coumarin	91-64-5	Annex III: Labelling req. if above 0.001%/0.01%
49	Eugenol	97-53-0	Annex III: Labelling req. if above 0.001%/0.01%
50	Geraniol	106-24-1	Annex III: Labelling req. if above 0.001%/0.01%
51	Hydroxy-citronellal	107-75-5	Annex III: Labelling req. if above 0.001%/0.01%
52	Hydroxy-methylpentylcyclohexenecarboxaldehyde	31906-04-4	Annex III: Labelling req. if above 0.001%/0.01%
53	Isoeugenol	97-54-1	Annex III: Labelling req. if above 0.001%/0.01%
54	Oakmoss extracts	90028-68-5	Annex III: Labelling req. if above 0.001%/0.01%
55	Treemoss extracts	90028-67-4	Annex III: Labelling req. if above 0.001%/0.01%

No.	Fragrance	CAS No.	Cosmetic Products Regulation (No 1223/2009)
	Fragrances with labelling requirements		
1	Anisyl alcohol	105-13-5	Annex III: Labelling req. if above 0.001%/0.01%
2	Benzyl benzoate	120-51-4	Annex III: Labelling req. if above 0.001%/0.01%
3	Benzyl cinnamate	103-41-3	Annex III: Labelling req. if above 0.001%/0.01%
4	Citronellol	106-22-9	Annex III: Labelling req. if above 0.001%/0.01%
5	Farnesol	4602-84-0	Annex III: Labelling req. if above 0.001%/0.01%
6	Hexyl cinnamaldehyde	101-86-0	Annex III: Labelling req. if above 0.001%/0.01%
7	Lilial	80-54-6	Annex III: Labelling req. if above 0.001%/0.01%
8	d-Limonene	5989-27-5	Annex III: Labelling req. if above 0.001%/0.01%
9	Linalool	78-70-6	Annex III: Labelling req. if above 0.001%/0.01%
10	Methyl heptine carbonate	111-12-6	Annex III: Labelling req. if above 0.001%/0.01%
11	3-methyl-4-(2.6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2- one	127-51-5	Annex III: Labelling req. if above 0.001%/0.01%

IFRA, 2011

IFRA, The International Fragrance Association, has prepared the so-called IFRA Standards (IFRA, 2011) which include a list of recommendations for 184 different fragrance ingredients that according to IFRA should be either prohibited, restricted (in concentration or in specific product types) or should only be used if it meets certain purity criteria or if used in conjunction with other materials.

39 of the 55 banned fragrances in toys are also prohibited under the IFRA standards, meaning that the material should not be used as a fragrance ingredient.

SCCS opinion 1459, 2011

SCCS has made an opinion on fragrance allergens in cosmetic products (SCCS/1459/11, 2011). In this opinion SCCS states that:

- 82 fragrances are categorised as established contact allergens in humans (54 individual chemicals and 28 natural extracts (Table 13-1 in the SCCS document)). This means that for these 82 fragrances, human data shows that the fragrances are known to be contact allergens. Of these, 20 fragrances are considered of special concern, i.e. they pose a particularly high risk of sensitisation to the consumer (12 individual chemicals and 8 natural extracts). The existing 26 fragrances that must be declared in cosmetic products are all included in this list of the 82 established contact allergens.
- 24 fragrances are categorised as established contact allergens in animals (22 individual chemicals and 2 natural extracts (Table 13-2 in the SCCS document)).
- 23 fragrances (individual chemicals) are categorised as likely contact allergens by a combination of evidence (e.g. limited clinical data combined with SAR (Structure Activity Relationship) considerations). (Table 13-3 in the SCCS document).

- 50 fragrances are categorised as possible contact allergens based on SAR considerations (37 individual chemicals and 13 natural extracts (Table 13-4 in the SCCS document)).

This means that according to the SCCS, 129 fragrances (Table 13-1 to Table 13-3) are either established contact allergens or likely contact allergens, and further 50 fragrances are possible contact allergens. However, more data is needed (experimental or clinical data) in order to establish their allergenic potential (SCCS/1459/11, 2011). This means that according to SCCS many more fragrance substances (than the 26 substances identified earlier, which are now subject to labelling requirements if exceeding 0.001%/0.01% according to the Cosmetic Products Regulation (No 1223/2009)) have been shown to be human sensitisers and consequently need to be subject of additional labelling provisions in the Cosmetic Products Regulation. The exiting 26 fragrance substances, which are subject to labelling requirement in the Cosmetic Products Regulation, are included in the 129 fragrance substances discussed in the SCCS opinion. This clearly illustrates that a limitation of 55 fragrances in the Toy Safety Directive is outdated and that the list of restricted fragrances in toys should be much longer.

The following important conclusions are also made in this opinion (SCCS/1459/11, 2011):

- Fragrance allergens act as haptens, i.e. low molecular weight chemicals that are immunogenic only when attached to a carrier protein. However, not all sensitising fragrance chemicals are directly reactive, but require previous activation.
- Many fragrances can act as prehaptens[19] or prohaptens[20], forming new or more potent allergens by air oxidation and/or metabolic activation. Non/low-sensitising compounds are thereby transformed into potent sensitisers. Such activation processes are of concern as they increase the risk of sensitisation and also the risk of cross activity between fragrance substances.
- Known haptens are e.g. limonene, linalool, linalyl acetate, cinnamyl alcohol, eugenol, isoeugenol, isoeugenol acetate, geraniol and alpha-terpinene.
- Substances known to be transformed (e.g. hydrolysis of esters or oxidation or bioactivation) to known contact allergens should be treated as equivalent to these known contact allergens. I.e. the same restrictions and other regulatory requirements should apply.
- Most experimental studies are done on individual fragrance ingredients, while exposure to allergens in cosmetic products is usually to mixtures of allergens. The risk of sensitisation and elicitation may depend on the mixture of substances, but very few studies on this exist. It is necessary to improve the knowledge base on cocktail effects on sensitisation/elicitation to improve the basis of risk assessment and management.
- The SCCS considers that the 129 fragrances are those fragrances that the consumers should be made aware of when present in cosmetic

[19] Prehaptens is a chemical that itself is non- or low-sensitising, but that is transformed into a hapten outside the skin by simple chemical transformation (air oxidation, photoactivation) and without the requirement of specific enzymatic systems.
[20] A prohapten is a chemical that itself is non- or low-sensitising but that is transformed into a hapten in the skin (bioactivation) usually via enzyme catalysis.

products. This means that the declaration duty for cosmetic products should be widely expanded.

- In cases where specific data of sufficient quality on threshold levels for a particular allergen is available, this data should be used to set an individual safe threshold. However, when such quality data is not available and a substance has been identified to pose a high risk of sensitisation to the consumer, a general threshold limit of 100 ppm in cosmetic products can be applied. This threshold of 100 ppm could be used as indicative for safe use in cosmetic products. This approximation may hold for weak to strong allergens. However, some strong and extreme sensitisers may require lower individual thresholds. It is important to stress that this general threshold, although limiting the problem, does not preclude that the most sensitive segment of the population may react upon exposure to these levels. Hence, this threshold does not remove the necessity of providing information to the consumer concerning the presence of the fragrance substance in cosmetics.
- Oxidised limonene and oxidised linalool are allergens of high concern which pose a high risk of sensitisation to the consumer. For these substances, the presence of the oxidised fraction represented by the peroxide content should not be higher than 10 ppm. Alternatively, the suggested general threshold of 100 ppm in cosmetic products could be applicable to the total oxidised fraction, i.e. not only peroxides but also secondary oxidation products such as aldehydes and epoxides.
- One of the 129 fragrances called HICC (hydroxyisohexyl 3-cyclohexene carboxaldehyde) should, according to SCCS, not be used in consumer products in order to prevent further cases of contact allergy to HICC and to limit the consequences to those who already have become sensitised.
- Similar the SCCS concludes that choroatranol and atranol, the main allergenic constituents of Evernia prunastri and Evernia furfuracea are not safe and should not be present in products for the consumer.

To conclude, the SCCS suggests that the declaration duty for cosmetic products should be expanded to cover 126 fragrances (3 fragrances are not safe and should not be present in products for the consumer). Furthermore, a general limit value of 100 ppm should be used, if no other data is available. On the other hand, a limit value of 10 ppm should be used for oxidised limonene and oxidised linalool.

It should be noticed that of the 12 individual chemical substances of special concern, 3 fragrances are on the list of 11 fragrances that are not limited in toys other than by a labelling requirement. Two of these fragrances are limonene (oxidised) and linalool (oxidised). This means that two of the most potent sensitisers and two of the most common used sensitisers are allowed today in toys as long as they are declared above the labelling requirement of 100 ppm. SCCS suggests that the limit value of these two fragrances should be 10 ppm. Furthermore, the remaining 9 individual chemical substances of special concern are today allowed to be used in olfactory board games, cosmetic kits and gustative games with no limit as long as their presence is declared on these toys. These facts also show that the restrictions on fragrances in toys are outdated and do not protect children sufficiently against the risk of sensitisation.

BfR opinion No. 010, 2012

BfR (the German Federal Institute for Risk Assessment) states in an opinion paper (BfR No. 010, 2012) that the trace limit of 100 ppm permitted in toys is too high. BfR is of the opinion that the 55 banned allergenic fragrances should not be detectable in toys and that the declaration threshold for the 11 fragrances that must be declared is lowered to 10 ppm instead of 100 ppm. Furthermore, the BfR is of the opinion that toys for children below 3 years of age and toys which children can put in their mouth due to their size should not contain any fragrances.

Article from University of Copenhagen, 2011

In the SCCS opinion (SCCS/1459/11, 2011), it is stated that they have reviewed literature up to 2010. They also state that the risk of sensitisation and elicitation may depend on the mixture of allergens, but very few studies exist on this subject. This means that the SCCS opinion has not taken a more recent study into consideration.

The scientists behind this recent study on sensitisation from mixtures of allergens (Bonefeld et al., 2011) initiated the study because they wondered why so many consumers develop an allergy towards fragrances even though many fragrances are weak allergens and that the consumers are often only exposed to small concentrations.

The study certainly illustrates that the cocktail effect is relevant for allergens as well. In the study they sensitised mice with three different concentrations of three fragrances alone or as a mixture. The three fragrances used were isoeugenol, cinnamal and HICC. All three fragrances are contact allergens of special concern according to SCCS (SCCS/1459/11, 2011). The results showed that there was a dose-dependant sensitisation response for each of the allergens and that an increased response was seen when the allergens were mixed. They concluded that allergen mixtures enhance both induction and elicitation of contact allergy.

These results suggest that it is reasonable to use a more conservative approach in order to protect children against the risk of sensitisation.

Article from Danish National Research Centre, 2011

An investigation (Heisterberg et al., 2011) from the Dermato-Allergology department of the Copenhagen University Hospital Gentofte has showed that 13% of eczema patients in Denmark had a fragrance allergy (patch tests from January 2008 to July 2010 with 1508 eczema patients) when patch testing with the 26 fragrances (with declaration duty for cosmetic products) and a mixture of fragrances (fragrance mix I, fragrance mix II and Myrozxylon pereirae). However, only 7.6 % of the eczema patients had a fragrance allergy when only testing for the 26 fragrances individually. The most frequent allergens were Evernia furfuracea (3.3%), Evernia prunastri (2.1%) and HICC (1.6%).

This investigation shows that consumers develop an allergy towards other fragrances than the 26 fragrances with a declaration duty in cosmetic products and to some extent in toys.

ANEC/BEUC, 2012c

ANEC and BEUC describe in a joint position paper that the requirements for allergenic fragrances in the new Toy Safety Directive are deficient as in some cases only labelling is required. ANEC and BEUC are of the opinion that all listed fragrances should have been banned.

ANEC and BEUC are furthermore of the opinion that the fragrance substances described in the opinion by SCCS (SCCS/1459/11, 2011) need to be evaluated with respect to toys and that changes accordingly should be made through comitology, as many of these fragrances have been shown to be sensitizers in humans (ANEC/BEUC, 2012c).

Nordic Ecolabelling of toys

According to the Nordic Ecolabelling of toys (Nordic Ecolabelling, 2012) the following criteria apply when it comes to fragrances:

- Fragrances must not be added neither to the toy nor the ingoing materials in the toy.

Nordic Ecolabelling of cosmetic products

According to the Nordic Ecolabelling of cosmetic products (Nordic Ecolabelling, 2010), the following criteria apply when it comes to fragrances:

- Fragrances must be used in accordance to IFRA guidelines.
- Fragrance substances in plant extracts must not be added to infant, baby and/or child products (i.e. products for below the age of 12).
- Fragrances in plant extracts must not be present in quantities greater than 10 ppm in leave-on products or 100 ppm in rinse-off products. This only applies for fragrances classified as sensitising with risk phrase H317 or H334 or for one of the 26 fragrances subject to declaration.

Nordic Ecolabelling policy on fragrances

In December 2012, Nordic Ecolabelling has prepared a document concerning the future requirements regarding fragrances in Nordic Ecolabelling criteria (Nordic Ecolabelling policy, 2012). The policy document is referring to the SCCS Opinion (SCCS/1459/11, 2011) and the fact that many more fragrances have a scientific documentation for allergenic effects. Nordic Ecolabelling states that they cannot and/or will not introduce a total ban on fragrances in all product groups. The reason for this is that in product groups with a high proportion of fragrance-containing products on the market, a very high proportion of the products on the market would not be able to achieve the Nordic Ecolabel and the opportunity to improve the environmental profile in these areas might be missed. Instead Nordic Ecolabelling will use a ban of all fragrances in product groups with a low proportion of fragrance-containing products.

The following conclusions are mentioned in the policy document from Nordic Ecolabelling:

- Nordic Ecolabelling should ensure that particularly vulnerable population groups, such as children, are protected from fragrances via a ban on fragrances in products for children.

- Nordic Ecolabelling should ensure that product groups where the market share of fragrance-containing products is low have a ban on fragrances.
- It is the task of Nordic Ecolabelling to ensure that only the fragrances that are least harmful to the environment and health are added to the product (if allowed).
- Nordic Ecolabelling will push for the list of fragrances that are excluded/limited due to allergenic effects (currently 26 substances) to be expanded to contain the 127 fragrances[21] for which SCCS has found scientific documentation of allergenic effects. The goal is hence that in the future, the 127 fragrances will be limited/banned based on their allergenic effects. Implementation is expected to take a few years (until around 2016).

3.3.1.1 Conclusion fragrances

Type of limit value

Fragrances are volatile substances that are intended to evaporate to a certain point in order to carry out their function. Inhalation exposure is therefore also a relevant exposure pathway, but the exposure pathway mainly discussed when it comes to fragrances are skin exposure. The most relevant type of limit value therefore seems to be content based as it is also discussed in the various documents above.

Limit values

The SCCS opinion (SCCS/1459/11, 2011) concludes that a limit value of 100 ppm could be used as a generic limit value for all 126 different fragrances listed (3 fragrances should not be used at all) if no specific data exists for individual fragrances as for e.g. limonene and linalool (10 ppm). SCCS, however, emphasises that the knowledge base on cocktail effects on sensitisation/elicitation needs to be improved.

A Danish study (after the SCCS opinion was published), shows that a cocktail effect on fragrances does exist and that a mixture of allergens enhances both induction and elicitation of contact allergy compared to exposure to the single allergens. The results therefore suggest that it is reasonable to use a more conservative approach in order to protect children against the risk of sensitisation than has been presented in the SCCS opinion.

These considerations are discussed for cosmetic products, but are relevant for toys as well because children have long daily contact with toys. Especially more chemical types of toys (like modelling clay, finger paint, soap bubbles etc.) should be without allergenic fragrances, in order to protect children from the risk of sensitisation.

Nordic Ecolabelling has in general a ban on fragrances used in products for children (is valid for toys and cosmetic products).

[21] It is unclear why Nordic Ecolabelling is referring to 127 fragrance substances, when 129 fragrance substances are listed in the SCCS opinion.

BfR is of the opinion that the 55 banned allergenic fragrances should not be detectable in toys and that the declaration threshold for the 11 fragrances that must be declared is lowered to 10 ppm instead of 100 ppm. Furthermore, the BfR is of the opinion that toys for children below 3 years of age and toys which children, due to their size, can put in the mouth should not contain any fragrances.

Based on these above opinions and based on the fact that consumers (and also children) are often exposed to a mixture of fragrances instead of just single fragrances, it is suggested that a conservative approach is used in order to protect children from the risk of sensitisation:

- All 129 listed contact allergens by the SCCS (SCCS/1459/11, 2011 – Table 13-1 to Table 13-3) should be banned from all toys in non-detectable amounts (alternatively 10 ppm).

Test methods

The Q&A document on Toy Safety does not mention any specific test method for the 66 listed fragrances in the Toy Safety Directive. Neither does the Ecolabelling criteria documents (here documentation is the recipe or declarations).

Suggestion: Fragrances

The following suggestions for chemical requirements are made for fragrances.

Table 12: Suggested chemical requirements regarding fragrances in toys

Fragrances **(in all materials)**	**Type of limit value:** Content based **Limit value:** All 129 listed contact allergens (as listed by SCCS/1459/11 (2011) – Table 13-1 to 13-3) should be banned from all toys in non-detectable amounts (alternatively in an amount of 10 ppm). **Test method:** No suggestions

3.3.2 Isothiazolinones

Isothiazolinones are preservatives with different uses, e.g. in cosmetic products, but are also used in “chemical toys” like finger paint. Known and used isothiazolinones are:

- MI – 2-methylisothiazolin-3(2H)-one
- MCI – 5-chloro-2-methylisothiazolin-3(2H)-one
- BIT – 1,2-benzisothiazol-3(2H)-one
- Kathon (a mixture of MI and MCI, mixed in a ratio of 3:1)

Today Kathon is restricted in finger paints (according to EN 71-7 (2002)) in a maximum concentration of 15 ppm (0.0015%).

In EN 71-9 (2007), the isothiazolinones are listed with the following limit values. However, EN 71-9 (2007) is not a harmonised standard and therefore has no legal status.

- Kathon – 15 mg/kg (0.0015%)
- MI – 10 mg/kg (0.0010%)

- MCI – 10 mg/kg (0.0010%)
- BIT – action limit, i.e. 5 mg/kg (0.0005%)

The restriction of Kathon in the new version of EN 71-7 is being prepared (at the moment of writing). In the draft standard sent to the formal vote in June 2013, the limit value of Kathon is set at 0.0008% and the limit value for MI alone is set at 0.01%. A limit value for BIT was suggested but was not accepted in the draft standard.

In April 2012 Member States have agreed to follow the recommendation of the Chemicals Subgroup of the Expert Group on Toy Safety and ban Kathon in appendix C of the new Toy Safety Directive. However, so far no action has been taken[22].

SCCS opinion, 2009

According to a SCCS opinion on Kathon (SCCS/1238/09, 2009), the mixture of MI and MCI does not pose a risk to the health of the consumers when used as a preservative in a maximum concentration of 15 ppm (0.0015%) in rinse-off products (cosmetics) – apart from its sensitising potential. Kathon is an extreme sensitiser.

Rinse-off products are not that relevant for toys. However, products like soap-bubbles, finger paints, etc., may be regarded as a kind of "rinse-off" products, as they are washed of after use.

SCHER opinion, 2007

In an opinion paper from SCHER (SCHER, 2007), it is stated that the use of Kathon (or its two components) in toys is not recommended because of its sensitising potential.

SCCS opinion, 2012

SCCS has made an opinion on benzisothiazolinone (SCCS/1482/12, 2012) in order to assess if the substances are safe to use in cosmetic products. SCCS concludes that benzisothiazolinone is safe for use as a preservative in cosmetics products in concentrations up to 0.01% with respect to systemic toxicity. However, its sensitising potential is of concern.

The SCCS notes the following regarding the sensitising potential of benzoisothiazolinone: Benzisothiazolinone is known to be a sensitiser in man and has induced sensitisation at circa 20 ppm in gloves. There is no information on what may be safe levels of exposure to benzisothiazolinone in cosmetic products from the point of view of sensitisation. Until safe levels of exposure have been established, the use of benzisothiazolinone in cosmetic products as a preservative or for other functions cannot be considered safe in relation to sensitisation.

Nordic Ecolabelling, 2012

In the Nordic Ecolabelling of toys, there is a general requirement that Kathon must no be used in a concentration exceeding 0.0015% by weight (15 ppm)

[22] Information from Franz Fiala, The Consumer Council at the Austrian Standards Institute

and that isothiazolinones in general must not be used in concentrations above 0.05% (500 ppm).

3.3.2.1 Conclusion isothiazolinones

Type of limit value

Isothiazolinones are in general known to be skin sensitisers. Kathon and especially MCI is an extreme skin sensitiser. Hence, it is necessary to base the restriction of isothiazolinones on content.

Limit value

SCCS states that the use of Kathon (or its to components MI and MCI) is safe in rinse-off cosmetics – apart from its sensitising potential. SCHER recommends that Kathon is not used in toys at all. Therefore it is suggested to restrict the use of Kathon and other isothiazolinones to a non-detectable level.

Test methods

According to the SCCS opinion (SCCS/1238/09, 2009), HPLC can be used to analyse for the content of Kathon. However, it is important to use a chemical analysis that can detect Kathon and other isothiazolinones in a concentration well below the allowed 15 ppm in cosmetic products today. According to a report (Poulsen & Schmidt, 2007), a detection limit of 2 ppm is possible in cosmetic products. However, it could be a problem to be able to achieve this low detection limit in special matrixes like slimy toys, modelling clay, etc. This aspect should be investigated further.

Suggestion: Isothiazolinones

The following suggestions for chemical requirements are made for isothiazolinones.

Table 13: Suggested chemical requirements regarding isothiazolinones in toys

Isothiazolinones **(in "chemical" toys)**	**Type of limit value:** Content based **Limit value:** Use of isothiazolinones in toys is not allowed (non-detectable). **Test method:** HPLC, detection limit 2 ppm.

3.3.3 Nickel

The new Toy Safety Directive (2009/48/EC) sets migration requirements for nickel in line with 18 other elements. The migration requirements for nickel in powder-like toy material, liquid toy material and scraped-off toy material are 75, 18.8 and 930 ppm respectively. Furthermore, nickel is restricted through appendix XVII of REACH entry 27: "In articles intended to come into direct and prolonged contact with the skin the rate of nickel release should be equal to or below 0.5 µg/cm^2/week" (test method: EN 1811:2011).

SCHER opinion, 2012

In an opinion paper from 2012, SCHER has assessed the risk to children's health from the presence of metallic nickel in toys (SCHER Nickel, 2012). According to SCHER, the nickel induced sensitisation by skin contact is addressed by the REACH regulation limiting nickel release from materials with potential frequent skin contact.

BfR opinion, 2012

BfR points out that the Toy Safety Directive does not lay down a threshold limit value, limiting nickel release from toys for skin contact. BfR is of the opinion that the limit for nickel release specified in the REACH regulation should also apply to toys consisting of metal alloys and which come into intensive contact with the skin for extended periods of time. However, BfR also states that the EU Commission now has confirmed in its "Explanatory Guidance Document" on the Toy Safety Directive that the limit value of the REACH regulation has to be applied to toys as well. It is stated in the guidance document of the Toy Safety Directive that "the nickel requirements apply to any article intended for direct and prolonged contact with the skin. Toys that fall into that category would be covered by the nickel Directive (currently the restrictions in Annex XVII of REACH)" (European Commission – TSD, 2012).

3.3.3.1 Conclusion nickel

According to the "Explanatory Guidance Document" on the Toy Safety Directive, Toys are covered by the REACH Annex XVII restriction on nickel. However, only for toys with "prolonged" contact with skin. The question is, however, how the term "prolonged contact with skin" should be defined, when it comes to toys. It is therefore suggested, that this aspect should be clarified. This could be done by preparing a guidance document to clarify the concept.

It is therefore suggested not to restrict nickel further than what is already included through the REACH restriction – however, clarification on the term "prolonged contact with skin" is needed.

3.3.4 Generic – Other sensitisers

Other sensitisers than the sensitisers already mentioned above are not restricted in the new Toy Safety Directive.

ANEC/BEUC, 2012c

ANEC and BEUC describe in a joint position paper that sensitizers other than allergenic fragrances are not covered by the requirements of the new Toy Safety Directive. ANEC and BEUC are of the opinion that sensitizers other than allergenic fragrances must be banned as a group in toys (ANEC/BEUC, 2012c).

3.3.4.1 Discussion – generic – other sensitisers

The SCCS opinion (SCCS/1459/11, 2011) concludes that a limit value of 100 ppm could be used as a generic limit value for all fragrances that are found to be sensitising. They specify that a lower or higher limit value may be

used dependant on the specific substances; however, the generic limit value could be used if no data exists.

A similar value could be used for all sensitising substances present in toys – including substances that are sensitising to the respiratory tract. The definition of sensitising substances could be substances that are classified as sensitising, e.g. with the hazard statement H317 "May cause an allergic skin reaction" and/or H334 "May cause allergy or asthma symptoms or breathing difficulties if inhaled" in the REACH Classification & Labelling Inventory Database[23]. However, if data exists on safe limits for these sensitising substances, these limits should of course be used instead.

ECHA's Classification & Labelling Inventory Database (under the REACH regulation) contains classification and labelling information on notified and registered substances received from manufacturers and importers. This database contains (spring 2013) the notified classification of about 110,000 substances. It is important to notice that a harmonised classification only exists for about 4,500 substances (out of the 110,000 substances). The classifications for the rest of the substances are classifications suggested (notified) by manufactures and importers. Therefore, the database also contains several suggestions for a classification per substance. One way (the easiest way) to operationalise the use of the C&L Inventory Database could be to exclude the use of substances with a certain classification if just one manufacturer/importer has classified the substance with the specific classification, regardless of whether the classification is harmonised or not.

The limit value should be content based in order to limit the total content of sensitising substances.

Table 14: Suggested chemical requirements regarding sensitising substances in toys

Sensitising substances **(in all materials)**	**Type of limit value:** Content based **Limit value:** All sensitising substances, i.e. substances classified as sensitising with H317 "May cause an allergic skin reaction" and/or H334 "May cause allergy or asthma symptoms or breathing difficulties if inhaled" according to REACH C&L Inventory Database (harmonised or non-harmonised classification) should not be present in all toys in a concentration higher than 100 ppm. If substances are sensitising in lower concentrations than 100 ppm, the sensitisation level of the specific substances must not be exceeded. **Test method:** Dependant on the substance

[23] http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database

3.4 Flame retardants

No specific requirements for flame retardants are set in the new Toy Safety Directive – except for flame retardants classified as CMR and except for the general statement that the chemical substances used in toys must not present a risk of adverse effects to human health.

EN 71-9 (2007) contains some limited requirements regarding flame retardants (table 2A). Requirements are set for the following flame retardants; however, EN 71-9 (2007) is not a harmonised standard and therefore has no legal status. The limit value set is the "action limit", i.e. the limit of the applicable method as specified in EN 71-11 (2005).

- Tri-o-cresyl phosphate – action limit 50 mg/kg
- Tris(2-chloroethyl) phosphate (TCEP) – action limit 50 mg/kg

Tri-o-cresyl phosphate is also a plasticiser and has been described and suggested restricted as well in section 3.1.4 "Phthalates and other plasticisers".

According to REACH appendix XVII, entry 4, 7 and 8, the following three flame retardants are banned in textiles articles with skin contact and therefore also in toys:

- TRIS – tris (2,3 dibromopropyl) phosphate (CAS 126-72-7)
- TEPA – tris(aziridinyl)phosphinoxide (CAS 545-55-1)
- PBB – polybrominatedbiphenyls (CAS 59536-65-1)

The Commission intends to ban the following flame retardant in toys intended for use by children below the age of 36 months or in other toys intended to be placed in the mouth (COM/2012/003, 2012; CEN/TC 252, 2012):

- TCEP – tris(2-chloroethyl) phosphate (CAS 115-96-8)

TCEP has been identified as SVHC and is on the REACH candidate list of SVHCs.

Two similar substances are under scrutiny:

- TDCP/TDCPP – tris(1,3-dichloropropyl-2)phosphate (CAS 13674-87-8)
- TCPP – tris-monochloro-propyl phosphate (CAS 13674-84-5)

3.4.1 TCEP, TCPP and TDCP

TCEP, TCPP and TDCP are not restricted today in the Toy Safety Directive, but according to a Commission proposal document (COM/2012/003, 2012), TCEP is suggested to be restricted in toys (intended for use by children below the age of 36 months) with a limit value of 5 ppm via an entry in Annex C "Specific limit values for chemicals used in toys intended for use by children below the age of 36 months or in other toys intended to be placed in the mouth".

SCHER opinion, 2012

SCHER has in 2012 performed a risk assessment of TCEP in toys (SCHER TCEP, 2012). TCEP is classified as a carcinogen category 2 and toxic to reproduction category 1B and may therefore occur in toys up to a concentration of 0.5% (0.3% starting from 2015). Based on a "provisional" TDI value for TCEP, SCHER has calculated that the exposure of TCEP from other sources (excluding toys) is similar to the TDI value. For this reason SCHER is of the opinion that TCEP should be avoided in toys and that the limit value should be set at the detection limit of a sufficiently sensitive analytical method. No specific detection limit is mentioned.

Furthermore, SCHER is of the opinion that TCEP should be avoided in all toys (also above the age of 3) and not just in toys intended for children below the age of 36 moths.

Finally, SCHER concludes that there is sufficient information to support read-across between TCEP and the alternative flame retardants TDCP and TCPP and other halogenated alternatives as well, meaning that considerations given for TCEP could also be applied to its halogenated alternatives, if used in toy manufacturing.

ANEC/BEUC joint position, 2012

ANEC and BEUC agree with the conclusions of the SCHER opinion on TCEP, i.e. that TCEP should be banned from all toys irrespective of age. ANEC and BEUC state that it is unacceptable that the new Toy Safety Directive does not allow adopting specific requirements for toys that are intended for children above 36 months of age. They call for a comitology procedure allowing setting limits for all kind of toys (irrespective of age) and all kind of substances, and, while this happens, they call for an emergency measure based on article 13 of the General Product Safety Directive should be implemented[24] (ANEC/BEUC, 2012b).

Furthermore, ANEC and BEUC agree with SCHER that a read-across approach can be used on the alternative flame retardants TCPP and TDCP given the structural similarities to TCEP. ANEC and BEUC therefore conclude that all three substances (TCEP, TCPP and TDCP) should be banned from all toys irrespective of age.

3.4.1.1 Conclusion TCEP, TCPP and TDCP

Type of limit value

According to the SCHER opinion (SCHER TCEP, 2012), TCEPis already at the exposure level similar to the TDI value from other sources than toys, it will be necessary to ban the use of TCEP and therefore base the restriction of the flame retardant on content.

[24] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety foresees in article 13 that the Commission can adopt a decision if it becomes aware of a serious risk from certain products to the health and safety of consumers after having consulted Member States and the Scientific Committee competent to deal with the risk concerned.

Limit value

SCHER is of the opinion that no limit value should be set, i.e. TCEP should be restricted at the lowest level of detection possible. No information has been found on this level of detection. In the proposal from the EU Commission, the detection limit is set at 5 ppm (5 mg/kg) and this level is therefore used for the other flame retardants as well. As described in both documents, the SCHER opinion paper and in the joint ANEC/BEUC position paper, the banning of the three flame retardants should be valid for all toys and not just toys under the age of 36 months.

Test methods

No suggestions for test methods have been identified.

Suggestion: TCEP, TCPP and TDCP

The following suggestions for chemical requirements are made for the specific flame retardants.

Table 15: Suggested chemical requirements regarding TCEP, TCPP and TDCP in toys

TCEP, TCPP and TDCP **(in all materials)**	**Type of limit value:** Content based **Limit value:** Use of TCEP, TCPP and TDCP in all toys is not allowed (non-detectable), i.e. 5 ppm (5 mg/kg) or lower depending on the test method used. **Test method:** No suggestions

3.4.2 Diantimony trioxide

As described in chapter 3.2.3 “Antimony”, SCHER has made an opinion on diantimony trioxide (SCHER Diantimony Trioxide, 2010). This opinion has been described in the ‘elements’ chapter and the risk assessment performed by SCHER is based on the toxicity of antimony. The limit value proposed for antimony therefore also accounts for the toxicity of diantimony trioxide so there is no reason for setting a specific limit for diantimony trioxide, as the proposed antimony level also accounts for the toxicity of diantimony trioxide.

3.4.3 Generic – flame retardants

CEN/TC 52, 2002

A comprehensive assessment of flame retardants has been made by a group of toxicologists in the development of EN 71-9/10/11, regarding organic chemical compounds in toys. The CEN/TC 52 working group received a list of over 800 different organic chemicals potentially used in toys. This list was reviewed and the flame retardants were identified as well as their hazard. The work resulted in different lists of classified flame retardants (CEN/TC 52, 2002):

- The most hazardous flame retardants (hazardous because of carcinogenic effects, mutagenic effects, skin sensitisation and/or severe organ toxicity). Table 2 in the CEN/TC52 document contains 20 flame retardants or groups of flame retardants.

- Flame retardants for which migration limits may be set. Table 3 in the CEN/TC 52 document contains 4 flame retardants or groups of flame retardants.
- Flame retardants with insufficient data. Table 4 in the CEN/TC52 document contains 26 flame retardants or groups of flame retardants.

The working group suggested the following approach regarding flame retardants in toys:

1. Flame retarding substances should not be used in toys for children below the age of 3 years (because of insufficient exposure data to consider their use for this age group safe).
2. The most hazardous flame retarding substances (Table 2 in the document) should not be used in any of the toys (all categories of toys). The content of these flame retardants should not exceed the detection limit (however, analytical methods should be developed).
3. For specific flame retardants (Table 3 in the document), migration limits should be set based on maximum exposure of 10% of the TDI value.
4. For a long list of flame retardants, the available toxicological data was insufficient for an evaluation (Table 4 in the document).

SCHER, 2007 & CSTEE, 2003 – response to CEN/TC 52, 2002

Both CSTEE (2003) and SCHER (2007) have reviewed the work carried out by the CEN/TC 52 working group described above. They criticize the CEN/TC 52 report for the following aspects:

- The CEN/TC 52 report is based on a long list of chemicals used in toys. The chemicals have been proposed by interested parties (member states, industry, regulators and consumer organisations). However, no systematic search for compounds used in toys has been performed.
- The report focuses on hazards of the chemicals and not on risks. There has not been performed a risk assessment of the aforementioned hazardous chemicals in order to calculate if there is a risk of using these chemicals in toys.
- Action limits/limit values have been established for use in the standard EN 71-9 (2007) for certain chemicals. These limit values are, according to SCHER, based on migration data without sufficient description of to what extent exposure and toxicological data such as NOEL have been considered.
- Consequently SCHER and CSTEE are not in a position to evaluate whether the standards on organic chemicals proposed by CEN have been set on a scientifically defendable basis.

ANEC position, 2007

In a position paper from ANEC on flame retardants standards for upholstered furniture, ANEC states that industry must get a clear indication of which flame retardants are allowed to be used; meaning that the flame retardants should be identified and incorporated in form of a positive list. This should apply for all items/products for which flammability requirements are to be set and thereby also for toys (ANEC, 2007).

ANEC hence calls for some kind of regulation (or annex included in all relevant standards) for all flame retardants in all products by use of a positive

list of flame retardants that are allowed to be used. Flame retardants should only be put on the positive list once they are approved by an independent toxicological organisation such as SCHER (Scientific Committee on Health and Environmental Risks). Thus. these general aspects suggested by ANEC for flame retardants are:

- Regulation of use of all flame retardants in all products by use of a positive list.
- Independent toxicological assessment of all flame retardants.

Nordic Ecolabelling, 2012

In the Nordic Ecolabelling of toys, there is a more or less general requirement stating that halogenated flame retardants must not be added to toys. The requirement is listed for plastic materials, rubber, textiles, leather, chemical products used for surface treatment of wood and metal, electric toys, adhesives and glue. The limit value is, for some materials, set at 100 ppm (Nordic Ecolabelling, 2012).

Oeko-Tex 100, 2013

Oeko-Tex 100 (the "Confidence in textiles" labelling) sets requirements for flame retardants in textiles in their Oeko-Tex Standard 100. The requirements for all product classes are in general that no flame retardants must be used – with the exception of treatments accepted by Oeko-Tex. An assessment carried out by Oeko-Tex must reveal that the flame retarded textile may be used from a human-ecological point of view without any restrictions or that the flame retardant agents are harmless to human health. Oeko-Tex 100 distinguishes between fibre materials which receive the flame retardant properties in the spinning mass already (co-polymers, additives) and a finish with flame retardant agents in a later processing step (Oeko-Tex 100, 2013). From a health perspective the exposure will be lower if the flame retardant agents are incorporated into the textile fibres compared to being added in a textile finishing step (Oeko-Tex 100, 2013).

It is furthermore specified that the following flame retardants must not be used (will not be approved to be used):

- PBB, TRIS, and TEPA (restricted in REACH Appendix XVII in textiles to come into contact with skin).
- pentaBDE, octaBDE, decaBDE (restricted in electronics (RoHS).
- HBCDD, SCCP and TCEP (are on the REACH candidate list of SVHCs), and HBCDD and TCEP are on appendix XIV of REACH "List of substances subject to authorisation").

According to the supplement to the Oeko-Tex Standard 100 (Oeko-Tex 100 Supplement, 2013), textile toys can also receive the Oeko-Tex mark by complying with the Oeko-Tex requirements. The requirements for toys are that all textile and non-textile components of textile toys must comply with the above requirements that no flame retardant agents are to be used unless they have been approved by Oeko-Tex.

3.4.3.1 Conclusion generic flame retardants

The above grouping of flame retardants (CEN/TC-52, 2002) was based on a work performed before 2002. Hopefully, REACH has delivered more data on flame retardants since then so some of the flame retardants from Table 4 with

insufficient data today could be evaluated better. One option could be to use the existing lists from the work of CEN/TC 52 (Table 2, 3 and 4) and set requirements based on these lists. Another option could be to use the generic idea behind the requirements for flame retardants in the CEN/TC 52 document and exclude flame retardants based on their classification. A third option could be to exclude all halogenated flame retardants as it is done in the Nordic Ecolabelling of toys or all flame retardants which have not been approved (by Oeko-Tex) as it is done in the Oeko-Tex 100. The latter approach is, however, problematic as it is not known exactly which flame retardants that are approved by Oeko-Tex. A list of approved flame retardants is available on the Oeko-Tex website[25], but the list contains approved compounds by their trade name. It is not possible to see or identify the chemical composition of the flame retardants. Finally, the generic option presented by ANEC (2007) of using a positive list of flame retardants for all products could be used.

It should be mentioned that both, SCHER and CSTEE, have criticized the work of CEN/TC 52. Their main concern is that substances are suggested regulated (limit values have been set) based on only a hazard assessment and not a risk assessment. Even though this is true, it is important to notice that a risk assessment is carried out for one single chemical. If more than 800 different chemicals have been found in toys several of these may have the same endpoint effect. For this reason, it may be safer and much more effective to regulate by generic requirements on hazards instead of a comprehensive risk assessment on each single chemical as it will take years to perform risk assessments on each chemical found in toys. Instead the opposite approach could be used. Higher limit values of specific substances could be allowed if a risk assessment indicates that it is reasonable to allow for higher concentrations in toys.

ECHA's Classification & Labelling Inventory Database (under the REACH regulation) contains classification and labelling information on notified and registered substances received from manufacturers and importers. Today (spring 2013) this database contains the notified classification of about 110,000 substances; however, a harmonised classification only exists for about 4,500 substances. The classifications for the rest of the substances are classifications as suggested (notified) from manufactures and importers. Therefore the database also contains several suggestions for a classification per substance. One way (and the easiest way) to operationalise the use of the C&L Inventory Database could be to exclude the use of substances with a certain classification if just one manufacturer/importer has classified the substance with the specific classification.

Type of limit value

It is suggested to use the idea behind the work carried out on flame retardants by CEN/TC 52 to set generic requirements for flame retardants but in combination with the idea of a positive list of flame retardants in line with the Oekotex 100 philosophy.

A content based limit value seems to be the most obvious choice to ensure that the most toxic flame retardants are not used at all. This will also eliminate

[25] https://www.oeko-tex.com/en/manufacturers/certified_products/active_chemical_products/flame_retardant_products/flame_retardant_products.html

environmental related problems as some flame retardants (e.g. brominated flame retardants) are considered environmentally problematic.

Limit value

By using a combination of the generic requirements set by CEN/TC 52 and the idea of a positive list in line with the Oekotex 100 philosophy for flame retardants, the generic requirements for flame retardants could be:

- Only use of flame retardants that have been approved by SCHER on the basis of a full risk assessment (= positive list of flame retardants that can be used with specific concentrations).
- Until the positive list of flame retardants has been established, a generic exclusion of flame retardants with the properties below are to be excluded: No use of the most hazardous flame retardants in all toys (for all ages), i.e. in non-detectable levels. The most hazardous flame retardants could be defined as in CEN/TC52 (2002), i.e. CMR substances, sensitising substances and substances with severe organ toxicity. However, as exclusion of CMR flame retardants already is covered by the general CMR exclusion, and that exclusion of sensitising flame retardants already is covered by the proposed general exclusion of sensitising substances, these effects will not be taken into consideration here. This rest of the effects could be translated to the following classification:
    - H370 – Causes damage to organs
    - H371 – May cause damage to organs
    - H372 – Causes damage to organs through prolonged or repeated exposure
    - H373 – May cause damage to organs through prolonged or repeated exposure
- A limit value of 5 mg/kg has been suggested for TCEP. It is therefore suggested to use the same limit value as a generic limit value for flame retardants.

Test method

The test method will depend on the type of flame retardant used.

Suggestion: Generic flame retardants

The following suggestions for chemical requirements are made generic for flame retardants.

Table 16: Suggested chemical requirements regarding flame retardants (generic) in toys

Flame retardants **(in all materials)**	**Type of limit value:** Content based and based on migration **Limit value:** 1. It is only allowed to use flame retardants that have been approved by SCHER on the basis of a full risk assessment (= positive list of flame retardants that can be used with specific migration concentrations). 2. Until the positive list of flame retardants has been established, a generic exclusion of flame retardants with the properties below should be excluded. Use of flame retardants with the following classification according to REACH C&L Inventory Database is not allowed in all toys (non-detectable content, i.e. detection level of 5 mg/kg): • H370 – Causes damage to organs • H371 – May cause damage to organs • H372 – Causes damage to organs through prolonged or repeated exposure • H373 – May cause damage to organs through prolonged or repeated exposure **Test method:** Depends on the substance

3.5 Colourants and primary aromatic amines

No specific requirements for colourants and primary aromatic amines are set in the new Toy Safety Directive – except for colourants and primary aromatic amines classified as CMR and except for the general statement that the chemical substances used in toys must not present a risk of adverse effects to human health.

However, **azocolourants and azodyes** are regulated in toys through REACH Regulation No. 1907/2006 Annex XVII entry No. 43. Azodyes that, by reductive cleavage of one or more azo groups, may release one or more of the 22 **primary aromatic amines** listed in Appendix 8 of REACH may not be detectable, i.e. concentrations above 30 mg/kg or 0.0030%, in textile or leather toys and toys which include textile or leather garments. The primary aromatic amines are all regarded as being carcinogenic (are either classified as 1A, 1B or 2 according to the CLP Regulation).

EN 71-7 (2002) and EN 71-9 (2007) include some requirements for colourants and primary aromatic amines.

In EN 71-7 (2002) the following requirements are listed:

Colourants:

1. The use of colourants listed in annex A is permitted. However annex A is not compulsory list of colourants to be used. Annex A consists of colourants falling in one or more of the following categories: food colourants, colourants permitted for the use in cosmetics without limitation in the field of application and which fulfill the requirements given there, other pigments, which meet the general requirements of not containing dangerous substances.

2. Colourants which are not classified as carcinogenic, mutagenic, toxic to reproduction, very toxic, toxic, harmful, corrosive, irritant or sensitising, may also be used in finger paints.
3. Finger paints shall not contain azocolourants that by cleavage of one or more azogroups can produce the primary aromatic amines listed in table 3 and 4 of the standard.

Primary aromatic amines:

- The following primary aromatic amines must not be used in finger paints (not determinable):
    - Benzidine
    - 2-Naphthylamine
    - 4-chloro-2-methyl-aniline (4-chloro-o-toluidine)
    - 4-aminobiphenyl
- Other 22 primary aromatic amines must not be present in a total amount exceeding 20 mg/kg, with no individual primary aromatic amine exceeding 10 mg/kg. It is emphasised that the list of primary aromatic amines only is an example, i.e. other primary aromatic amines not listed are encompassed by the restriction.

EN 71-7 is to be changed and a version of the new EN 71-7 requirements has been submitted to CCMC (CEN CENELEC Management Centre) for formal vote on July 19 2013. In this version of the EN 71-7 standard, the requirements regarding primary aromatic amines are the same, but the requirements regarding colourants have been changed a bit:

- Point 2 above now also contains hazard classes such as specific target organ toxicity (single exposure and repeated exposure) as well as aspiration hazard.

EN 71-9 (2007) contains some requirements regarding colourants (table 2B) and primary aromatic amines (table 2C). Requirements are set for the following colourants and primary aromatic amines; however, EN 71-9 (2007) is not a harmonised standard and therefore has no legal status. The limit value set is the "action limit", i.e. the limit of the applicable method as specified in EN 71-11 (2005).

- Colorants – action limit 10 mg/kg for all colourants below:
    - Disperse Blue
    - Disperse Blue 3
    - Disperse Blue 106
    - Disperse Blue 124
    - Disperse Yellow 3
    - Disperse Orange 3
    - Disperse Orange 37/76
    - Disperse Red 1
    - Solvent Yellow 1
    - Solvent Yellow 2
    - Solvent Yellow 3
    - Basic Red 9
    - Basic Violet 1
    - Basic Violet 3
    - Acid Red 26
    - Acid Violet 49
- Primary aromatic amines – action limit 5 mg/kg for all primary aromatic amines below:
    - Benzidine

- 2-Naphthylamine
- 4-Chloroaniline
- 3.3'-Dichlorobenzidine
- 3,3'-Dimethoxybenzidine
- 3.3'-Dimethylbenzidine
- o-Toluidine
- 2-Methoxyaniline (o-Anisidine)
- Aniline

CEN/TC 52, 2002

A comprehensive assessment of colourants has been made by a group of toxicologists in the development of EN 71-9/10/11 regarding organic chemical compounds in toys. The CEN/TC 52 working group received a list of over 800 different organic chemicals potentially used in toys. This list was reviewed and the colourants were identified as well as their hazard. The work resulted in the following overview of types of colourants used (CEN/TC 52, 2002):

- Disperse dyes – 12 different substances (16%)
- Azodyes (excluding disperse dyes) – 37 different substances (51%)
- Non-azocolourants – 22 different substances (30%)
- Inorganic colourants – 2 different substances (3%)

Based on this list of dyes/colourants, the CEN/TC 52 working group concluded to prioritise the following groups of colourants and make the following recommendations:

- Azodyes that break down into 22 certain primary aromatic amines should be banned. This means that this group of colourants is restricted in textile and leather toys today by the REACH Annex XVII restriction.
- Dyes that are classified as carcinogenic, mutagenic or toxic to reproduction as category 1A and 1B should not be used in toys.
- Disperse dyes that are potential skin sensitizers should be prohibited or limits should be identified and set.

Oeko-Tex 100, 2013

Oeko-Tex Standard 100 (the "Confidence in textiles" labelling) sets requirements for colourants used for colouring of textiles. The requirements for all product classes are that certain colourants listed in appendix 5 of the Oeko-Tex Standard 100 (Oeko-Tex 100, 2013) must not be used:

- Colourants that by cleavage can break down to 24 arylamines must not be used (quantification limit is 20 mg/kg),
- 9 colourants classified as carcinogenic must not be used (quantification limit is 50 mg/kg),
- 21 colourants classified as allergenic must not be used (quantification limit is 50 mg/kg), and
- 2 other colourants are banned (quantification limit is 50 mg/kg).

According to the supplement to the Oeko-Tex Standard 100 (Oeko-Tex 100 Supplement, 2013), textile toys can also receive the Oeko-Tex mark by complying with the Oeko-Tex requirements. The requirements to toys are that all textile and non-textile components of textile toys must comply with the above requirement that none of the listed colourants must be used in the textile toys.

3.5.1 Conclusions colourants and primary aromatic amines

The recommendations made by the CEN/TC 52 working group in 2002 have already been followed to some extent. Azodyes that break down to certain primary aromatic amines are today restricted in textile or leather toys through REACH Annex XVII entry No. 43. In addition, EN 71-7 (2002) and EN 71-9 (2007) set requirements for primary aromatic amines.

9 of the 22 primary aromatic amines restricted by REACH if they are formed from azocolourants are restricted by EN 71-9 (2007). An action limit is set for these 9 primary aromatic amines which means that these 9 aromatic amines must not be used above the level of detection for the analysis method used (i.e. 5 mg/kg or 0.0005%).

Furthermore, some disperse dyes that were found to be potential skin sensitizers by the working group have already been limited in their use in the EN 71-9 (2007) standard "Organic chemical compounds". An action limit is set for 8 disperse dyes and 8 other dyes, meaning that the limit value is the level of detection for the analysis method used (i.e. 10 mg/kg or 0.001%).

Colourants that are sensitizers also fall under the category sensitizers and are discussed in general in the chapter 3.3.4 "Generic – Other sensitisers" above. Colourants that are classified as CMR are discussed in general in the chapter 3.1.1 "Generic SVHCs including CMRs, PBTs, vPvB" above. Similarly, other primary aromatic amines with CMR properties, if not included in the list of the 22 primary aromatic amines banned by REACH Annex XVII entry no. 43, are covered by the proposal for a generic CMR restriction.

The EN 71-7 requirements are only valid for finger paints and the requirements listed in EN 71-9 (not a harmonised standard) do not have legal status. It is therefore suggested to include the general requirements on colourants and primary aromatic amines from EN 71-9 for all toys.

Suggestion: Colourants and primary aromatic amines

The following suggestions for chemical requirements are made for colourants and primary aromatic amines.

Table 17: Suggested chemical requirements regarding colourants and primary aromatic amines in toys

Colourants and primary aromatic amines **(in all materials)**	**Type of limit value:** Content based **Limit value:** • The use of the following colorants shall not be present in all toys – action limit 10 mg/kg for all colourants below: o Disperse Blue o Disperse Blue 3 o Disperse Blue 106 o Disperse Blue 124 o Disperse Yellow 3 o Disperse Orange 3 o Disperse Orange 37/76 o Disperse Red 1 o Solvent Yellow 1 o Solvent Yellow 2 o Solvent Yellow 3 o Basic Red 9 o Basic Violet 1 o Basic Violet 3 o Acid Red 26 o Acid Violet 49 • The use of the following primary aromatic amines shall not be present in all toys – action limit 5 mg/kg for all primary aromatic amines below: o Benzidine o 2-Naphthylamine o 4-Chloroaniline o 3.3'-Dichlorobenzidine o 3,3'-Dimethoxybenzidine o 3.3'-Dimethylbenzidine o o-Toluidine o 2-Methoxyaniline (o-Anisidine) o Aniline **Test method:** As described in EN 71-11

3.6 Monomers (migration)

A monomer is a molecule that forms the basic unit for polymers, i.e. monomers are molecules that bind to other monomers to form a repeating chain molecule (polymers/plastic materials). Monomers are by their very nature intrinsically reactive and hence likely to have hazardous properties. It is, however, expected that the presence of "free" monomers in finished products will be at very low levels (CEN/TC 52, 2002).

No specific requirements for monomers are set in the new Toy Safety Directive – except for monomers classified as CMR and for the general statement that the chemical substances used in toys must not present a risk of adverse effects to human health.

EN 71-9 (2007) contains some limited requirements monomers (table 2D). Requirements are set for the following monomers; however, EN 71-9 (2007) is not a harmonised standard and therefore has no legal status.

- Acrylamide – action limit of 0.02 mg/litre aqueous migrate

- Bisphenol A – 0.1 mg/litre aqueous migrate
- Formaldehyde – 2.5 mg/litre aqueous migrate
- Phenol – 15 mg/litre aqueous migrate
- Styrene – 0.75 mg/litre aqueous migrate

CEN/TC 52, 2002

The CEN/TC 52 working group reviewed in 2002 the presence of monomers in toys and concluded that the principles from the Food Contact Materials Regulation (No. 1935/2004) for plastics should be applied to plastic toys as well. The CEN/TC 52 working group divided the monomers into different lists based on their properties and based on their regulation in the Food Contact Materials Regulation:

- Monomers suitable for toys (i.e. allowed for food-contact materials with specific migration limits).
- Monomers that could be used for manufacturing of toys under strict regulation (i.e. substances that are allowed for food-contact materials if there is no detectable migration into food or food simulants by any agreed sensitive method for analysis).
- Monomers where no data exists. The release of these monomers should not be detected if used in toys.

ANEC position on SCHER opinion, 2010b

ANEC has made a position paper (ANEC position, 201b) on the SCHER opinion (SCHER opinion, 2010b) on organic CMR substances in toys. In this opinion, ANEC discusses the use of the principles from the Food Contact Materials Regulation as it is also discussed by SCHER.

Both ANEC and SCHER are of the opinion that the Food Contact Materials Regulation (as it is now) is not suited for the purpose of regulating chemicals in toys. However, ANEC is of the opinion that the requirements for plastic materials could be used as a starting point for developing a set of criteria applicable for toys. Both ANEC and SCHER have, however, pointed out that certain aspects need to be discussed further in order to use the Food Contact Materials legislation principles for toys. For example the specific migration limits should be based on a fraction of the TDI value (instead of the entire TDI value) and not related to adults of 60 kg but the weight of children instead. Other parameters that differ are contact times, temperature, simulants, the surface area and Food Contact Materials testing is based on static migration testing.

3.6.1 Conclusion monomers

The Toy Safety Directive itself calls for taking the Food Contact Materials Regulation into account when limits for toys for children below 36 months and toys intended to be placed in the mouth are established (preamble no. 24 and article 46). Both SCHER and ANEC have discussed the same possibility of using the principles on plastics from the Food Contact Materials Regulation on toys concerning the aspect of migration of monomers.

Type of limit value

It is suggested to use the approach from the Food Contact Materials Regulation, i.e. a positive list and the type of limit value as used in the Food Contact Materials Regulation for plastics, i.e. specific migration limit values for each monomer. However, this aspect will be discussed further in chapter 3.12 "Use of Food Contact Materials Regulation (FCM) legislation for toys" where other chemicals used in plastic materials are discussed as well based on the Food Contact Materials Regulation.

Limit value

It is suggested to use the specific limit values from the Food Contact Materials Regulation for plastics as suggested in preamble no. 24 and article 46 of the Toy Safety Directive. However, the limits must be adapted taking into account whether the specific limit values should be adjusted so they instead represent a fraction of the TDI value and related to the weight of a child.

Test method

The test method used should be based on the test method described in the Food Contact Materials Regulation for plastics, but instead of using food simulants, simulants relevant for child exposure should be used, i.e. artificial saliva and artificial sweat. In principle the test method used could be the test method in EN 71-10 (dynamic migration, "head-over-heal"), but some parameters may have to be modified (e.g. temperature, repeated extraction, water versus artificial saliva). These aspects have to be investigated further.

Suggestion: Monomers

The following suggestions for chemical requirements are made for monomers.

Table 18: Suggested chemical requirements regarding monomers in toys

Monomers **(in plastic materials)**	**Type of limit value:** Based on migration **Limit value:** For all toys: The specific migration limit values (SML) as used for monomers in Regulation No. 10/2011 on plastic materials and articles intended to come into contact with food (Annex I, Table I), but adjusted for weight of a child (instead of weight of adults) as well as only a fraction (10%) of the TDI value. **Test method:** As described in the Food Contact Materials Regulation, but by use of simulants relevant for child exposure, like e.g. artificial saliva and artificial sweat.

3.7 Solvents (migration and inhalation)

No specific requirements for solvents are set in the new Toy Safety Directive – except for solvents classified as CMR and the general statement that the chemical substances used in toys must not present a risk of adverse effects to human health.

One specific solvent, **benzene,** is restricted by REACH Regulation 1907/2006 Annex XVII entry no. 5. The concentration of free benzene must not exceed 5 mg/kg (or 0.0005%) in toys or in parts of toys.

Benzene is, according to the CLP Regulation, classified as carcinogenic, category 1A, and mutagenic, category 1B. This means that according to the general CMR restriction in the new Toy Safety Directive, the maximum allowed concentration of benzene in toys should be 0.1% (or 1000 mg/kg). However, a restriction of benzene in toys and parts of toys has been entered into REACH Annex XVII. According to REACH, benzene is restricted in toys at a concentration of 5 mg/kg or 0.0005%, i.e. 200 times lower than the general CMR requirement of the Toy Safety Directive. This is an example of the general CMR requirement being too high in certain cases. This aspect has been discussed in more details in chapter 3.1.1 "Generic SVHCs including CMRs, PBTs, vPvB" above.

EN 71-9 (2007) contains some limited requirements to solvents (table 2E – migration and table 2F - inhalation). Requirements are set for the following solvents; however, EN 71-9 (2007) is not a harmonised standard and therefore has no legal status.

Table 2E – migration:

- Trichloroethylene - action limit of 0.02 mg/litre aqueous migrate
- Dichloromethane – 0.06 mg/litre aqueous migrate
- The following solvents in a total of 0.5 mg/litre aqueous migrate:
    - 2-Methoxyethyl acetate
    - 2-Ethoxyethanol
    - 2-Ethoxyethyl acetate
    - Bis(2-methoxyethyl) ether
    - 2-Methoxypropyl acetate
- Methanol - 5 mg/litre aqueous migrate
- Nitrobenzene - action limit of 0.02 mg/litre aqueous migrate
- Cyclohexanone - 46 mg/litre aqueous migrate
- 3,5,5-Trimethyl-2-cyclohexene-1-one - 3 mg/litre aqueous migrate
- Toluene - 2 mg/litre aqueous migrate
- Ethylbenzene - 1 mg/litre aqueous migrate
- Xylene (all isomers) - 2 mg/litre aqueous migrate (total)

Table 2F – inhalation:

- Toluene - 260 μ/m^3
- Ethylbenzene - 5,000 μ/m^3
- Xylene (all isomers) - 870 μ/m^3 (total)
- 1,3,5-Trimethylbenzene (mesitylene) - 2,500 μ/m^3
- Trichloroethylene - action limit of 33 μ/m^3
- Dichloromethane - 3,000 μ/m^3
- n-Hexane - 1,800 μ/m^3
- Nitrobenzene - action limit of 33 μ/m^3

- Cyclohexanone - 136 µ/m^3
- 3,5,5-Trimethyl-2-cyclohexene-1-one - 200 µ/m^3

CEN/TC 52, 2002

A comprehensive assessment of solvents has been made by a group of toxicologists in the development of EN 71-9/10/11 regarding organic chemical compounds in toys. The CEN/TC 52 working group received a list of over 800 different organic chemicals potentially used in toys. This list was reviewed and the solvents were identified as well as their hazard. The work resulted in a total list of 65 different solvents being used in toys. The working group divided the solvents in the following types based on a hazard assessment/hazard ranking of the solvents (CEN/TC 52, 2002):

- 2 solvents that should not be used (not be detected in toys). These are benzene (today restricted in toys by REACH) and trichloroethylene.
- 27 solvents that should not intentionally be present in toys. Substance limits have to be set separately for two types of exposure: 1) oral intake and 2) inhalation.
- 29 solvents that may be present in toys with limitations.
- 15 solvents with insufficient data to be evaluated and where the use of these substances in toys was not recommended.

The working group has listed the critical effects for many of the solvents used in toys (in 2002). 13 solvents were considered to have toxicological effects of particular concern to humans, e.g. carcinogenic, mutagenic effects, toxic to reproduction or developmental effects. Some solvents have effects on the central nervous system (CNS) as the critical effect and a large group of solvents have irritating effects.

The working group has listed the occupational threshold limit value if such a limit value is set for the solvents. These limit values vary from 2 to 500 ppm depending on the solvent. However, the working group does not propose actual limit values for the specific solvents.

Nordic Ecolabelling, 2012

In the Nordic Ecolabelling of toys, different requirements are set for solvents or VOCs (Volatile Organic Compounds), depending on the materials and chemicals used in the toys (Nordic Ecolabelling, 2012):

- For plastic/plastic parts, rubber, adhesives and glue:
  - Halogenated organic compounds (including chlorinated polymers, PVC, chlorinated paraffins, fluoride compounds, flame retardants and organic bleaching agents) are in general prohibited, i.e. must not be actively added.
  - Volatile aromatic compounds that exceed 1% by weight are prohibited.
  - Volatile organic compounds in more than 3% by weight (i.e. boiling point below 250 °C at 0.013 kPa) are prohibited (only a requirement for adhesives/glues and not for plastic and rubber).
- For surface treatment of plastic, rubber and wood:
  - Halogenated organic compounds in general are prohibited (for plastic, rubber and metal surface treatment, yellow and green pigments are exempted).
  - Volatile organic compounds (VOC) that exceed the limit of 130 g/l chemicals used for surface treatment are prohibited.

    - Volatile aromatic compounds (VAH) added directly to the product are prohibited. Ingoing compounds containing VAH must not be added to the product if the total amount of VAH in the final product exceeds 0.1% by weight.
- For surface treatment of metal:
    - Halogenated organic compounds in general are prohibited, but yellow and green pigments are exempted.
    - Chemical products containing more than 5% by weight of organic solvents (i.e. boiling point below 250 °C at 0.013 kPa) must not be added. The content of aromatic compounds must not exceed 5% by weight.
- For chemical products used in wood-based materials:
    - Halogenated organic compounds (including halogenated organic flame retardants) must not be added to the chemical products.
    - Chemical products containing more than 5% by weight of organic solvents (i.e. boiling point below 250 °C at 0.013 kPa) must not be added. The content of aromatic compounds must not exceed 5% by weight.
    - Volatile aromatic compounds that exceed 1% by weight must not be added.
- For adhesives and glue:
    - Halogenated organic compounds (including chlorinated polymers, PVC, chlorinated paraffins, fluoride compounds, flame retardants and organic bleaching agents) are in general prohibited, i.e. must not be actively added.
    - Volatile aromatic compounds that exceed 1% by weight are prohibited.

3.7.1 Conclusions solvents

The critical effects of the solvents show that it may not be sufficient to restrict solvents based on a generic CMR requirement. The CEN/TC 52 working group found a number of solvents that they concluded should be restricted in toys as they have effects on the central nervous system (CNS), but no CMR effects.

One way to restrict solvents is to use a generic restriction on all solvents which have specific classifications (e.g. toxic and harmful) or with specific effects related to the CNS. However, this approach may be extremely difficult to verify for the manufacturer as the solvents are not constituents of the toy, but are residues from the material production. In case of e.g. colourants it may be possible to check safety data sheets or similar information for specific solvents, but for other materials it will be impossible to check or know about the content of solvent residues.

Another way to restrict solvents is to set specific limit values for each specific solvent, as it is actually done in the EN 71-9 (2007) standard where about 16 solvents have specific limit values for migration and/or inhalation. The limit values depend on the toxicity of the solvent and possible detection limits and they vary between 0.02 to 46 mg/l for migration and between 136 to 3,000 $\mu g/m^3$ for inhalation. However, these restrictions are only for certain toy materials, e.g. polymeric materials and textiles, and it should be noted that the test methods for inhalation have not been validated.

It should be mentioned that both SCHER and CSTEE have criticised the work of CEN/TC 52. Their main concern is that substances are suggested regulated (limit values have been set) based on only a hazard assessment and not a risk assessment. Even though this is true, it is important to notice that a risk assessment is carried out for one single chemical. A substance-by-substance risk assessment is very time consuming and requires that it is known which substances are used. However, the knowledge of this is rather fragmented. For this reason it may be safer and much more effective to regulate by generic requirements on hazards instead of a comprehensive risk assessment on each single chemical as it will take years to perform risk assessments on each chemical found in toys. Instead the opposite approach could be used. Higher limit values of specific substances could be allowed if a risk assessment indicates that it is reasonable to allow for higher concentrations in toys.

Type of limit value

It is suggested to use a combination of a migration limit value and an inhalation (evaporation) limit value for solvents. Most solvents will have a tendency to evaporate from the toys, for which reason the most relevant limit value will be inhalation (evaporation).

Limit value

It is suggested to call for an adoption of the already proposed limit values for certain solvents in EN 71-9 (2007) standard. However, a review may be needed in order to perhaps include further solvents as well as more research and validation of the test methods and limit values are needed.

Test method

The test method depends on the specific solvent; however, some test methods are already described in EN 71-10 (2005) and EN 71-11 (2005).

Suggestion: Solvents

The following suggestions for chemical requirements are made for solvents.

Table 19: Suggested chemical requirements regarding solvents in toys

Solvents **(in all materials)**	**Type of limit value:** Based on migration and inhalation **Limit value:** 1. Adoption of the already proposed limit values for certain solvents in EN 71-9 (2007) standard (table 2E migration and table 2F inhalation). 2. However, a review needs to be made if other solvents should be restricted as well; and more research and validation of the test methods and limit values are needed. **Test method:** Dependant on the specific solvent. Some test methods are described in EN 71-10 (2005) and EN 71-11 (2005).

3.8 Preservatives and biocides

Preservatives are added especially to water-based products in order to prevent the growth of microorganisms and thereby prolong the shelf-life of the products. Preservatives are regarded as biocidal products and must therefore apply to the new Biocidal Products Regulation No. 528/2012. According to this regulation, active substances of biocidal products must be approved before being placed on the market and only those substances that do not pose unacceptable risks may be introduced into the market. However, in the new Biocidal Products Regulation that enters into force on September 1, 2013, toys are excluded. This means that the preservatives used in toys do not have to apply to the approval procedure of the Biocidal Product Regulation.

Furthermore, no specific requirements for preservatives are set in the new Toy Safety Directive – except for preservatives classified as CMR and except for the general statement that chemical substances used in toys must not present a risk of adverse effects to human health.

However, the standards EN 71-5 (2013), EN 71-7 (2002) and EN 71-9 (2007) do set some requirements for the use of preservatives in specific types of toys. EN 71-5 (2013) concerns chemical toys, e.g. embedding sets, water-based adhesives and paints. EN 71-7 (2002) concerns finger paints. For these specific types of toys, it is only allowed to use certain types of preservatives:

- EN 71-5 (2013) (embedding sets, paints and adhesives): Only preservatives permitted in foods (Regulation no. 1333/2008) and/or cosmetic products (Directive 76/768/EEC) are allowed. However, it is not allowed to use preservatives from the Cosmetic Products Directive that are solely allowed in products which are rinsed off after use.
- EN 71-7 (2002) (finger paints): Only preservatives listed in Annex B of the standard are permitted. Furthermore, a maximum concentration, specific limitations and requirements for the preservatives are stated. The new EN 71-7 standard (for the new Toy Safety Directive) has been sent to formal vote in July 2013. The changes here are mainly that the list of preservatives allowed for use in finger paints has been expanded (from 37 to 43 groups of preservatives) and that some allowed concentrations have been lowered.
- EN 71-9 (2007): Six wood preservatives are restricted according to table 2G either with outdoor limits or indoor limits. Furthermore, six preservatives (other than wood preservatives) are restricted according to table 2H. These are phenol, formaldehyde and isothiazolinones, which are also dealt with in separate chapters.

The new EN 71-7 has been sent to formal vote in July 2013. In this version of EN 71-7 (2013), the maximum limit value of Kathon is being reduced (to 8 ppm). It was discussed during the revision of EN 71-7 that parabens should no longer be allowed in finger paints, but the final list of EN 71-7 sent to formal vote includes all parabens in the same concentration as in EN 71-7 (2002), i.e. as allowed in cosmetic products.

In a survey prepared for the Danish EPA (Poulsen et al., 2013), the use of preservatives in toys have been investigated. The survey shows that the typical preservatives used in toys are preservatives that are allowed in cosmetic products and the concentrations used do not exceed the maximum concentrations allowed in the Cosmetic Products Directive. The typical

preservatives used are parabens, 2-phenoxyethanol, formaldehyde, sodium benzoate, bronopol, Kathon and potassium sorbate. However, other isothiazolinones than Kathon are also used, such as e.g. BIT (1,2-Benzoisothiazol-3(2H)-one).

CEN/TC 52, 2002

A comprehensive assessment of preservatives has been made by a group of toxicologists in the development of EN 71-9/10/11 regarding organic chemical compounds in toys. The CEN/TC 52 working group received a list of over 800 different organic chemicals potentially used in toys. This list was reviewed and the preservatives were identified as well as their hazard. The work resulted in a total list of about 70 different preservatives being used in toys. The working group divided the preservatives into the following types based on a hazard assessment/hazard ranking of the preservatives (CEN/TC 52, 2002):

- Wood preservatives
    - "Heavy duty" wood preservatives – for impregnation of wood under high pressure
    - Preservatives applied on virgin wood against moulds and insects
    - Preservatives in coatings
- Preservatives other than wood preservatives – for use in water-based toys (i.e. "liquid toys")

The working group concluded that:

- Wood preservatives should not be used in toys for indoor use as there is no technical need for preservatives to be present in wood for indoor use.
- A list of 5 wood preservatives is not recommended for outdoor toys.
- Only preservatives which are allowed in the Cosmetic Products Directive should be allowed for use in toys – but excluding preservatives that are restricted in the Cosmetic Products Directive with the following statements:
    - Only for rinse-off products
    - No mucous membranes contact
    - Not for oral hygiene products
    - Avoid contact with eyes

ANEC/BEUC, 2012c

ANEC and BEUC have in a joint position paper criticised the fact that the Biocidal Products Regulation specifically does not cover biocides (preservatives) used in toys. ANEC and BEUC call for either an approval system for biocides to be introduced in the Toy Safety Directive or to remove the exemption for toys in the Biocidal Products Regulation (ANEC/BEUC, 2012c).

Nordic Ecolabelling, 2012

In the Nordic Ecolabelling of toys, there is a general requirement stating that biocides or biocide products are not to be added to the surface of the finished toy or parts of the toy in order to add a disinfecting or antibacterial effect (Nordic Ecolabelling, 2012).

Oeko-Tex 100, 2013

Oeko-Tex 100 (the "Confidence in textiles" labelling) sets requirements for biological active products in their Oeko-Tex Standard 100. The requirements for all product classes are that no biological active products are to be used in the textiles – with the exception of treatments accepted by Oeko-Tex (an assessment carried out by Oeko-Tex must reveal that the textile fabric with biological active agents may be used from a human-ecological point of view without any restrictions or that the biological active agents are harmless to human health). Oeko-Tex 100 distinguishes between fibre materials where the biological active agents are incorporated into the fibres and a treatment of textiles with biological active products in a later processing step (Oeko-Tex 100, 2013). From a health perspective, the exposure will be lower if the biological active agents are incorporated into the textile fibres compared to being added in a textile finishing step.

According to the supplement to the Oeko-Tex Standard 100 (Oeko-Tex 100 Supplement, 2013), textile toys can also receive the Oeko-Tex mark by complying with the Oeko-Tex requirements. The requirements to toys are that all textile and non-textile components of textile toys must comply with the above requirement that no biological active products are to be used.

3.8.1 Kathon

Kathon has been discussed in section 3.3.2 Isothiazolinones regarding its sensitising properties. SCHER (2007) states that the use of Kathon (or its two components) in toys is not recommended because of its sensitising potential.

3.8.2 Organic tin compounds

Organic tin compounds are very toxic to the aquatic environment with long lasting effects but are also classified as being toxic to humans (Acute Tox. 3). Organic tin compounds are restricted in the new Toy Safety Directive by the restriction of organic tin (see the section on elements Table 7). Organic tin is restricted by the following migration limit values:

- Dry, brittle, powder-like or pliable toy material: 0.9 mg/kg
- Liquid or sticky toy material: 0.2 mg/kg
- Scraped-off toy material: 12 mg/kg

EN 71-3 (2013) includes a test procedure for organic tin (Annex G) and certain organic tin compounds. Furthermore, Annex J contains a list of other organic tin compounds that may be present in toy materials (are found in food contact materials). However, the method described in Annex G has not been tested and validated for these other organic tin compounds.

The following organic tin compounds are restricted by REACH Annex XVII entry no. 20:

- TBT (tributyltin) compounds from 1 July 2010 (maximum allowed concentration in articles is 0.1% (1000 ppm) by weight of tin) in all articles.
- DBT (dibutyltin) compounds from 1 January 2012 (maximum allowed concentration in articles is 0.1% (1000 ppm) by weight of tin) in all articles.

- DOT (dioctyltin) compounds from 1 January 2012 (maximum allowed concentration in articles is 0.1% (1000 ppm) by weight of tin) in textile articles intended to come into contact with skin, in childcare articles and in other specific articles listed.

Oeko-Tex 100, 2013

Oeko-Tex Standard 100 (the "Confidence in textiles" labelling) sets requirements for organic tin compounds. The requirement to the organic tin compounds is that the following must not be used (Oeko-Tex 100, 2013):

- TBT (tributyltin) and TPhT (triphenyltin)
  - For Product Class I (for babies) the maximum allowed concentration is 0.5 mg/kg.
  - For Product Class II (direct skin contact), III (no direct skin contact) and IV (decoration materials) the maximum allowed concentration is 1.0 mg/kg.
- DBT (dibutyltin) and DOT (dioctyltin)
  - For Product Class I (for babies) the maximum allowed concentration is 1.0 mg/kg.
  - For Product Class II (direct skin contact), III (no direct skin contact) and IV (decoration materials) the maximum allowed concentration is 2.0 mg/kg.

Oeko-Tex thereby has a much stricter concentration limit value compared to the REACH restriction and Oeko-Tex also restricts the use of TPhT which is not restricted by REACH.

According to the supplement to the Oeko-Tex Standard 100 (Oeko-Tex 100 Supplement, 2013), textile toys can also receive the Oeko-Tex mark by complying with the Oeko-Tex requirements. The requirements to toys are that all textile and non-textile components of textile toys must comply with at least the requirements of Product Class II as listed above. Articles for babies and toddlers under the age of 3 must comply with the requirements for Product Class I as listed above.

In the testing procedure document (Oeko-Tex 100 Testing procedures, 2013), it is stated that the determination of organic tin compounds is performed by extraction of the testing material with an organic solvent and followed by derivatization with sodium tetraethylborate. The extract is analysed after clean-up by GC-MS.

3.8.2.1 Conclusions organic tin compounds

Organic tin compounds are already regulated by the Toy Safety Directive. Most organic tin compounds can be found by the method described in Annex G of EN 71-3 (2013); however, for some organic tin compounds that may be present in toy materials, no tested and validated method of analysis exists. Therefore, no new requirements regarding organic tin compounds are suggested but it will be necessary to investigate whether the organic tin compounds listed in Annex J of EN 71-3 could be present in toy materials and if so, find validated test methods.

3.8.3 Conclusions preservatives and biocides

ANEC and BEUC criticise the fact that biocides for use in toys are not covered by the Biocidal Products Regulation. This means that there is no approval system for biocides used in toys. ANEC and BEUC call for an introduction of such an approval system in the Toy Safety Directive or to remove the exemption for toys in the Biocidal Products Regulation. One way to introduce an approval system is to use the recommendation of the CEN/TC 52 working group, i.e. to introduce a positive list of preservatives to be used in toys (as it is used in EN 71-7 for finger paints only or in the Cosmetics Directive).

Type of limit value
It is suggested to use content based limit values as it is used in the Cosmetics Directive.

Limit value
It is suggested to use the recommendations of the CEN/TC 52 working group, i.e. what is done in EN 71-7 for finger paints, but with some modifications. It is suggested to use a generic exclusion of wood preservatives and instead introduce exemptions of use of wood preservative (but only for wooden toys for outdoor use) if the use is considered safe in a full risk assessment carried out by SCHER. Furthermore, it is suggested using the idea from the CEN/TC 52 working group of allowing the use of preservatives that are allowed to be used in cosmetic products – and the idea behind the positive list in EN 71-7 (2002) for finger paints which is also based on preservatives allowed in food and in cosmetic products.

However, certain preservatives may be necessary to exclude (e.g. preservatives that are only allowed to be used in rinse-off products). In addition, it may be necessary to rethink the concentration limits set in the cosmetic products directive – it may be possible that lower concentration limits are needed when the exposure group is children. For example the limit value of 2-phenoxyethanol has been criticised in France (ANSM, 2012) and the limit value of the parabens is being discussed as well (SCCS/1348/10, 2011). Finally, SCHER advises against the use of Kathon in toys (SCHER, 2007).

The suggested restrictions on preservatives are therefore:

- Wood preservatives should not be used in any toys. However, some wood preservatives may be used in wooden toys for outdoor use if they are considered safe in a full risk assessment carried out by SCHER.
- Use of a positive list of non-wood preservatives similar to the EN 71-7 (2002) list to be incorporated in the Toy Safety Directive. I.e. only preservatives which are allowed in the cosmetic products and in food should be allowed for use in toys.
    - But excluding preservatives that are restricted in the Cosmetic Products Directive with the following statements:
        - Only for rinse-off products
        - No mucous membranes contact
        - Not for oral hygiene products
        - Avoid contact with eyes

- And excluding the use of Kathon and possibly other substances.

Test method

The test method depends on the specific preservatives; however, some test methods are already described in EN 71-10 (2005) and EN 71-11 (2005) and the test method used for the cosmetic products can be used.

Suggestion: Preservatives and biocides

The following suggestions for chemical requirements are made for preservatives and biocides.

Table 20: Suggested chemical requirements regarding preservatives and biocides in toys

Preservatives and biocides **(in all materials)**	**Type of limit value:** Based on content **Limit value:** 1. Wood preservatives should not be used in any toys. However, some wood preservatives may be used in wooden toys for outdoor use if they are considered safe in a full risk assessment carried out by SCHER. 2. Use of a positive list of non-wood preservatives similar to the EN 71-7 (2002) list to be incorporated in the Toy Safety Directive. I.e. preservatives which are allowed in the Cosmetic Products Directive should be allowed for use in toys. • But excluding preservatives that are restricted in the Cosmetic Products Directive with the following statements: o Only for rinse-off products o No mucous membranes contact o Not for oral hygiene products o Avoid contact with eyes • And excluding the use of Kathon and possibly other substances. **Test method:** Dependant on the specific preservatives. Some test methods are described in EN 71-10 (2005) and EN 71-11 (2005) and the test method used for cosmetic products can be used.

3.9 N-nitrosamines and N-nitrosatable substances

Nitrosamines are chemical compounds that may be present as contaminants in a number of product including food, cosmetics and rubber products. Some of these nitrosamines, such as N-nitrosodiethanolamine (NDELA) and N-nitrosodimethylamine (NDMA), are classified as carcinogens category 1B (SCCS/1485/12, 2012). N-nitrosatable substances are substances that are capable of being converted into N-nitrosamines.

N-nitrosamines and N-nitrosatable substances are today restricted in:

- Elastomer or rubber teats and soothers (Directive 93/11/EEC).The limit values are:
  - 0.01 ppm in total of N-nitrosamines released (of the parts of teat or soother made of elastomer or rubber).
  - 0.1 ppm in total of N-nitrosatable substances (of the parts of teat or soother made of elastomer or rubber).
- The new Toy Safety Directive: Toys intended for use by children below the age of 36 months or in other toys intended to be placed in the mouth (this requirement enter into force on 20 July 2013), (Directive 2009/48/EC). The limit values are:
  - 0.05 ppm for nitrosamines and
  - 1 ppm for nitrosatable substances.

The standard EN 71-12 (2013) on N-nitrosamines and N-nitrosatable substances specifies the requirements and test methods for N-nitrosamines and N-nitrosatable substances and applies to:

- Toys and parts of toys made form elastomers and intended for use by children below the age of 36 months. Limit value for migration:
  - 0.05 ppm for nitrosamines – calculated as a sum of 13 specific N-nitrosamines. If there are indications of presence of other N-nitrosamines these should be tested as well.
  - 1 ppm for nitrosatable substances – calculated as a sum of all detected N-nitrosamines after nitrosation.
- Toys and parts of toys made from elastomers and intended to be placed in the mouth Limit value for migration:
  - 0.05 ppm for nitrosamines – calculated as a sum of 13 specific N-nitrosamines. If there are indications of presence of other N-nitrosamines these should be tested as well.
  - 1 ppm for nitrosatable substances – calculated as a sum of all detected N-nitrosamines after nitrosation.
- Finger paints for children below the age of 36 months. Limit value for migration:
  - 0.02 ppm for nitrosamines – calculated for the N-nitrosamine NDELA (N-nitrosodiethanolamine). If there are indications of the presence of other N-nitrosamines, these should also be tested.
  - 1 ppm for nitrosatable substances – calculated as a sum of all detected N-nitrosamines after nitrosation.

ANEC has commented on EN 71-12 (2013) and does not endorse the standard. The main reason for this is that it relies on a static migration procedure which inadequately mimics the release of chemicals from products used by small children.

German Consumer Goods Ordinance, 2008

Germany had already in 2008 set requirements for N-nitrosamines and N-nitrosatable substances in toys made of natural or synthetic rubber designed for children below the age of 36 months and intended or likely to be placed in the mouth. The requirement in Germany is a non-detectable migration of the substances. This means in practice below 0.01 ppm for N-nitrosamines and below 0.1 ppm for N-nitrosatable substances (Decision 2012/160). According to the Commission Decision 2012/160, the Commission has allowed Germany to maintain these stricter requirements on toys even though the EU Toy Safety Directive from 20 July 2013 sets a requirement for N-nitrosamines with higher limit values.

BfR opinion No. 005, 2011

BfR has in 2011 made an opinion on the release of N-nitrosamines from toys made of natural and synthetic rubber for children less than three years of age (BfR No. 005, 2011). BfR states that several N-nitrosamines are genotoxic carcinogens and therefore no safe toxicological threshold value can be derived for these substances. BfR is of the opinion that even trace quantities of them can cause cancer; therefore the ALARA principle ("as low as reasonably achievable") should be used to protect consumers and minimise risks by reducing exposure to N-nitrosamines to the maximum possible extent. BfR states that the application of the migration limits of the EU toy directive 2009/48/EC could lead to a worsening of the protection level as lower limit values are used in existing German regulation.

BfR states that the higher limit value in the Toy Safety Directive corresponds to the German limit value set for balloons. Small children put toys into their mouth more frequently and keep them there for longer time than they do with balloons. BfR is therefore of the opinion that the German lower limit values should be maintained, especially as the formation of N-nitrosamines during the manufacturing of products made of natural or synthetic rubber can be widely avoided through the choice of suitable vulcanisation accelerators.

SCCS opinion, 2012

In a SCCS opinion paper from 2012, SCCS assesses the use of N-nitrosamines (particular NDELA) in cosmetics and in balloons. SCCS concludes that it is not possible to calculate a reliable Virtually Safe Dose for NDELA in cosmetics and for nitrosamines in balloons (SCCS/1486/12, 2012).

ANEC/BEUC, 2012c

ANEC and BEUC describe in a joint position paper that the existing migration limits in the new Toy Safety Directive for nitrosamines and nitrosatable substances in toys intended for use by children below the age of 36 months or in other toys intended to be placed in the mouth (0.05 mg/kg for nitrosamines and 1 mg/kg for nitrosatable substances) are inadequate. ANEC and BEUC state that the Commission itself has admitted this in its response to the German request to maintain the more stringent national values of 0.01 mg/kg and 0.1 mg/kg respectively. ANEC and BEUC therefore call for a use of the more stringent existing German requirements, which have been accepted by the Commission. However, it is not possible to make the changes to the Toy Safety Directive by comitology – it requires a revision of the directive (ANEC/BEUC, 2012c).

3.9.1 Conclusion N-nitrosamines and N-nitrosatable substances

It is concluded by BfR and SCCS that no safe toxicological threshold value can be derived for these substances. The limit values should therefore be as low as possible. It thus seems reasonable to use a limit value of non-detectable migration as used in Germany as it has been accepted by the Commission as limit for toys. Moreover, the same limit values of non-detectable migration are used in the EU Directive on teats and soothers (Directive 93/11/EEC):

- 0.01 ppm in total of N-nitrosamines released.
- 0.1 ppm in total of N-nitrosatable substances.

The standard EN 12686:1999 specifies how to comply with the EU Directive 93/11/EEC and describes that static migration should be used in 24 hours. In the draft EN 71-12 standard, the use of static migration is suggested as well, but with use of a shorter migration time (15 minutes for finger paints, 1 hour for balloons and 4 hours for other toys). In the comments to the draft standard it is mentioned that discussion about the migration time is still ongoing. From an exposure perspective it seems reasonable to lower the migration time for toys to less than 24 hours compared to the use of teats and soothers. However, deciding on using static migration for comparison reasons does not seem to be a reasonable argument. If the purpose is to ensure that no children are exposed to the carcinogenic N-nitrosamines and N-nitrosatable substances then a dynamic migration should be used in order to simulate the mouthing exposure situation in the best possible way and this also includes using an appropriate migration time. An exposure time of 24 hours for toys is not realistic, but on the other hand a migration time of 15 minutes for finger paints seems to low. A suggested migration time of 4 hours for other toys (neither balloons nor finger paints) by Germany has been approved. This migration time seems reasonable as a British survey from 2002 has shown that the maximum daily mouthing time on toys for children below the age of 5 was 3 hours and 47 minutes (DTI, 2002). A Nordic survey (Norden, 2011) has suggested using an exposure time for finger paints of 45 minutes. This exposure time, however, covers dermal exposure and not mouthing. It should be discussed by experts exactly which migration time that should be used for the different products (finger paints, balloons and other toys).

Type of limit value

It is suggested to keep the existing type of limit value of non-detectable migration as used in Germany (and accepted by the Commission) and used by the EU Directive 93/11/EEC on teats and soothers, i.e. a migration limit value.

Limit value

It is suggested to use the lowest existing limit values as used by Germany and by EU Directive 93/11/EEC on teats and soothers, i.e.:

- 0.01 ppm in total of N-nitrosamines released (of the parts of the toys made of elastomer or rubber).
- 0.1 ppm in total of N-nitrosatable substances (of the parts of the toys made of elastomer or rubber).

Test method

The test method used should be the test method described in standard EN 71-12 (2013). However, it is suggested that the type of migration should be a dynamic migration (i.e. in principle a modification of the EN 71-10 procedure) in order to simulate the mouthing exposure situation in the best possible way. Exact migration time should be further discussed.

Suggestion: N-nitrosamines and N-nitrosatable substances

The following suggestions for chemical requirements are made for N-nitrosamines and N-nitrosatable substances.

Table 21: Suggested chemical requirements regarding N-nitrosamines and N-nitrosatable substances in toys

N-nitrosamines and N-nitrosatable substances **(in rubber materials)**	**Type of limit value:** Based on migration **Limit value:** For all toys: • 0.01 ppm in total of N-nitrosamines released. • 0.1 ppm in total of N-nitrosatable substances. **Test method:** As described in EN 71-12 (2013), but with dynamic migration. Migration time should be further discussed.

3.10 Other substances

Many different categories of hazardous chemicals have been discussed, but all hazardous chemicals may not be included in the proposed restrictions set. ANEC and BEUC describe in a joint position paper that toxic and very toxic substances also need to be addressed in the Toy Safety Directive (ANEC/BEUC, 2012c).

3.10.1 Substances classified as very toxic, toxic, harmful, corrosive, irritating etc.

The new Toy Safety Directive does not set requirements for other substances classified as e.g. very toxic, toxic, harmful, corrosive, irritating etc. These substances are only covered by the general broad requirement in Annex III point 1 of the Toy Safety Directive: "Toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain".

However, some exclusions of this kind do exist in EN 71-9 (2007). EN 71-9 (2007) is not a harmonised standard and therefore has no legal status. The requirement listed for liquid in toys (section 4.2) is:

- Toys shall not contain accessible liquids classified in accordance with Directive 1999/45/EC as very toxic, toxic, harmful, corrosive, irritant or sensitising; and the accessible liquids shall not contain substances that are classified as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2. However, as a derogation, liquids present as ink supplied in writing instruments, may be classified 'R36 Irritating to eyes'.

This means that the requirement is only valid for accessible liquids and not for inaccessible liquids that children may be exposed to when the toy breaks.

Furthermore, similar exclusions can be found in EN 71-7 (2013) submitted for formal vote. According to EN 71-7 (2013) only colourants, colouring materials, binding agents, extenders, humectants, and surfactants not fulfilling the following hazard criteria shall be used in finger paints:

- "Acute toxicity" (hazard class 3.1),
- "Skin corrosion/irritation" (hazard class 3.2),
- "Serious eye damage/eye irritation" (hazard class 3.3),
- "Respiratory or skin sensitisation" (hazard class 3.4),
- "Germ cell mutagenicity" (hazard class 3.5),
- "Carcinogenicity" (hazard class 3.6),
- "Reproductive toxicity" (hazard class 3.7),
- "Specific target organ toxicity – single exposure" (hazard class 3.8),
- "Specific target organ toxicity – repeated exposure" (hazard class 3.9),
- "Aspiration hazard" (hazard class 3.10).

ANEC/BEUC, 2012c

ANEC and BEUC describe in a joint position paper that chemicals falling in other classes of dangerous substances such as very toxic, toxic, harmful, corrosive, irritating or non-classified (i.e. not yet classified) substances which pose a health hazard must be addressed in the Toy Safety Directive (ANEC/BEUC, 2012c).

Nordic Ecolabelling, 2012

In the Nordic Ecolabelling of toys, there is a requirement stating that dyes, pigments and auxiliary chemicals classified as toxic and highly toxic shall not be used in textiles, skin and leather that constitutes more than 1% of the toy. Furthermore, chemical products in wood-based products, and chemicals products used for surface treatment of wood and metal must not be classified as toxic or highly toxic (Nordic Ecolabelling, 2012).

3.10.1.1 Conclusion substances classified as very toxic, toxic, harmful, corrosive, irritating etc.

ANEC and BEUC have not suggested how these substances should be restricted (limit values or type of limit value). Only the Nordic Ecolabelling of toys sets requirements for toxic and highly toxic substances and only in some materials with a limit value of 1% (i.e. 10,000 ppm).

Whether or not hazardous substances with all these classification should be restricted in toys – or maybe only chemicals classified as toxic and very toxic – it definitely needs a much further debate/assessment. The question is what the limit value should be and which classifications should be included in order to protect the safety of children from these hazardous chemicals.

In section 3.4.3 "Generic – flame retardants", it was suggested to exclude flame retardants resulting in organ toxicity, as other hazard classes were excluded by other generic requirements.

It is suggested to use an exclusion of the general hazard classes as excluded in EN 71-7 (2013) for finger paints, but as a general exclusion criteria in all toy

materials. However, this should be investigated more thoroughly as there may be overlap to other requirements and chemicals already restricted. Furthermore, it may be necessary to allow for exemptions if a risk assessment conducted by a scientific committee, e.g. SCHER, considers the use of a specific substance in a specific product/material for safe.

Suggestion: Substances classified as very toxic, toxic, harmful, corrosive, irritating etc.

The following suggestions for chemical requirements are made for substances classified as very toxic, toxic, harmful, corrosive, irritating etc.

Table 22: Suggested chemical requirements regarding substances classified as very toxic, toxic, harmful, corrosive, irritating etc. in toys

Substances classified as very toxic, toxic, harmful, corrosive, irritating etc. **(in all materials)**	**Type of limit value:** Based on content **Limit value:** For all toys: Only chemicals not fulfilling the following hazard criteria shall be used in toy materials: • "Acute toxicity" (hazard class 3.1), • "Skin corrosion/irritation" (hazard class 3.2), • "Serious eye damage/eye irritation" (hazard class 3.3), • "Respiratory or skin sensitisation" (hazard class 3.4), • "Germ cell mutagenicity" (hazard class 3.5), • "Carcinogenicity" (hazard class 3.6), • "Reproductive toxicity" (hazard class 3.7), • "Specific target organ toxicity – single exposure" (hazard class 3.8), • "Specific target organ toxicity – repeated exposure" (hazard class 3.9), • "Aspiration hazard" (hazard class 3.10). **Test method:** None suggested. Perhaps based on SDS on used chemicals.

3.10.2 PFOA/PFOS

PFOA (perfluorooctanoic acid) or PFOS compounds (perfluorooctane sulfonates) are not restricted in the new Toy Safety Standard. Some PFOS compounds are, however, on the REACH candidate list of SVHCs and PFOA is submitted as an SVHC intention (for inclusion of a substance on the candidate list).

Perfluorooctane sulfonic acid and their derivatives (PFOS) are restricted by Regulation No. 850/2004 on persistent organic pollutants. According to this POP Regulation, PFOS compounds are not allowed to be used in articles in higher concentrations than 0.1% by weight (1000 mg/kg) or for textiles or coated materials in 1 µg/m^2 of the coated material.

Nordic Ecolabelling, 2012

In the Nordic Ecolabelling of toys, there is a more or less general requirement stating that PFOA (perfluoroctanic acid and salts/esters thereof) and PFOS (Perfluoro octane sulphonic acid and compounds thereof) shall not be actively added to the toy material (plastic materials, rubber, chemical products used in wood-based materials, chemical products used for surface treatment of wood and metal, and adhesives and glue). The limit value is for some materials set at 100 ppm (Nordic Ecolabelling, 2012).

Oeko-Tex 100, 2013

Oeko-Tex Standard 100 (the "Confidence in textiles" labelling) sets requirements for PFOS and PFOA in textiles. The requirement to PFOS compounds (perfluorooctane sulfonates) and PFOA (perfluorooctanoic acid) is that the substances must not be used in concentrations higher than listed below (Oeko-Tex 100, 2013):

- PFOS
  - For all product classes the maximum allowed concentration is 1.0 µg/m^2 textile fabric.
- PFOA
  - For Product Class I (for babies) the maximum allowed concentration is 0.1 mg/kg.
  - For Product Class II (direct skin contact) and III (no direct skin contact) the maximum allowed concentration is 0.25 mg/kg.
  - For Product Class IV (decoration materials) the maximum allowed concentration is 1.0 mg/kg.

Oeko-Tex thereby uses the same concentration limit value compared to the POP Regulation, but Oeko-tex also restricts the use of PFOA which is not restricted by the POP Regulation.

According to the supplement to the Oeko-Tex Standard 100 (Oeko-Tex 100 Supplement, 2013), textile toys can also receive the Oeko-Tex mark by complying with the Oeko-Tex requirements. The requirements to toys are that all textile and non-textile components of textile toys must comply with at least the requirements of Product Class II as listed above. Articles for babies and toddlers under the age of 3 must comply with the requirements for Product Class I as listed above.

In the testing procedure document (Oeko-Tex 100 Testing procedures, 2013), it is stated that the determination of PFOS/PFOA is performed by an extraction step using methanol and a subsequent LC/MS/MS analysis. It is stated that when the official testing method according to Directive 2006/122/EC is available, this testing method should be used instead.

3.10.2.1 Conclusion PFOS/PFOA

It is suggested not to set any specific requirements for PFOS/PFOA as these substances are already being restricted in textile toys by the POP Regulation. It can, however, be discussed whether these levels are strict enough for protection of children.

3.11 Nanomaterials

No requirements on nanomaterials are set in the new Toy Safety Directive.

SRU, 2011

The German Advisory Council on the Environment (SRU) has, in 2011, issued a report on precautionary strategies for nanomaterials. The report includes recommendations regarding further risk research, social dialogue, legal regulations, product labellings, and environmental laws. SRU states the following concerning the risks of nanomaterials:

- Nanomaterials differ from their macro counterparts not just physically and chemically, but also in their behaviour and effects in living organisms and the environment.
- It is not possible to make general statements about the risks of nanomaterials. On current knowledge, some materials essentially raise no concern, while research on others shows significant potential risks.
- There is no scientific proof so far that nanomaterials, as they are made and used today, cause actual harm to the environment or human health. However, this cannot be taken as an all-clear because for many nanomaterials there is a lack of standardised test methodologies for a full risk assessment and knowledge of their potential adverse effects is limited. A number of products and uses raise concern (e.g. nanomaterials in consumer sprays, use of silver nanoparticles in consumer products, and use of carbon nanofibres).

SRU made the following recommendations for a precautionary approach to nanomaterials:

- Makers of nanomaterials should be placed under stricter obligation to file data on the risks of nanomaterials.
- For an overarching definition of nanomaterials, an upper size limit of 300 nm is recommended. A smaller size limit may be appropriate for specific regulatory purposes.
- In many areas of the law, there are nano-specific regulatory gaps that should be closed as soon as possible on the basis of the precautionary principle.
- To enhance market transparency, existing labelling obligations should be supplemented with an additional ‘nano’ indication. Products that release nanomaterials or make use of them to achieve specific properties (such as antibacterial properties) should also require mandatory labelling. For other nanoproducts, a notification requirement should be introduced that feeds into a semi-public product register.
- Extensive changes are necessary in chemicals legislation (REACH): Nanomaterials should be consistently treated as if they were substances in their own right and registered with dossiers of their own. A core data set should have to be submitted for them which ensures observation or a preliminary risk estimation according to their size. Quantity thresholds must be reduced for nanomaterials and the standard information requirements need to be supplemented. Authorisation should be based more closely on the precautionary principle. It should also be possible to restrict or prohibit nanomaterials merely on the basis of an abstract concern.

- In product legislation, it must be ensured in existing authorisation procedures that nanomaterials are always approved separately. For weakly regulated products, the foundations should be laid for powers to intervene on the basis of the precautionary principle.
- In environmental law, there is a considerable need for research and assessment. Operators of industrial facilities should be obliged to minimise emissions of nanomaterials for which there is an abstract concern.

SCCS opinion 1484, 2012

SCCS has prepared a guidance document on the safety assessment of the use of nanomaterials in cosmetics (SCCS/1484/12, 2012). In this guidance document SCCS highlights the need for special considerations in relation to the safety of nanomaterials in cosmetics. SCCS emphasises that any testing of nanomaterials for hazard identification/dose-response characterisation must be carried out in consideration of the nano-related aspects, i.e. it is not sufficient to assume that nanomaterials of a specific substance will have the same effects as the specific substances on non-nano-scale. The hazards must be identified for the nanomaterial on nano-scale.

SCCS furthermore states that at present validated alternative test methods that can be used in place of animal tests are only available for conventional substances (non-nano-scale) and not for nanomaterials. This poses an insurmountable obstacle to safety assessment of cosmetic nanomaterials (also because of the complete ban on in vivo testing of cosmetic ingredients and products in 2013), and further research work is needed in this area. Finally, SCCS is of the opinion that a risk assessment of each nanomaterial needs to be carried out on a case-by-case basis (read-across is currently not feasible for nanomaterials) (SCCS/1484/12, 2012).

Nordic Ecolabelling, 2012

In the Nordic Ecolabelling of toys, the requirement on nanomaterials/nanoparticles (defined as microscopic particles where at least one of the dimensions is less than 100 nm) is that nanomaterials shall not be actively added to chemical products unless sufficient documentation exists which shows that they will not cause health and environmental problems. However, particles in nano-size which are not added for a specific function are exempt from the requirement and carbon black is allowed in plastic and rubber (Nordic Ecolabelling, 2012).

In ecolabelling the conformance requires a declaration from the toy manufacturer. It is difficult to specify an analysis method to be used to check for conformance.

3.11.1 Conclusions nanomaterials

As stated by the German Advisory Council on the Environment (SRU) above, it is not possible to make general statements about the risks of nanomaterials. On current knowledge, some materials essentially raise no concern while research on others shows significant potential risks. SCCS highlights the need for special considerations in relation to the safety of nanomaterials in cosmetics. Cosmetics may be applied directly to the skin of the consumer

which means that there is a direct human exposure. However, small children may suck on toys and this means that there is a direct exposure to children from toys as well if these should contain nanomaterials.

SCCS emphasises that the hazards of the nanomaterials must be identified for the nanomaterial on nano-scale, i.e. it is not sufficient to assume that nanomaterials of a specific substance will have the same effects as the specific substances on non-nano-scale.

SRU recommends using a precautionary principle in dealing with nano-materials and recommends an introduction of labelling of products containing nanomaterials. SRU furthermore recommends that nanomaterials should be approved separately (in existing authorisation procedures).

Type of limit value

The type of limit value should be based on content to ensure that nanomaterials are not used unless a risk assessment shows that the nanomaterials are safe to use.

Limit value

It is suggested to use the idea behind the Ecolabelling of toys that nanomaterials shall not be actively added to the toys (i.e. limit value is "non-detectable") unless sufficient documentation exists which shows that they will not cause health and environmental problems. It should, of course, be discussed whether some exemptions already should be introduced, like e.g. carbon black that has been used already for a long time. Furthermore, exemptions may be granted but only on the basis of a full risk assessment and a positive opinion by SCHER. This could in time lead to a positive list of nanomaterials to be used in toys.

It could also be discussed whether or not this restriction on nanomaterials should be for all toys or only for toys intended for children below the age of 3. However, as children below the age of 3 also play with toys for older children, it is suggested to make the restriction on nanomaterials for toys for all ages.

It is suggested to use the definition of nanomaterials as included in the Commission Recommendation No. 696 (2011): "'Nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm."

Test method

The test method will depend on the type of nanomaterials used.

Suggestion: Nanomaterials

The following suggestions for chemical requirements are made for nanomaterials in general.

Table 23: Suggested chemical requirements regarding nanomaterials in toys

Nanomaterials **(in all materials)**	**Type of limit value:** Content based **Limit value:** 1. Nanomaterials shall not be actively added to any toys (i.e. limit value is "non-detectable"). 2. Exemptions may be granted but only on the basis of a full risk assessment and a positive opinion by SCHER. **Test method:** Depends on the substance

3.12 Use of Food Contact Materials Regulation (FCM) legislation for toys

Article 46 of the new Toy Safety Directive provides for the option to "adopt specific limit values for chemicals used in toys intended for use by children below the age of 36 months or, in other toys intended to be placed in the mouth, taking into account the packaging requirements for food as laid down in Regulation (EC) No 1935/2004 and the related specific measures for particular materials, as well as the differences between toys and materials which come into contact with food". This means that it is possible to establish specific requirements for some toy categories which will supersede the requirements applicable for toys in general. This option has not yet been used (June 2013), and organisations like BfR questions why the rules that exist for food contact materials have not been transferred to toys (BfR opinion No. 51, 2009).

As described in the section on 3.1 "SVHCs including CMRs, PBTs, vPvBs", the new Toy Safety Directive sets a general requirement on CMR substances in toys. However, according to its Annex II (point III.7), the restrictions on the CMR substances do "not apply to materials that comply with the specific limit values set out in Appendix C" (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".

The first aspect concerning specific limit values in Appendix C is problematic because it suggests that even if just a few limits have been incorporated in appendix C, the general CMR exclusion does not apply anymore – or at least one could interpret the text like this. Another interpretation would be that the generic limit does not apply for the substances with a limit in appendix C (this was apparently the intention when the new Toy Safety Directive was made), but the provision does not really state that. This is an aspect that should be made clearer in a future revision of the Toy Safety Directive.

This latter aspect regarding the food contact materials regulation means that materials that comply with the requirements in the Regulation No. 1935/2004 for food contact materials do not have to comply with the CMR requirements – at least until specific limit values have been set out in Appendix C. This is problematic as it is only for plastic materials that somewhat comprehensive rules have been established (and rules regarding CMR substances). In fact, this means that compliance with the FCM Regulation does not rule out the possibility to use CMR substances.

Another problem by referring directly to the food contact materials regulation is that the limit values used in the food contact materials regulation are based on an adult's body weight and not on the body weight of children (see the discussions below and the SCHER opinion paper).

BfR Opinion No. 51, 2009

In this opinion paper, BfR recommends that regulations of CMR substances in toys should in general refer rather to migration than content as it is applied for plastic materials and articles intended to come into contact with food. For these materials, it is required that the migration of CMR substances is undetectable. BfR therefore suggests that the Regulation for Food Contact Materials should be assumed for all types of toy materials and without age limit in order to minimise children's exposure to CMR substances. According to BfR, this is technologically feasible and already best practise.

SCHER opinion, 2010b

In this opinion SCHER was asked if the migration limits set out in the Food Contact Materials Regulation are appropriate to ensure that the use of such materials in toys poses no risk to the health of children. If materials apply with the Food Contact Materials Regulation (No. 1935/2004) today they do not have to apply with the CMR requirements – at least until specific limit values have been set out in Appendix C.

SCHER is of the opinion that the Food Contact Materials Regulation cannot be generally used to assess the risk to children from exposures to CMR in toys as it has been done for the new Toy Safety Directive. SCHER is of the opinion that a case by case adaption would be necessary. The reasons for this are e.g. that:

- Specific migration limits are currently established only for plastics, ceramics, regenerated cellulose and some individual substances (vinyl chloride, nitrosamines, and certain epoxy derivatives).
- The migration tests used in the Food Contact Materials legislation would never be representative for toys in general because of:
    - Migration tests in the Food Contact Materials system are performed under static conditions. This does not simulate mouthing or chewing of toys.
    - The simulants used in the Food Contact Materials legislation are distilled water, 3% acetic acid, 10% ethanol and olive oil. They represent food categories and not children's saliva, sweat or gastric juice.
    - The specific migration limit values used in the Food Contact Materials legislation are based on toxicological evaluations related only to the oral route. Sensitisation aspects for dermal contact are not considered.

ANEC position on SCHER opinion, 2010b

ANEC has made a position paper (ANEC position, 201b) on the above SCHER opinion (SCHER opinion, 2010b). ANEC agrees with SCHER on the point that the Food Contact Materials Regulation is (as it is now) not suited for the purpose of regulating chemicals in toys. However, ANEC is of the opinion that the requirements for plastic materials could be used as a

starting point for developing a set of criteria applicable for toys for children below the age of 36 months and toys intended to be placed in the mouth. ANEC advocates for the principles used in the Food Contact Materials Regulation:

- Only approved materials are allowed to be used.
- Non-approved materials may be used only under restrictive conditions (functional barrier, no CMR's) and only if the migration into food simulant does not exceed 0.01 mg/kg (10 ppb).
- An overall migration limit of 60 mg/kg is defined to ensure the inertness of plastic materials.
- However, other aspects need to be discussed further in order to use the Food Contact Materials Regulation principles for toys. For example, the specific migration limits should be based on a fraction of the TDI value (instead of the entire TDI value) and not related to adults of 60 kg but the weight of children instead.

Overall ANEC proposes that the use of legislation for food contact materials – in particular for plastics materials – should be further discussed.

ANEC/BEUC, 2012c

ANEC and BEUC describe in a joint position paper that the materials used in toys for children below the age of 3 years should follow the principles of the plastic materials in contact with food legislation, i.e. only approved substances should be allowed to be used. In ANEC's opinion, it would not be very difficult to convert the limits contained in the regulation on plastic materials in contact with food into toy limits. Furthermore, ANEC states that this approach would cover only plastic materials at the time being (and even here gaps would be left) and would have to be complemented step by step with rules for other materials. But it would be a good start (ANEC/BEUC, 2012c).

3.12.1 Conclusions use of FCM legislation for toys

At the time being, implementing measures have been adopted only for a few materials in the Food Contact Materials Regulation, i.e. regenerated cellulose films, ceramics (lead and cadmium), elastomers and rubbers (N-nitrosamines in teats and soothers) and for plastic materials. Of these materials, plastic materials may be the only material of relevance for toys as migration of elements and migration of nitrosamines are already included in the new Toy Safety Directive.

As suggested by organisations, such as BfR and ANEC, it could be possible to use the principles behind the Food Contact Materials Regulation for toys – at least the requirements for plastic materials which are also very relevant for toys (or at least for toys intended for children up to the age of 36 months and for toys intended to be placed in the mouth). These are:

- Use of positive list of authorised substances that may be used for manufacturing of plastic materials in toys.
- Use of an overall migration limit.
- Use of a limit of detection for non-authorised substances.

The concept should, however, be adjusted as toys have children as the target group:

- Skin contact as exposure route should be included as well, and skin sensitisation of the substances on the list of authorised substances for plastic materials should be investigated. Highly sensitising substances on this list should not be approved.
- Other relevant simulants for toys should be used instead of food simulants for migration, i.e. test conditions should be broadly in line with EN 71-10 but modified as mentioned earlier in this report. SCHER has for example suggested a use of artificial saliva as well as artificial gastric juice (SCHER Opinion, 2010b), but it should be investigated whether simply using water could give the same results.
- Dynamic migration should be used instead of static migration to mimic children sucking/chewing on the plastic materials. SCHER has for example suggested replenishment of the artificial saliva in order to simulate sucking/chewing and recommends that 4 x 30 minutes migration from a toy sample should be determined (with recovery periods of at least 12 hours between each migration test) and the average migration rate is calculated (SCHER Opinion, 2010b). At least repeated extraction with several hours pause should be used.
- Different migration temperatures should be used. SCHER has, for example, recommended using 37 °C (SCHER Opinion, 2010b).
- The specific migration limits should be based on a fraction of the TDI value (instead of the entire TDI value) and not related to the weight of adults but the weight of children instead.
- Other parameters should be discussed as well, e.g. the surface area used (is different in the food contact field than in the field of toys) and contact times.

Type of limit value

The type of limit value should be migration, as used in the Food Contact Materials Regulation for plastic materials.

Limit values

The migration limit values should be substance specific as used in the Food Contact Materials Regulation, but should be adjusted for the parameters stated above (children's weight, skin contact exposure, part of the TDI value). Furthermore, an overall migration limit value should be set as used in the Food Contact Materials Regulation. This should, however, also be adjusted for the parameters stated above. Finally, non-authorised substances should be allowed if the migration is non-detectable (i.e. 0.01 mg/kg (10 ppb)).

The migration limit values should be restricted to toys intended for the children of below the age of 3 as already suggested in the new Toy Safety Directive.

Test methods

Test methods should be substance specific. Test method could be comparable to the test methods used in the Food Contact Materials Regulation but the test media should be different (not food simulants).

ANEC emphasises that a dynamic migration should be used and SCHER emphasises that artificial saliva and a temperature of 37 °C should be used as

well as a method where replenishment of artificial saliva is required. Of course the exact test method needs to be discussed further.

The test method for the migration could be based on the elements recommended by SCHER as stated earlier (SCHER Opinion, 2010b) and supplemented with the dynamic requirement by ANEC:

- Relevant simulant should be found/discussed (combination of artificial saliva and gastric juice for simulating migration by sucking and swallowing or simply using water?)
- Test at 37° C
- Samples should represent all parts of the toy
- Use of repeated extraction with several hours pause.
- Use of dynamic migration.

Suggestion: Use of FCM legislation for toys

The following suggestions for chemical requirements are made for use of FCM legislation for toys. The requirements are set for plastic materials only.

Table 24: Suggested chemical requirements regarding FCM legislation for toys

Use of FCM legislation **(in plastic materials)**	**Type of limit value:** Migration based limit values as used in the FCM Regulation for plastic materials in toys intended for children below the age of 3. **Limit value:** A combination of the following limit values should be used as used in the FCM Regulation for plastic materials: • Only substances on the positive list of authorised materials may be used for manufacturing of plastic materials for toys. • Use of the specific migration limit values for each substance (as set in the FCM Regulation for plastic materials – however, adjusted for parameters such as children's weight, skin contact exposure, part of the TDI value etc.). • Use of an overall migration limit value (maximum total migration as set in the FCM Regulation for plastic materials – however, adapted to the test conditions). • Non-authorised substances are allowed if the migration is non-detectable (i.e. 0.01 mg/kg (10 ppb)). **Test method:** Must be further discussed, but on broadly in line with EN 71-10, but modified (e.g. with principles from SCHER (2010b) and ANEC proposal (2011b)): • Relevant simulant should be found/discussed (combination of artificial saliva and gastric juice for simulating migration by sucking and swallowing or simply using water?) • Test at 37° C • Samples should represent all parts of the toy • Use of repeated extraction with several hours pause. Calculation of average migration. • Use of dynamic migration.

4 General discussion

In the previous chapter, suggestions for several chemical requirements for toys, that could be introduced, have been discussed and presented. The total list of chemical requirements from the previous chapter is summarised in chapter 5 "Suggested chemical requirements". In this chapter 4, a general discussion of the overall aspects of the chemical requirements set for toys is made. It is not an in-depth discussion as the overall regulatory aspects for chemical requirements in toys and in consumer products in general have been reviewed and discussed in the former three ASI Consumer Council reports – "Chemical requirements for consumer products" Part I (Poulsen et al., 2010), Part II (Poulsen & Strandesen, 2011) and III (Strandesen and Poulsen, 2012).

4.1 Overall regulatory aspects

The chemical requirements suggested for toys in this report can only be introduced as requirements in the Toy Safety Directive if a brand new Toy Safety Directive is being prepared (i.e. it is necessary to change the whole toy legislation in the European Parliament and the Council). This is due to the fact that no general comitology procedure exists in the new Toy Safety Directive. The new Toy Safety Directive has only a comitology procedure for toys intended to be used by children below the age of 36 months, for toys intended to be placed in the mouth, for allergenic fragrances and for elements.

As described in the previous reports prepared for the ASI Consumer Council ("Chemical requirements for consumer products" Part I (Poulsen et al., 2010), Part II (Poulsen & Strandesen, 2011) and III (Strandesen and Poulsen, 2012)), ANEC has called for an implementation of a general comitology procedure so it is possible to change existing limit values and introduce restrictions of new chemicals for all kind of toys and substances without having to change the existing directive.

The chemical requirements suggested in this report could be implemented in a new version of the Toy Safety Directive. However, as also discussed in the previous ASI Consumer Council reports, another way to introduce chemical requirements in toys could be to introduce a brand new horizontal legislation with chemical requirements that covers all consumer products and not just toys. In the former ASI Consumer Council reports, the following possibilities for the regulatory framework were discussed:

a. Expand/revise existing product directives to (adequately) cover chemicals in all relevant consumer products.
b. Introduce specific chemical legislation for every sector following the RoHS model with legislation targeted the sector of the electronic products sector.
c. Adopt a horizontal directive for chemicals in products.
d. Extend REACH to address chemicals in consumer products in a comprehensive way.
e. Extend the Energy-Related Products (ERP) Directive to include generic and specific chemical restrictions, in principle, for all product groups.

It was suggested that an extension of the Energy-Related Products Directive to include generic and specific chemical restrictions, in principle, for all product groups would be the best possibility for combining a horizontal approach for chemical and other environmental aspects with a product specific dimension. This aspect is therefore not discussed further in this report.

4.2 Market surveillance

As quoted by Becker et al. (2010) in the introduction, there are two major reasons why toys contain toxic chemicals: lack of regulation and violation of existing regulation. It is therefore crucial (as also pointed out in the former ASI Consumer Council reports) that the market surveillance is strengthened. The yearly (and monthly) RAPEX reports are also examples of this. Chemical risks and toys both represent the second highest number of RAPEX notifications by type of notifications and type of products respectively.

4.3 Substances that should be regulated

The substances or topics suggested to be addressed in toys in this report are based on existing opinions/discussions/reviews found. This means that it is chemicals of particular concern for which chemical requirements have been suggested. The group of substances/topics suggested to be addressed in this report covers:

1. SVHCs including CMRs, PBTs, vPvBs and others (e.g. EDCs)
2. Elements (heavy metals)
3. Sensitisers - Fragrances
4. Flame retardants
5. Colourants and primary aromatic amines
6. Monomers (migration)
7. Solvents (migration and inhalation)
8. Preservatives and biocides
9. N-nitrosamines and N-nitrosatable substances
10. Other substances
11. Nanomaterials
12. Use of FCM legislation for toys

A total list of the suggested requirements within these areas is listed in Table 25 in the next chapter.

These requirements are a substantial expansion of the chemical requirements in the new Toy Safety Directive. However, the chemical requirements listed represent the “gaps” in the existing legislation that should be closed from a risk assessment perspective.

Aspects that have not been discussed in this report are:

- Requirements versus materials
- Multiple exposures and combination effects
- Other relevant substances

In this report the requirements (limit values) have been suggested without looking at the specific materials or kind of toys. Of course some of the

requirements may only be relevant for certain types of materials. E.g. phthalates and other plasticisers are only relevant for plastic materials. This has to some extent just been listed in brackets in the tables listing the suggested requirements. This does, however, deserve much more discussion and description but it was not possible to go to this level of detail in this study. Therefore additional discussion is needed on this aspect.

From a precautionary principle it may be necessary to account for both multiple exposures and combinations effects when setting the limit value. Combination effects are very difficult to deal with by use of existing risk assessment methods and are therefore typically not dealt with in existing chemical legislation and have not been dealt with in this study. As mentioned in the introduction, the European Commission has called for a precautionary principle and preventive action in their draft proposal "Living well, within the limits of our planet" which is meant to function as a General Union Environmental Action Programme to 2020. One of their statements and intentions is exactly to "ensure that by 2020 the combination effects of chemicals … are effectively addressed, and risks for the environment and health associated with the use of hazardous substances, including chemicals in products, is assessed and minimised". This is, however, an aspect that needs further research.

Finally, it should be mentioned that it was not possible in this study to go into detail with every relevant type of chemical/every relevant substance. This study has focused on the substances being discussed most intensively and the most relevant substances, but of course other relevant substances may be relevant to include as well.

5 Suggested chemical requirements

This chapter contains a total list of the suggested chemical requirements based on the review in chapter 3 ”Review: Chemical requirements”.

Table 25: Suggested chemical requirements for toys

Group of chemicals	Suggested chemical requirements
SVHCs including: **CMRs** **PBTs** **vPvBs** **and others (e.g. EDCs)** **(all materials)**	**Type of limit value:** Migration or content based limit values depending on the toy material and the nature of the substances: Non-volatile substances: • Dry, brittle, powder-like or pliable: Content based • Liquid or sticky: Content based • Solid: Migration based Volatile substances: • All toys: Evaporation based **Limit value CMRs (category 1A, 1B and 2) and EDCs (proposed category 1A and 1B):** Migration based limit value: Must not be detectable, i.e. 0.01 mg/kg (10 ppb) in all toys. Content and evaporation based limit value: Need to be discussed. Exemptions can be made, but only on the basis of a full risk assessment and a positive opinion by SCHER. **Limit value PBTs and vPvBs:** PBTs and vPvBs must not be present in all toys in a content above 0.1 %. **Test method:** Content: None suggested. Dependant on the substance. Migration: Must be further discussed, but based on the dynamic migration test method contained in EN 71-10 (2005) with some improvements called for by organisations such as SCHER and ANEC.
PAHs **(in rubber and elastomer materials)**	**Type of limit value:** Content based **Limit value:** 0.2 mg/kg as for each of the 8 carcinogenic PAHs in all toys. However, a lowering of the limit value should be possible when validated test methods with lower detection limit values exist in the future. **Test method:** Test method used for the German GS (certified safety) mark.

Group of chemicals	Suggested chemical requirements
Phthalates and other plasticisers **(in plastic materials)**	**Type of limit value:** Content based **Limit value:** • No phthalates (esters of o-phthalic acid) are allowed in toys (for all ages). Limit value: 0.05% (500 ppm). • Exemptions may be granted but only on the basis of a full risk assessment and a positive opinion by SCHER. • It is only allowed to use other plasticisers that have been approved by SCHER on the basis of a full risk assessment (= positive list of other plasticisers that can be used in specific concentrations). **Test method:** None suggested. Dependant on the substance.
Formaldehyde **(in textiles, wood, paper, as preservative and monomer)**	**Type of limit value:** Dependant on the material **Limit value:** • Textiles: Accessible textile components of toys intended for children under 3 years of age shall not contain free and hydrolyzed formaldehyde in excess of 30 mg/kg when tested in accordance with EN ISO 14184-1. • Paper: Accessible paper components of toys intended for children under 3 years of age shall not contain formaldehyde in excess of 30 mg/kg when tested in accordance with EN 645 and EN 1541. • Wood: Accessible resin-bonded wood components of toys intended for children under 3 years of age shall not release formaldehyde in excess of 80 mg/kg when tested in accordance with EN 717-3. • Migration of formaldehyde (as a monomer) shall not exceed the action limit of 2.5 mg/l simulant. • Formaldehyde (free) (as a preservative) shall not exceed the limit of 0.05%. **Test method:** Use of existing test methods, but to be discussed further.
Phenol	**Type of limit value:** Migration and content based **Limit value:** • As a monomer: 4 mg/l in aqueous migrate • As preservative: 10 mg/kg in toy material (content based) **Test method:** Use of existing test methods (in EN 71-9 (2007) and EN 71-11 (2005)).

<table>
<tr><th>Group of chemicals</th><th>Suggested chemical requirements</th></tr>
<tr><td>Elements

(in all materials)</td><td>
Type of limit value: Migration limit values split into three depending on the toy material:

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

Limit value: Migration limit values for all toys as listed in the table below. Changes compared to the new Toy Safety Directive are marked with grey shading.
<table>
<tr><th>Element</th><th>Dry, brittle, powder-like or pliable toy material</th><th>Liquid or sticky toy material</th><th>Scraped-off toy material</th></tr>
<tr><td>Aluminium</td><td>5,625</td><td>1,406</td><td>70,000</td></tr>
<tr><td>Antimony</td><td>45</td><td>11.3</td><td>560</td></tr>
<tr><td>Arsenic</td><td>1.9</td><td>0.6</td><td>24</td></tr>
<tr><td>Barium</td><td>150</td><td>37</td><td>1,867</td></tr>
<tr><td>Boron</td><td>1,200</td><td>300</td><td>15,000</td></tr>
<tr><td>Cadmium</td><td>1.3</td><td>0.3</td><td>17</td></tr>
<tr><td>Chromium (III)</td><td>37.5</td><td>9.4</td><td>460</td></tr>
<tr><td>Chromium (VI)</td><td>0.02</td><td>0.005</td><td>0.2</td></tr>
<tr><td>Cobalt</td><td>10.5</td><td>2.6</td><td>130</td></tr>
<tr><td>Copper</td><td>622.5</td><td>156</td><td>7,700</td></tr>
<tr><td>Lead</td><td>1.9</td><td>0.49</td><td>22.9</td></tr>
<tr><td>Manganese</td><td>1,200</td><td>300</td><td>15,000</td></tr>
<tr><td>Mercury</td><td>7.5</td><td>1.9</td><td>94</td></tr>
<tr><td>Nickel</td><td>75</td><td>18.8</td><td>930</td></tr>
<tr><td>Selenium</td><td>37.5</td><td>9.4</td><td>460</td></tr>
<tr><td>Strontium</td><td>4,500</td><td>1,125</td><td>56,000</td></tr>
<tr><td>Tin</td><td>15,000</td><td>3,750</td><td>180,000</td></tr>
<tr><td>Organic tin</td><td>0.9</td><td>0.2</td><td>12</td></tr>
<tr><td>Zinc</td><td>3,750</td><td>938</td><td>46,000</td></tr>
</table>
Test method: As described in EN 71-3 (2013), but improvements need to be made in order to ensure better reproducibility (as described in CEN/TC 52).
</td></tr>
<tr><td>Fragrances

(in all materials)</td><td>
Type of limit value: Content based

Limit value:
All 129 listed contact allergens (as listed by SCCS/1459/11 (2011) – Table 13-1 to 13-3) should be banned from all toys in non-detectable amounts (alternatively in an amount of 10 ppm).

Test method: No suggestions
</td></tr>
<tr><td>Isothiazolinones

(in “chemical” toys)</td><td>
Type of limit value: Content based

Limit value:
Use of isothiazolinones in toys is not allowed (non-detectable).

Test method: HPLC, detection limit 2 ppm.
</td></tr>
</table>

Group of chemicals	Suggested chemical requirements
Sensitising substances **(in all materials)**	**Type of limit value:** Content based **Limit value:** All sensitising substances, i.e. substances classified as sensitising with H317 "May cause an allergic skin reaction" and/or H334 "May cause allergy or asthma symptoms or breathing difficulties if inhaled" according to REACH C&L Inventory Database (harmonised or non-harmonised classification) should not be present in all toys in a concentration higher than 100 ppm. If substances are sensitising in lower concentrations than 100 ppm, the sensitisation level of the specific substances must not be exceeded. **Test method:** Dependant on the substance
TCEP, TCPP and TDCP **(in all materials)**	**Type of limit value:** Content based **Limit value:** Use of TCEP, TCPP and TDCP in all toys is not allowed (non-detectable), i.e. 5 ppm (5 mg/kg) or lower depending on the test method used. **Test method:** No suggestions
Flame retardants **(in all materials)**	**Type of limit value:** Content based and based on migration **Limit value:** 1. It is only allowed to use flame retardants that have been approved by SCHER on the basis of a full risk assessment (= positive list of flame retardants that can be used with specific migration concentrations). 2. Until the positive list of flame retardants has been established, a generic exclusion of flame retardants with the properties below should be excluded. Use of flame retardants with the following classification according to REACH C&L Inventory Database is not allowed in all toys (non-detectable content, i.e. detection level of 5 mg/kg): • H370 – Causes damage to organs • H371 – May cause damage to organs • H372 – Causes damage to organs through prolonged or repeated exposure • H373 – May cause damage to organs through prolonged or repeated exposure **Test method:** Depends on the substance

Group of chemicals	Suggested chemical requirements
Colourants and primary aromatic amines **(in all materials)**	**Type of limit value:** Content based **Limit value:** • The use of the following colorants shall not be present in all toys – action limit 10 mg/kg for all colourants below: o Disperse Blue o Disperse Blue 3 o Disperse Blue 106 o Disperse Blue 124 o Disperse Yellow 3 o Disperse Orange 3 o Disperse Orange 37/76 o Disperse Red 1 o Solvent Yellow 1 o Solvent Yellow 2 o Solvent Yellow 3 o Basic Red 9 o Basic Violet 1 o Basic Violet 3 o Acid Red 26 o Acid Violet 49 • The use of the following primary aromatic amines shall not be present in all toys – action limit 5 mg/kg for all primary aromatic amines below: o Benzidine o 2-Naphthylamine o 4-Chloroaniline o 3.3'-Dichlorobenzidine o 3,3'-Dimethoxybenzidine o 3.3'-Dimethylbenzidine o o-Toluidine o 2-Methoxyaniline (o-Anisidine) o Aniline **Test method:** As described in EN 71-11
Monomers **(in plastic materials)**	**Type of limit value:** Based on migration **Limit value:** For all toys: The specific migration limit values (SML) as used for monomers in Regulation No. 10/2011 on plastic materials and articles intended to come into contact with food (Annex I, Table I), but adjusted for weight of a child (instead of weight of adults) as well as only a fraction (10%) of the TDI value. **Test method:** As described in the Food Contact Materials Regulation, but by use of simulants relevant for child exposure, like e.g. artificial saliva and artificial sweat.

Group of chemicals	Suggested chemical requirements
Solvents **(in all materials)**	**Type of limit value:** Based on migration and inhalation **Limit value:** 1. Adoption of the already proposed limit values for certain solvents in EN 71-9 (2007) standard (table 2E migration and table 2F inhalation). 2. However, a review needs to be made if other solvents should be restricted as well; and more research and validation of the test methods and limit values are needed. **Test method:** Dependant on the specific solvent. Some test methods are described in EN 71-10 (2005) and EN 71-11 (2005).
Preservatives and biocides **(in all materials)**	**Type of limit value:** Based on content **Limit value:** 1. Wood preservatives should not be used in any toys. However, some wood preservatives may be used in wooden toys for outdoor use if they are considered safe in a full risk assessment carried out by SCHER. 2. Use of a positive list of non-wood preservatives similar to the EN 71-7 (2002) list to be incorporated in the Toy Safety Directive. I.e. preservatives which are allowed in the Cosmetic Products Directive should be allowed for use in toys. • But excluding preservatives that are restricted in the Cosmetic Products Directive with the following statements: o Only for rinse-off products o No mucous membranes contact o Not for oral hygiene products o Avoid contact with eyes • And excluding the use of Kathon and possibly other substances. **Test method:** Dependant on the specific preservatives. Some test methods are described in EN 71-10 (2005) and EN 71-11 (2005) and the test method used for cosmetic products can be used.
N-nitrosamines and N-nitrosatable substances **(in rubber materials)**	**Type of limit value:** Based on migration **Limit value:** For all toys: • 0.01 ppm in total of N-nitrosamines released. • 0.1 ppm in total of N-nitrosatable substances. **Test method:** As described in EN 71-12 (2013), but with dynamic migration. Migration time should be further discussed.

Group of chemicals	Suggested chemical requirements
Substances classified as very toxic, toxic, harmful, corrosive, irritating etc. **(in all materials)**	**Type of limit value:** Based on content **Limit value:** For all toys: Only chemicals <u>not</u> fulfilling the following hazard criteria shall be used in toy materials: • "Acute toxicity" (hazard class 3.1), • "Skin corrosion/irritation" (hazard class 3.2), • "Serious eye damage/eye irritation" (hazard class 3.3), • "Respiratory or skin sensitisation" (hazard class 3.4), • "Germ cell mutagenicity" (hazard class 3.5), • "Carcinogenicity" (hazard class 3.6), • "Reproductive toxicity" (hazard class 3.7), • "Specific target organ toxicity – single exposure" (hazard class 3.8), • "Specific target organ toxicity – repeated exposure" (hazard class 3.9), • "Aspiration hazard" (hazard class 3.10). **Test method:** None suggested. Perhaps based on SDS on used chemicals.
Nanomaterials **(in all materials)**	**Type of limit value:** Content based **Limit value:** 1. Nanomaterials shall not be actively added to any toys (i.e. limit value is "non-detectable"). 2. Exemptions may be granted but only on the basis of a full risk assessment and a positive opinion by SCHER. **Test method:** Depends on the substance

Group of chemicals	Suggested chemical requirements
Use of FCM legislation **(in plastic materials)**	**Type of limit value:** Migration based limit values as used in the FCM Regulation for plastic materials in toys intended for children below the age of 3. **Limit value:** A combination of the following limit values should be used as used in the FCM Regulation for plastic materials: • Only substances on the positive list of authorised materials may be used for manufacturing of plastic materials for toys. • Use of the specific migration limit values for each substance (as set in the FCM Regulation for plastic materials – however, adjusted for parameters such as children's weight, skin contact exposure, part of the TDI value etc.). • Use of an overall migration limit value (maximum total migration as set in the FCM Regulation for plastic materials – however, adapted to the test conditions). • Non-authorised substances are allowed if the migration is non-detectable (i.e. 0.01 mg/kg (10 ppb)). **Test method:** Must be further discussed, but on broadly in line with EN 71-10, but modified (e.g. with principles from SCHER (2010b) and ANEC proposal (2011b)): • Relevant simulant should be found/discussed (combination of artificial saliva and gastric juice for simulating migration by sucking and swallowing or simply using water?) • Test at 37° C • Samples should represent all parts of the toy • Use of repeated extraction with several hours pause. Calculation of average migration. • Use of dynamic migration.

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