

Chemical requirements for child use and care articles



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Summary

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. The area of child care articles is an example of consumer products where only some chemical requirements are set, but where the chemical requirements should be stricter as young children and babies are exposed to the chemicals in these products.

This study explores the area of child care articles and child use articles in depth when it comes to chemical requirements. The existing chemical requirements set by legislation have been described and reviewed as well as the chemical requirements set by standards on child care articles.

The definition of child care articles has been discussed and it is concluded that chemical requirements are needed not only for child care articles, but also for child use articles that are used for the intended purposes described in the definition below. The definition of products covered by child use and care articles is therefore:

“Child use and care articles include any product designed or obviously intended to safely ensure and facilitate seating, bathing, changing and general body care, feeding, sleeping, sucking, (dressing,) transportation and protection of children up to four (or 14) years”

The reason for using this broader definition than the existing definition used in REACH Annex XVII is to ensure that all relevant products designed to be used by children are covered, as several examples of problematic chemicals identified in child use articles exist.

The review of the existing chemical requirements set by legislation shows that in general it is a few chemical requirements that are restricted in child use and care articles. Most of the restrictions are not limited to child use and care articles, but are general restrictions on either all articles or on e.g. textile articles. These restrictions are on:

- Phthalates
- Nickel
- Cadmium
- Lead – but only in jewellery and hair accessories
- PAHs (upcoming legislation – valid from December 27 2015)
- Flame retardants – but only in textile articles
- Azo colourants and azo dyes – but only in textile and leather articles
- Organic tin compounds
- Chromium VI – but only in leather articles
- Proposed restriction on nonylphenol and nonylphenol ethoxylates – but only in textile articles
- N-nitrosamines and N-nitrosatable substances – but only in teat or soothers made of elastomer or rubber

In addition, child use and care articles that facilitate feeding will also be covered by the chemical requirements set (mostly for plastic materials) in the Food Contact Materials Regulation.

Furthermore, some chemical requirements have been set in standards covering specific child use and care articles that are used directly in the mouth of babies and young children, i.e. products such as soothers, baby bottles, and cutlery and feeding utensils. Standards are voluntary to follow even if they are harmonised. The chemical requirements set in standards are listed below:

- Migration on elements is generally limited in the standards.
- Nickel is only limited in three standards.
- N-nitrosamines and N-nitrosatable substances are limited in the two standards dealing with soothers and baby bottles.
- MBT is limited in the two standards dealing with soothers and baby bottles.
- Certain antioxidants are limited in the two standards dealing with soothers and baby bottles.
- Formaldehyde is limited in the two standards dealing with soothers and cutlery/feeding utensils.
- Bisphenol A is limited in the three standards dealing with soothers, baby bottles and cutlery/feeding utensils.
- Volatile compounds are only limited in the two standards dealing with soothers and cutlery/feeding utensils.
- Phthalates are only limited in the standard dealing with cutlery and feeding utensils.

However, it may also be relevant to restrict other groups of chemicals such as CMR substances, allergenic substances etc. in line with the Toy Safety Directive in child use and care articles. This is illustrated by the review of several examples of chemicals identified in different child use and care articles. These examples illustrate that problematic chemicals in consumer products such as child use and care articles are common and support the criticism regarding the current European regulatory framework on chemicals in consumer products being insufficient.

It should, however, be stressed that even though the different chemicals are found in the different child use and care products, they may not necessarily be found in high amounts or in amounts that would result in health effects when performing a risk assessment on the individual consumer products. Children are, however, exposed to small amounts of many different chemicals from many different consumer products, indoor air, outdoor air, food and water. For this reason, it will be necessary to limit or restrict problematic chemicals in child use and care articles to lower the total chemical burden of children today.

Therefore, in this report, it is suggested to restrict chemicals in a similar way as has been suggested for chemical requirements for toys in the former ASI Consumer Council study “Chemical requirements for toys” (Poulsen, 2013). The reason for the use of the chemical requirements for toys as a basis for the chemical requirements for child use and care articles is based on the following considerations:

1. Child use and care articles belong to a similar type of product and user group as toys.

2. Chemicals in toys have been given much more attention in the past and therefore the rules are more advanced (though still not satisfactory from a consumer protection perspective).

Actually, this former study has been used as the starting point for a suggestion of chemical requirements to be set for child use and care articles.

The suggested chemical requirements are discussed briefly in chapter 6 “Suggestion of chemical requirements for child use and care articles” and are summarised in chapter 7 “Suggested chemical requirements” in one long table.

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.

1.1 Conclusions from former studies

The current regulatory framework in the European Union to protect consumers from chemicals contained in consumer articles has been found insufficient in former review studies commissioned by The Consumer Council at the Austrian Standards Institute (ASI) and funded by the Austrian Ministry of Labour, Social Affairs and Consumer Protection. A summary of these former studies will be presented here.

1.1.1 Summary of 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 ((Poulsen et al., 2010; Poulsen and Strandesen, 2011))) 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.
- Provide 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. a 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

This means 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

Some directives, e.g. the Toys Directive, take into account that exposure to the same substance may occur from other products as well. This is often done by using a fraction of the Tolerable Daily Intake value.

However, in general multiple exposures are not considered in the 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 is related to the use and regulation of nanosubstances, among these the lack of suitable measurement methods and proper toxicological evaluations is found. 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 for 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 thus demonstrated that the current European legal framework concerning chemicals in products is insufficient. There is a lack of security for a high level of safety to consumers. These studies concluded that the adoption of a new regulatory framework – or a serious amendment of the existing - for chemicals in consumer products is necessary.

The following options for the changes in the regulatory framework were discussed:

- a. Expansion/revision of existing product directives to (adequately) cover chemicals in all relevant consumer products.
- b. Introduction of specific chemical legislation for each sector following the RoHS model with legislation targeted the sector of the electronic products sector.
- c. Adoption of a horizontal directive for chemicals in products.
- d. Extension of REACH to address chemicals in consumer products in a comprehensive way.
- e. Extension of 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 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.

Therefore, the main conclusions were 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 Summary of 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 of 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. 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. including products such as child care articles, toys and child use articles. However, the ASI Consumer Council study Part III was superseded by part IV that elaborated only on the product group toys.

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

- Induction of a comitology procedure in all product legislations.
- Strengthening of the market surveillance of consumer products.
- A general strengthening of the chemical requirements in product legislation.

1.1.3 Summary of ASI Consumer Council study part IV

In order to go more in depth with chemical requirements for products for children, the Consumer Council at the Austrian Standards Institute (ASI) first commissioned a study (funded by the Austrian Ministry of Labour, Social Affairs and Consumer Protection) on “Chemical requirements for toys” (Poulsen, 2013) and later on this present project “Chemical requirements for child use and care articles”.

The aim of the project “Chemical requirements for toys” was to investigate chemical requirements for toys in details and to use existing risk assessments of chemicals to suggest new chemical requirements for toys for several chemicals. This study was among other things commissioned because the chemical requirements for toys have been discussed intensely in recent years and also after adoption of the new Toy Safety Directive (2009/48/EC). Improvements in the form of more and stricter chemical requirements were made in some areas where the new Toy Safety Directive has been criticised for not being strict enough.

In this project “Chemical requirements for toys”, new limits were suggested for existing restricted chemicals in toys as well as new chemicals restrictions. This was 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.

The ASI Consumer Council study on toys was divided into different subjects/groups of chemicals, and for each subject/group of chemicals the existing legislation in the Toy Safety Directive was described as well as the normative requirements in the EN 71 series, and finally relevant information from different literature was presented and discussed for each subject/group of chemicals. The chemicals and groups of chemicals discussed in the toys report were:

1. CMRs, PBTs, vPvBs and others (e.g. EDCs)
 - CMRs, PBTs, vPvBs and EDCs in general
 - PAHs
 - BPA
 - Phthalates and other plasticizers
 - Nickel
 - Formaldehyde
 - Phenol
2. Elements
 - Lead
 - Cadmium
 - Antimony
 - Arsenic
 - Mercury
 - Barium
3. Sensitisers – fragrances
 - Fragrances
 - Isothiazolinones
 - Nickel
 - Sensitisers in general
4. Flame retardants
 - TCEP, TCPP and TDCP
 - Diantimoy trioxide
 - Flame retardants in general
5. Colourants and primary aromatic amines
6. Monomers
7. Solvents
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

For each chemical substance or group of chemical substances, chemical requirements were suggested. The requirements covered suggestions for:

- Type of limit value (e.g. migration or content based limit value)
- Level for the limit value (e.g. 0.2 mg/kg for PAH)
- Test method to be used for testing compliance

Product coverage of the limit value was not discussed in details, e.g. if the limit values set should be valid for all toys, only for toys intended for children of the age of 0-3 years or only for toys that could be put in the mouth. In general, all limit values were suggested for all toys. Furthermore, a discussion of materials versus the limit values was not discussed in details either. The requirements (limit values) were 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 plasticizers are only relevant for e.g. plastic and rubber materials. This subject does, however, deserve much more discussion and description but it was not possible to go into this level of detail in the study.

The suggested requirements are listed in one (long) table in Appendix 1 to this report.

A discussion of in which context the proposed chemical requirements for toys should be made was not carried out; 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.

1.1.4 General conclusions from all studies

The conclusions from the previous studies clearly indicate that the area of consumer products for children is insufficiently regulated. The conclusions from the study on “Chemical requirements for toys” illustrate that the regulation on toys needs to be even stricter in order to protect children sufficiently from chemicals in toys. However, all other products for children, i.e. child use and care articles, are not regulated on the same level as toys, when it comes to chemical requirements. Therefore, this present study will go into more depth on the area of child use and care articles.

1.2 Future intentions for chemicals in products

In October 2013, the European Parliament has adopted a proposal for a decision of the European Parliament and of the Council on a General Union Environmental Action Programme to 2020 called “Living well, within the limits of our planet”. This 7th Environment Action Programme is based on the precautionary principle and preventive actions. One of the priority objectives listed is “Priority objective 3: To safeguard the Union’s citizens from environmental-related pressures and risks to health and well-being”. The following statements are listed (European Parliament, 2013):

- “Horizontal chemicals legislation (REACH and CLP Regulations), as well as legislation on biocidal products and plant protection products, provides baseline protection for human health and the environment... **However, there is still uncertainty about the full impacts on human health and the environment of combined effects of different chemicals (mixtures), nanomaterials, chemicals that interfere with the endocrine (hormone) system (endocrine disruptors) and chemicals in products...** The Union will further develop and implement approaches to address combination effects of chemicals and safety concerns related to endocrine disruptors in all relevant Union legislation.... **The Union will also set out a comprehensive approach to minimising exposure to hazardous substances, including chemicals in products”**.
- “In order to safeguard the Union’s citizens from environment-related pressures and risks to health and well-being, **the 7th Environmental Action 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 in all**

relevant Union legislation, and risks for the environment and health, in particular in relation to children, associated with the use of hazardous substances, including chemicals in products, are assessed and minimised. Long-term actions with a view to reaching the objective of a non-toxic environment will be identified”.

- “This requires, in particular:” (six points are listed – one of them is):
 - “Developing by 2018 a Union strategy for a non-toxic environment that is conducive to innovation and the development of sustainable substitutes including non-chemical solutions, building on horizontal measures to be undertaken by 2015 to ensure: ... (4) **the minimisation of exposure to chemicals in products, including inter alia imported products, with a view to promoting non-toxic material cycles and reducing indoor exposure to harmful substances”.**

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

From this follows that chemical requirements in the European product legislation must be strengthened in the future.

2 Purpose

This study explores the area of child use and care articles in depth when it comes to chemical requirements and gives examples of requirements that could be introduced in order to protect children from harmful health effects. **The purpose of this study is** to go into further details regarding which specific requirements that are needed in order to make sure that children are not exposed to chemicals from child use and care articles in a manner, which causes health concerns.

This will be done through:

- Review of the existing chemical requirements in legislation for child use and care articles.
- Review of the chemical requirements in existing standards related to child use and care articles.
- Listing examples of hazardous chemicals found in child use and care articles.
- Discussion of the specific ‘necessary or needed’ chemical requirements in order to ensure the safety of children when child use and care articles are used.
- Discussion of other relevant aspects, such as:
 - Should the chemical requirements be different for mouthed products compared to products not possible to put in the mouth?
 - Which chemical requirements should be set for which materials?

It should be emphasised that the chemical requirements set for toys in the previous study “Chemical requirements for toys” will be used as a basis for chemical requirements for child use and care articles. This means that discussion of the scientific justifications (risk assessments) carried out in the previous study on toys will not be repeated in this report, only referred to.

It has not been a purpose of this study to discuss in which context the proposed chemical requirements for child use and care articles should be made – i.e. whether the chemical requirements could be introduced in a new ‘Products for children Directive’ or an expanded 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 ASI Consumer Council studies part I and II”, including an expansion of REACH, 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.

This study has been performed as a desk-top study meaning that the relevant existing legislation and the relevant standards on the area of child use and care articles have been reviewed and discussed. Furthermore, a broad search has been made in order to find examples of hazardous chemicals found when different child use and care articles were tested.

3 Definition of child care articles and child use and care articles

In this chapter different definitions of child use and child care articles are presented and discussed. First of all, it must be emphasised that in general the term ‘child care articles’ seems to be used, whereas the term ‘child use and care articles’ only seems to be used by CEN (the European Committee for Standardization).

Just by looking at the words and their meaning, ‘child care articles’ should cover all articles used to ‘care for’ children or to ‘take care of’ children, whereas ‘child use and care articles’ should have a much broader meaning and also cover ‘products used by children’. The term ‘products used by children’ is, however, a very large term and only makes sense to use if it is used in the meaning of products being designed to be used by children – otherwise all consumer products will in theory be covered as almost all consumer products may be used by children intentionally or by accident.

Furthermore, it should be emphasised that even though CEN uses the term ‘child use and care articles’ in the English versions of the standards, the differentiation in using the term ‘child use articles’ is not used when translating the standards – or at least not in neither the German nor the Danish translation of the standards. Here the term ‘child use and care articles’ has been translated to ‘child care articles’.

Below the terms used in the REACH Regulation, in standardisation, and in other parts of the world are presented and discussed.

3.1 Definitions of child care articles in the literature

3.1.1 REACH Annex XVII

According to entry no. 51 and 52 in Annex XVII of REACH “Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles” concerning phthalates, child care articles are defined as:

“Any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.”

REACH Annex XVII uses the term ‘child care articles’ and not ‘child use articles’.

No specific age limit is mentioned for child care articles in REACH Annex XVII.

In a guideline document¹ describing the interpretation of this REACH restriction on phthalates in child care articles, the following clarification has been made:

Childcare articles are defined as “any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children”. It is the Commission’s interpretation that the entry in Annex XVII covers the accessible parts of articles such as push chairs, car seats and bike seats which are intended to facilitate sleep and relaxation during transport.

The main purpose of pyjamas is to dress children when sleeping and not to facilitate sleep. Therefore, pyjamas should be regarded as textiles and, like other textiles, do not fall under the scope of the entry in Annex XVII. Sleeping bags are designed to facilitate sleep and should therefore fall under the entry in Annex XVII.”

3.1.2 CEN/TC 252 Child use and care articles

The CEN Technical Committee on child use and care articles (CEN/TC 252) has in their business plan defined the scope of the technical committee as (CEN/TC 252, 2010):

“Standardization of requirements of any product designed or obviously intended to safely ensure and facilitate seating, bathing, changing and general body care, feeding, sleeping, transportation and protection of young children. Standardization of all products related to child use and care for which no other Technical Committee exists.

Comment: Child care articles are intended to be used with children up to four years.”

CEN/TC 252 hence uses the more broad definition of ‘child use and care articles’.

3.1.3 United States Consumer Product Safety Improvement Act

According to American ban on phthalates in children’s toys and child care articles (Section 108 of the Consumer Product Safety Improvement Act (CPSIA, 2008)), child care articles are defined as:

“Child care articles” are defined as consumer products that are designed or intended by the manufacturer for a child who is 3 years old or younger, to facilitate sleeping or feeding, or to help a child who is sucking or teething.”

Only the term ‘child care articles’ and not ‘child use articles’ are used by CPSIA (2008).

This definition was provided by Congress in the CPSIA and the Commission has not issued further interpretive guidance. However, on the CPSC website it is noted that “the staff has interpreted ***items such as children’s sleepwear, infant and toddler bottles, sippy cups, utensils, bibs, pacifiers, and teething*** to be child care

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http://echa.europa.eu/documents/10162/13645/guideline_interpretation_concept_mou th_en.pdf

articles'. Furthermore, it is noted on the CPSC website that the staff determinations have not been approved by the Commission and the Commission may review and/or supersede the staff guidance and determinations².

This interpretation of child care articles has been commented by e.g. the American Apparel & Footwear Association that disagrees with the interpretation of children's sleepwear and bibs should be characterised as child care articles as pyjamas do not facilitate sleep and as bibs do not facilitate feeding³.

3.1.4 Hong Kong restriction on phthalates in toys and child care articles

In a Hong Kong proposal for a restriction on phthalates in toys and child care articles (Bureau Veritas, 2012), a child care article is defined as:

“Product that is intended to facilitate the relaxation, sleep, hygiene, feeding, sucking or teething of a child under 48 months of age.”

Again, in this definition only the term 'child care articles' are used and not the broader term 'child use and care articles'.

3.2 Definition used in this study

In general all of the definitions above agree on the fact that child care articles are products intended to facilitate sleep and facilitate the feeding of children. The US CPSIA definition, the REACH definition and the Hong Kong definition, which is almost identical to the REACH definition, also include products intended to facilitate sucking. Furthermore, the REACH definition and the Hong Kong definition include products intended to facilitate relaxation and hygiene. The US CPSIA definition specifically mentions teething as well.

The CEN/TC 252 definition is much broader as products designed or obviously intended to safely ensure and facilitate seating, bathing, changing and general body care, transportation and protection of young children are included as well. Furthermore, the CEN/TC 252 definition includes products related to 'child use and care' and not just 'child care', which is a broader definition as other products such as crayons for children and children furniture are covered by the term 'child use and care articles', but not by the term 'child care articles'. However, the CEN/TC 252 definition only includes products related to 'child use and child care for which no other Technical Committee exists'. Therefore, this excludes sleepwear (e.g. children pyjamas which are covered by TC 248 "Textile and textile products"). The official name of CEN/TC 252 is also "Child use and care articles", which of course implies a cover of several other products than just child care products.

Regarding the **age group** which child care articles are intended for, no specific age limit is mentioned in REACH Annex XVII. Actually the REACH Annex XVII restriction concerns both toys and child care articles, and the age group

² <http://www.cpsc.gov/en/Regulations-Laws--Standards/CPSIA/Phthalates/FAQs-Bans-on-Phthalates-in-Childrens-Toys/>

³ <https://www.wewear.org/assets/1/7/011209CPSIA.pdf>

used for toys is up to 14 years of age. However, as stated, this is not specified in the legislation.

Both the definition by CEN/TC 252 and the Hong Kong restriction use an age group of up to four years (or 48 months). The US CPSIA operates with a definition of 3 years old or younger.

In this study, it has been decided to **use a modification of the definition made by CEN/TC 252** in order to use the broadest definition possible and to include as many products as possible. A modification of the CEN/TC 252 definition is needed, as this definition excludes articles covered by other technical committees such as clothes. It is therefore suggested to expand the definition of child use and care articles to cover dressing as well (is listed in brackets in the definition below). Similarly, it is suggested to include products intended to facilitate sucking (intended to be sucked on by children) as it is included in the REACH definition of child care articles.

Concerning the age group, it is suggested to use the age group of up to 14 years of age – similar to toys and as suggested by the REACH restriction. However, a more in depth discussion is needed in order to investigate the implication of raising the age limit to up to 14 instead of up to four years.

The suggested **definition of ‘child care articles’** (or ‘child use and care articles’) is therefore:

“Child use and care articles include any product designed or obviously intended to safely ensure and facilitate seating, bathing, changing and general body care, feeding, sleeping, sucking, (dressing) transportation and protection of children up to four (or 14) years”

A use of this broader definition would also include products such as pyjamas and bibs that have been a discussion point in the US of whether or not such products fall under the category child care articles.

For the purpose of the present study, child care articles are therefore actually called “child use and care articles” and are defined as “all products related to child use and child care”. As a starting point, child use and care articles are defined as CEN/TC 252 as products intended for children under the age of four (or 14).

4 Chemical requirements in present legislation and standards

In this chapter the present chemical requirements for child use and care articles in legislation and standards are presented.

4.1 Existing chemical requirements in legislation

The existing chemical requirements in legislation for child use and care articles can be found in:

- General Product Safety Directive
- REACH
- Directive on rubber teats and soothers
- Food Contact Materials Regulation

4.1.1 General Product Safety Directive

The General Product Safety Directive (Directive 2001/95E/EC) is intended to ensure a high level of product safety throughout the EU for consumer products that are not covered by specific sector legislation (e.g. chemicals, cosmetics). According to the Directive ***“producers shall be obliged only to place safe products on the market”*** (Article 3 §1).

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

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

The General Product Safety Directive does not contain any chemical requirements – only the indirect statement, that “products must be safe”, which also refer to chemical safety. However, as the directive does not set any chemical requirements it is difficult for both companies and authorities to know when a chemical content in a consumer product is safe.

A numerous list of European harmonised standards based on the GPSD has been established. One example is general safety requirements for soothers for babies and young children. In some cases, the harmonised standards specify which chemical requirements that should be followed, like e.g. for soothers for babies and young children. In the few cases where chemical requirements have been specified in the harmonised standards, only a few chemicals are listed (like certain heavy metals and nitrosamines). However, many of these standards merely refer to the physical safety of the products.

A revision of the General Product Safety Directive is on its way (COM/2013/078 final). A proposal has been forwarded to the Parliament and the Council 14.2.2013. However, the proposed new Regulation on consumer product safety does not change the general overall purpose of 'safe products on the market'. No changes regarding chemical requirements have been made, but it has been an objective to strengthen and streamline market surveillance for all products.

The General Product Safety Directive does not provide an instrument (comitology) to establish chemical rules or restrictions of chemicals – nor does the revised proposal. Only emergency measures (formal decisions) can be made for a maximum of one year.

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

4.1.2 REACH

The REACH Regulation contains different chemical requirements relevant for child use and care articles. These are:

- Restriction on phthalates in toys and child care articles
- Restriction on nickel
- Restriction on cadmium
- Restriction on lead
- Restriction on PAHs
- Restriction on flame retardants
- Restriction on azo colourants and azo dyes
- Restriction on organostannic compounds
- Restriction on chromium VI
- Proposed restriction on nonylphenol and nonylphenoethoxylates

4.1.2.1 Restriction on phthalates

Certain phthalates are restricted in toys and child care articles by the REACH Regulation No. 1907/2006 Annex XVII entry No. 51 and 52. The REACH Regulation only restricts phthalates in 'child care articles' and not in 'child use and care articles':

- 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 child care 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 child care articles which can be placed in the mouth by children.

The term ‘which can be placed in the mouth’ is defined in a guideline document by ECHA⁴. In this document it is stated that:

- “Placing in the mouth” means that the article or parts of an article can actually be brought to the mouth and kept in the mouth by children so that it can be sucked and chewed. If the object can just be licked, it cannot be regarded as “placed in the mouth”.
- Articles which exceed a size of 5 cm in all three dimensions can as a starting point not be placed in the mouth by children. If an article or a part of an article in one dimension is smaller than 5 cm, it can be taken into the mouth. However, the shape of the article, e.g. the existence of detachable or protruding parts and its resistance to compression or deformation also needs to be given consideration.
- Also inaccessible parts of articles cannot be taken into the mouth. Articles or parts of articles should be considered inaccessible if, during proper use or reasonably foreseeable improper use by children, they cannot be reached.
- Handheld toys are more likely to be placed into the mouth, but it cannot be excluded that toys which are not handheld also can be placed into the mouth.

Furthermore, certain phthalates are on the REACH candidate list of SVHC⁵ meaning that they are subject to an information requirement (article 33 of REACH) if the content in articles is higher than 0.1%. These 11 phthalates are: DEHP, DBP, BBP, DIPP, DIBP, DIHP, DHNUP, DPP, DMEP, N-pentyl-isopentyl phthalate and DHP (as of 16 December 2013).

4.1.2.2 Restriction on nickel

Nickel is restricted in articles intended to come into direct and prolonged contact with the skin by the REACH Regulation No. 1907/2006 Annex XVII entry No. 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/cm²/week” (test method: EN 1811:2011).

Of course, such articles also cover child use and care articles.

4.1.2.3 Restriction on cadmium

Cadmium is restricted according to REACH Regulation No. 1907/2006 Annex XVII entry No. 23 in articles produced from a long list of synthetic organic polymers (such as e.g. PUR, PVC, PET, PP etc.) and therefore also in child care articles containing these synthetic organic polymers. The limit value is 0.01% by weight of the plastic material. Furthermore, cadmium is restricted (limit value of 0.01%) in metal beads and other metal components for jewellery making, metal parts of jewellery, imitation jewellery and hair accessories, including e.g. bracelets, necklaces, rings and wrist-watches.

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http://echa.europa.eu/documents/10162/13645/guideline_interpretation_concept_mouth_en.pdf

⁵ Substances of Very High Concern

4.1.2.4 Restriction on lead

Lead is restricted according to REACH Regulation No. 1907/2006 Annex XVII entry No. 63 in any individual part of jewellery articles (jewellery and hair accessories such as bracelets, necklaces, rings and wrist-watches). The limit value is 0.05% by weight.

4.1.2.5 Restriction on PAHs

Eight specific PAHs are restricted according to the REACH Regulation No. 1907/2006 Annex XVII entry No. 50 in toys and child care articles. The restriction has the following wording (Regulation No 1272/2013):

- “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 reasonably foreseeable conditions of use, contain more than 0.5 mg/kg (0.00005 % by weight of this component) of any of the listed PAHs.”
- For other consumer articles the limit value should be 1 mg/kg (0.0001% by weight) instead, for any of the listed PAHs. Therefore it depends on the REACH definition of ‘child care articles’, whether the 0.5 or 1 mg/kg limit value is valid.
- The restriction concerning PAHs applies to articles placed on the market for the first time before December 27 2015.

4.1.2.6 Restriction on flame retardants

Specific flame retardants are restricted according to REACH Regulation No. 1907/2006 Annex XVII in textiles articles with skin contact and therefore also in child care articles with skin contact. These are:

- TRIS (entry no.4) – tris (2,3 dibromopropyl) phosphate (CAS 126-72-7).
- TEPA (entry no. 7) – tris(aziridinyl)phosphin oxide (CAS 545-55-1)
- PBB (entry no. 8) – polybrominatedbiphenyls (CAS 59536-65-1)

4.1.2.7 Restriction on azo colourants and azo dyes

Azo colourants and azo dyes, which by reductive cleavage of one or more of the azo groups, may release one or more of the aromatic amines listed in Appendix 8 of the REACH Regulation No. 1907/2006 are restricted in textile and leather articles which come into direct and prolonged contact with the human skin or oral cavity, such as clothing, nappies, straps etc. (Regulation No. 1907/2006 Annex XVII entry No. 43). The limit value is 30 mg/kg (or 0.003%) by weight for the listed aromatic amines. Therefore, this restriction also applies for child care articles made of textile or leather, which are in direct and prolonged contact with the skin or oral cavity.

4.1.2.8 Restriction on organic tin compounds

Organic tin compounds are restricted by REACH Regulation No. 1907/2006 annex XVII entry no. 20. The following organic tin compounds are restricted:

- TBT (tributyltin) compounds (limit value in articles is 0.1% (1000 ppm) by weight of tin) in all articles.
- DBT (dibutyltin) compounds (limit value in articles is 0.1% (1000 ppm) by weight of tin) in all articles.
- DOT (dioctyltin) compounds (limit value 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.

4.1.2.9 Restriction on chromium VI

Chromium VI compounds are restricted in leather articles or in articles containing leather parts coming into contact with skin according to the REACH Regulation No. 1907/2006 Annex XVII entry no. 47. The limit value is 3 mg/kg (0.0003% by weight) of the total dry weight of the leather (Regulation No. 301/2014). This restriction therefore also applies for child care articles made of leather or consisting of leather.

4.1.2.10 Proposed restriction on nonylphenol and nonylphenoethoxylates

Sweden has made a restriction proposal on nonylphenol (NP) and nonylphenoethoxylates (NPE) concerning textile clothing, fabric accessories and interior textile articles containing NP and NPE that can be washed in water. For these textiles articles, it is proposed that the limit value is 100 mg/kg textile for NP and NPE in combination or alone. The limit value includes prints on the textiles and articles as well (Annex XV Restriction Report – NP and NPE, 2013).

4.1.3 Directive 93/11/EEC on rubber teats and soothers

Directive 93/11/EEC concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers sets the following requirements (limit values) for N-nitrosamines and N-nitrosatable substances in teats and soothers:

- 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).

No other chemical requirements are set in this Directive.

4.1.4 Food Contact Materials Regulation

The Food Contact Materials (FCM) Regulation 1935/2004 has been discussed in details in the previous studies “Chemical requirements for consumer products – Part II” (Poulsen & Strandesen, 2011), “Chemical requirements for consumer products – Part III” (Strandesen & Poulsen, 2012) and “Chemical requirements for toys” (Poulsen, 2013) and therefore they will not be described in details here.

It is obvious that child use and care articles which facilitate feeding – such as baby spoon, baby plates, baby bottles etc. – also fall under the FCM Regulation.

Overall the FCM Regulation sets detailed chemical requirements for food contact materials, but only for a few groups of materials such as plastics, elastomers/rubbers and ceramics. Especially plastics are regulated most thoroughly. However, areas such as paper and boards, metal alloys, coatings, printing inks, textiles, glass etc. are not regulated on EU level, but some regulations may be in the individual EU member state countries. Furthermore, there are still gaps within the few groups of materials that are regulated (i.e. colorants and solvents are not regulated within plastic materials).

Plastic materials are regulated through an overall migration limit, which ensures that the total migration of chemical substances is limited. Furthermore, chemicals in plastic materials are regulated by use of a positive list (authorisation list), i.e. only certain chemicals are allowed to be used in plastics. Finally, specific migration limits may be set for specific substances. All other materials ought to be regulated in the same way on an EU level. Too many national measures illustrate that the missing EU regulation on other materials is not satisfactory.

A comitology procedure is in place and does allow for establishing new chemical requirements or e.g. a lowering of the limit value for the existing requirements.

4.1.4.1 Special national legislation on Bisphenol A

In Austria, a ban has been adopted in 2011 concerning the manufacturing of soothers and teething rings with Bisphenol A (Regulation 327, 2011). According to an associated recommendation this ban is complied with if the content of Bisphenol A in the extract is below 1 mg/kg polymer. Extraction must be carried out by means of 16-hour Soxhlet extraction method using methanol (Bundesministerium für Gesundheit, 2012).

In Denmark, a special article on Bisphenol A has been inserted in the Food Materials Contacts Legislation. According to Danish legislation (Stat. Order no. 822, 2013), it is not allowed to use Bisphenol A or all compounds that Bisphenol A is a part of in materials that are especially designed to be in contact with food targeted children of the age of 0 to 3 years.

France has adopted legislation on Bisphenol A similar to the Danish regulation on Bisphenol A in food contact materials. However, the French legislation has a much broader scope and covers all food contact materials and not just food contact materials for products for children. The French regulation will enter into force on January 1st 2015 (LOI No. 2012-1442, 2012).

4.2 Existing chemical requirements in standards

On their webpage, the European Committee for Standardization (CEN) has listed all published standards and technical reports regarding child use and care articles. These are listed in Table 1 below.

Table 1: CEN/TC 252 Published standards

Standard	Title	Directive
CEN/TR 13387:2004	Child use and care articles - Safety guidelines	-
CEN/TR 15775:2008	Child use and care articles - National translations of warnings and instructions for use in child use and care articles standards	-
CEN/TR 16411:2012	Child use and care articles - 2012 compiled interpretations of CEN/TC 252 standards	-
EN 12221-1:2008+A1:2013	Child use and care articles - Changing units for domestic use - Part 1: Safety requirements	-

Standard	Title	Directive
EN 12221-2:2008+A1:2013	Child use and care articles - Changing units for domestic use - Part 2: Test methods	-
EN 12586:2007+A1:2011	Child use and care articles - Soother holder - Safety requirements and test methods	2001/95/EC (Expected)
EN 1272:1998	Child care articles - Table mounted chairs - Safety requirements and test methods	-
EN 1273:2005	Child use and care articles - Baby walking frames - Safety requirements and test methods	2001/95/EC (C 38, 2009-02-17)
EN 12790:2009	Child use and care articles - Reclined cradles	-
EN 12868:1999	Child use and care articles - Methods for determining the release of N-Nitrosamines and N-Nitrosatable substances from elastomer or rubber teats and soothers	89/109/EEC (No)
EN 12868:1999/AC:2002	Child use and care articles - Methods for determining the release of N-Nitrosamines and N-Nitrosatable substances from elastomer or rubber teats and soothers	-
EN 13209-1:2004	Child use and care articles - Baby carriers - Safety requirements and test methods - Part 1: Framed back carriers	2001/95/EC (C 171, 2006-07-22)
EN 13209-2:2005	Child use and care articles - Baby carriers - Safety requirements and test methods - Part 2: Soft carrier	2001/95/EC (Expected)
EN 13210:2004	Child use and care articles - Children's harnesses, reins and similar type articles - Safety requirements and test methods	-
EN 1400:2013	Child use and care articles - Soothers for babies and young children - Safety requirements and test methods	2001/95/EC (Expected)
EN 14036:2003	Child use and care articles - Baby bouncers - Safety requirements and test methods	-
EN 14344:2004	Child use and care articles - Child seats for cycles - Safety requirements and test methods	2001/95/EC (C 256, 2005-10-15)
EN 14350-1:2004	Child use and care articles - Drinking equipment - Part 1: General and mechanical requirements and tests	2001/95/EC (C 256, 2005-10-15)
EN 14350-2:2004	Child use and care articles - Drinking equipment - Part 2: Chemical requirements and tests	-
EN 14372:2004	Child use and care articles - Cutlery and feeding utensils - Safety requirements and tests	-
EN 1466:2004+A1:2007	Child care articles - Carry cots and stands - Safety requirements and test methods	2001/95/EC (Expected)
EN 16120:2012	Child use and care articles - Chair mounted seat	-
EN 16232:2013	Child use and care articles - Infant swings	-

Standard	Title	Directive
EN 1888:2012	Child care articles - Wheeled child conveyances - Safety requirements and test methods	-
EN 1930:2011	Child use and care articles - Safety barriers - Safety requirements and test methods	-

Furthermore, a number of standards are under development. These are listed in Table 2 below.

Table 2: CEN/TC 252 standards under development

Standard	Title	Candidate citation in OJEU*
prEN 1466	Child use and care articles - Carry cots and stands - Safety requirements and test methods	Yes (2001/95/EC)
FprCEN/TR 16512	Child use and care articles - Guidelines for the safety of children's slings	No (-)
prEN 13209-2 rev	Child use and care articles - Baby carriers - Part 2: Soft carrier	No (-)
FprCEN/TR 16411	Child use and care articles - 2013 compiled interpretations of CEN/TC 252 standards	No (-)
EN 1400:2013/FprA1	Child use and care articles - Soothers for babies and young children - Safety requirements and test methods	Yes (2001/95/EC)
EN 16120:2012/FprA1	Child use and care articles - Chair mounted seat	No (-)

* OJEU = Official Journal of the European Union

In the following sections (section 4.2.1 to section 4.2.17), the above mentioned standards (listed in Table 1 and Table 2) are reviewed and the chemical requirements in the standards are briefly described. A summary of the chemical requirements in these standards can be found in Table 9 and Table 10. However, the standards only describing test methods or more general aspects – and not chemical requirements – are not discussed in the following sections.

4.2.1 EN 1272:1998 – Table mounted chairs

The only chemical requirement listed in EN 1272 (1998) dealing with table mounted chairs is that the surfaces of the materials shall meet the requirements of EN 71-3:1994, i.e. the migration limits for the eight metals listed.

4.2.2 EN 1273:2001 – Baby walking frames

The only chemical requirement listed in EN 1273 (2001) dealing with baby walking frames is that any surface, plastics, coatings or finishes shall comply with EN 71-3. Castors and wheels are excluded from this requirement.

There is no specific dated reference for EN 71-3 which means that the latest edition of EN 71-3 applies, i.e. EN 71-3:2013, meaning that the requirements for the extended list of 18 different elements apply.

4.2.3 EN 1466:2004+A1 and draft new version – Carrycots and stands

The only chemical requirement listed in EN 1466+A1 (2007) dealing with carrycots and stands is that inside surfaces of parts accessible to the child of the carrycot shall be made with use of materials which in their soluble state have a metal content not exceeding the values listed in EN 71-3.

There is no specific dated reference for EN 71-3 which means that the latest edition of EN 71-3 applies, i.e. EN 71-3:2013, meaning that the requirements for the extended list of 18 different elements apply.

In Annex C of the standard it is mentioned that nickel has been considered, but was not found to be relevant with the use of carrycots. No such material parts are bound to be in contact with a child or and adult of the carrycot.

A new version of EN 1466 is available in its draft version. Currently (December 2013), the draft version is under approval. In this new draft version the same requirements regarding migration of metals are listed; however, in the draft 2013 version a specific reference is made to the EN 71-3:1994 version, i.e. it is the 'old' migration limits that apply for the eight metals and not the 'new' migration limits for the 18 elements as listed in EN 71-3:2013.

4.2.4 EN 1930:2011 – Safety barriers

EN 1930 (2011) deals with safety barriers, i.e. products designed to limit a child's access inside the home. The only chemical requirement listed in EN 1930 (2011) is that the migration of synthetic or natural elements from coatings of paint, varnish, lacquer, printing ink, polymer and similar coatings and from any other accessible surfaces or materials whether mass coloured or not shall not exceed the migration limits as listed in EN 71-3.

It is stated in the standard that the test sample shall not include the base material where a surface is coated with a multi-layer of paint or similar coating.

There is no specific dated reference for EN 71-3 which means that the latest edition of EN 71-3 applies, i.e. EN 71-3:2013, meaning that the requirements for the extended list of 18 different elements apply.

4.2.5 EN 12221-1:2008+A1 – Changing units for domestic use

The standard EN 12221-1 (2013) deals with changing units for domestic use. The only chemical requirement listed in EN 12221-1 (2013) is that any coating of paint, varnish, lacquer or similar substances and parts consisting of dyed materials, leather, textiles and plastic materials within the accessibility zone shall be made by use of products which in their soluble compound do not exceed the amounts as listed in EN 71-3.

It is stated in the standard that the test sample shall be taken down to the base material where a surface is coated with a multi-layer of paint or similar coating.

There is no specific dated reference for EN 71-3 which means that the latest edition of EN 71-3 applies, i.e. EN 71-3:2013, meaning that the requirements for the extended list of 18 different elements apply.

4.2.6 EN 1400:2013 – Soothers

The standard EN 1400 (2013a) deals with soothers for babies and young children and contains several chemical requirements for the following types of chemicals:

- Elements – migration
- N-nitrosamines and N-nitrosatable substances – release
- 2-Mercaptobenzothiazole (MBT) – release
- Antioxidants – release
- Formaldehyde – migration
- Bisphenol A – release
- Volatile compounds – content

The standard contains an overview of the types of materials that should be tested for the chemicals listed above. This overview is taken directly from the standard and is reproduced in Table 3. It is mentioned in the standard that soothers or components of soothers shall be subjected to the tests marked with an “x” in the table.

Table 3: Requirements and tests for different materials in soothers according to EN1400 (2013a), Table 4.

	Migration of certain elements	N-Nitrosamines and N-Nitrosatables release	2-Mercaptobenzothiazole release	Antioxidants release	Formaldehyde release	Bisphenol A release	Colour Fastness	Volatile compound content
Requirement Clause	10.3.1	10.4.1	10.5.1	10.5.1	10.5.1	10.6. 1 ^a	10.7.1	10.8.1
Test Clause	10.3.2	10.4.2	10.5.2	10.5.2	10.5.2	10.6.2	10.7.2	10.8.2
Vulcanised rubber	x	x	x	x	x		x	
Silicone rubber	x	x			x		x	x
Thermoplastics	x					x	x	
TPEs	x	x					x	
All Decorations	x						x	

^a Bisphenol A Migration should only be carried out on thermoplastics that use Bisphenol A in their manufacture, such as polycarbonates. Bisphenol A is not used in the production of other common thermoplastics, such as polypropylene and polyethylene.

4.2.6.1 Requirements for elements in EN 1400

The requirement for elements in EN 1400 (2013a) refers to EN 71-3 (undated reference) for test methods; however, the migration limits that are listed differ from the migration limits in EN 71-3 (2013). In Table 4 below the migration limits in EN 71-3 (2013) are listed for comparison as well as the migration limits listed in EN 1400 (2013a) for soothers.

In general, lower migration limit values are set for soothers compared to the category III migration limits in EN 71-3. The reason for using these lower limit values compared to the limit values for toys is that a body weight of 2.5 kg (instead of 7.5 kg for toys) is used, that an amount of ingested material of 25 g (instead of 8 g for toys) is used, and that in some cases a lower TDI has been used (e.g. for barium and lead). This results in almost a factor 10 lower limit values.

Table 4: Comparison of migration limits for elements listed in EN 71-3 (2013) and EN 1400 (2013a) for soothers. All migration limits are measured in mg/kg.

Element	EN 71-3 (based on TSD 2009/48/EC)			EN 1400 (2013a)
	Category I Dry, brittle, powder-like or pliable toy material (mg/kg)	Category II Liquid or sticky toy material (mg/kg)	Category III Scraped-off toy material (mg/kg)	Limits of elements migration from soothers (mg/kg)
Aluminium	5,625	1,406	70,000	1,430
Antimony	45	11.3	560	60
Arsenic	3.8	0.9	47	2.5
Barium	1,500	375	18,750	200
Boron	1,200	300	15,000	1,600
Cadmium	1.3	0.3	17	1.8
Chromium (III)	37.5	9.4	460	50
Chromium (VI)	0.02	0.005	0.2	
Cobalt	10.5	2.6	130	14
Copper	622.5	156	7,700	830
Lead	13.5	3.4	160	2.5
Manganese	1,200	300	15,000	300
Mercury	7.5	1.9	94	10
Nickel	75	18.8	930	100
Selenium	37.5	9.4	460	50
Strontium	4,500	1,125	56,000	6,000
Tin	15,000	3,750	180,000	20,000
Organic tin	0.9	0.2	12	
Zinc	3,750	938	46,000	5,000

4.2.6.2 N-nitrosamines and N-nitrosatable substances limit values in EN 1400

The requirement for N-nitrosamines and N-nitrosatable substances in EN 1400 (2013a) refers to EN 12868 (undated reference) for test methods. The limit values for N-nitrosamines and N-nitrosatable substances are as listed in Directive 93/11/EEC concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers:

- 0.01 ppm (mg/kg) in total of N-nitrosamines released (of the parts of teat or soother made of elastomer or rubber).
- 0.1 ppm (mg/kg) in total of N-nitrosatable substances (of the parts of teat or soother made of elastomer or rubber).

The standard specifies that the limits are expressed as an amount of substances migrating from 1 kg of elastomer or rubber component.

4.2.6.3 Requirements for MBT release in EN 1400

The following migration limit value for MBT (2-mercaptobenzothiazole, CAS 149-30-4) is listed in EN 1400 (2013a) and is valid for the vulcanised rubber components of the soothers:

- MBT: 8 mg/kg (ppm)

The limit is expressed as amount of substance migrating from 1 kg of rubber. The test method is specified in the standard (EN 1400, 2013a).

4.2.6.4 Requirements for antioxidant release in EN 1400

The following release limit values for certain antioxidants are listed in EN 1400 (2013a) and are valid for the vulcanised rubber components of the soothers:

- BHT (CAS 128-37-0): 0.3125 mg/l simulant
- Cyanox 425 (CAS 88-24-4) and Antioxidant 2246 (CAS 119-47-1): 0.0625 mg/l simulant
- Wingstay L (CAS 68610-51-5): 0.25 mg/l simulant
- Irganox 1520 (CAS 110553-27-0) and Irganox 1726 (CAS 110675-26-8): 0.25 mg/l simulant

4.2.6.5 Requirements for formaldehyde migration in EN 1400

The following migration limit value for formaldehyde (CAS 50-00-0) is listed in EN 1400 (2013a) and is valid for the vulcanised rubber and silicone components of the soothers:

- Formaldehyde (CAS 50-00-0): 0.375mg/l simulant

The limit is expressed as amount of substance per litre of simulant (EN 71-11). The test method is specified in EN 71-11:2005.

4.2.6.6 Requirements for Bisphenol A migration in EN 1400

The following migration limit value for Bisphenol A (CAS 80-05-7) is listed in EN 1400 (2013a) and is valid for the thermoplastic parts of the soothers:

- Bisphenol A (CAS 80-05-7): 0.125 mg/l simulant

The limit is expressed as amount of substance per litre of simulant (EN 71-11). The test method is specified in EN 71-11:2005. It is emphasised that Bisphenol A migration should only be carried out on thermoplastics that use Bisphenol A in their manufacture, such as polycarbonates. Bisphenol A is not used in the production of other common thermoplastics, such as polypropylene and polyethylene (EN 1400, 2013a).

4.2.6.7 Requirements for content of volatile compounds in EN 1400

According to EN 1400 (2013a), the content of volatile compounds shall not exceed 0.5% (5000 ppm) based on the test method listed in the standard. This limit value only applies for silicone rubber components.

4.2.6.8 Requirements listed in draft new version: EN1400:2013/ FprA1

The draft new version of EN1400/FprA1 (2013b) does not contain any changes to the chemical requirements of EN 1400 (2013a).

4.2.7 EN 12790:2002 – Reclined cradles

The standard EN 12790 (2002) deals with reclined cradles, which are intended for accommodating a child in a reclined position either as static,

rocker or bouncer type or a combination of these. The only chemical requirement listed in EN 12790 (2002) is that the surface of any parts, plastic coatings or finishes shall comply with EN 71-3.

There is no specific dated reference for EN 71-3 which means that the latest edition of EN 71-3 applies, i.e. EN 71-3:2013, meaning that the requirements for the extended list of 18 different elements apply.

4.2.8 EN 1888:2012 – Wheeled child conveyances

The standard EN 1888 (2012) deals with wheeled child conveyances which are defined as vehicles designed for the carriage of one or more children consisting of a chassis to which a pram body (bodies) or car seat unit(s) or combination of these is (are) attached, which can be manually steered while being pushed or pulled. The only chemical requirement listed in EN 1888 (2012) is that migration of elements from coatings of paint, varnish, lacquer, printing ink, polymer and similar coatings and from any other accessible surfaces of materials within the protected volume whether mass coloured or not shall not exceed the amounts listed in EN 71-3:1994.

It is stated in the standard that the test sample shall not include the base material where a surface is coated with a multi-layer of paint or similar coating.

A specific reference is made to the EN 71-3:1994 version, i.e. it is the 'old' migration limits that apply for the eight metals and not the 'new' migration limits for the 18 elements as listed in EN 71-3:2013.

4.2.9 EN 13209-1:2004 – Baby carriers (framed back carriers)

The standard EN 13209-1 (2004) deals with baby carriers, which are defined as child back carriers with framed support. The only chemical requirement listed in EN 13209-1 (2004) is that migration of elements from coatings of paint, varnish, lacquer, printing ink, polymer and similar coatings and from other materials whether mass coloured or not shall comply with the limit values listed for the eight metals in EN 71-3.

It is stated in the standard, that the test sample shall not include the substrate where a surface is coated with a multi-layer of paint or similar coating.

There is no specific dated reference for EN 71-3 which means that the latest edition of EN 71-3 applies, i.e. EN 71-3:2013, meaning that the requirements for the extended list of 18 different elements apply.

The standard also includes a requirement for flammability of textiles, coated textiles, supports and plastic coverings. The requirement concerns the rate of the spread of a flame. This requirement could be fulfilled by the use of chemical flame retardants, but the requirements are not demanding the use of such flame retardants. Other solutions may be used as well.

4.2.10 EN 13209-2:2005 and draft new version – Baby carriers (soft carriers)

The standard EN 13209-2 (2005) deals with soft baby carriers, which are defined as child back carriers without framed support. The only chemical

requirement listed in EN 13209-2 (2005) is that migration of elements from coatings of paint, varnish, lacquer, printing ink, polymer and similar coatings and from other materials whether mass coloured or not shall comply with the limit values listed for the eight metals in EN 71-3. Furthermore, it is stated that any surface coatings of paint, varnish, lacquer or similar substances and parts consisting of dyed materials, leather and textiles shall be made by use of products, which in their soluble compound do not exceed the limit values listed for the eight metals in EN 71-3.

It is stated in the standard, that the sample shall not include the substrate where a surface is coated with a multi-layer of paint or similar coating. A separate sample shall be used to assess these requirements.

There is no specific dated reference for EN 71-3 which means that the latest edition of EN 71-3 applies, i.e. EN 71-3:2013, meaning that the requirements for the extended list of 18 different elements apply.

The standard also includes a requirement for flammability. The requirement concerns the rate of the spread of a flame. This could indirectly imply the need for use of chemical flame retardants.

The draft new version of EN13209-2 (2012) contains one change: now a specific reference to EN 71-3: 1994 is listed, which means that it is the 'old' migration limits that apply for the eight metals and not the 'new' migration limits for the 18 elements as listed in EN 71-3:2013.

4.2.11 EN 13210:2004 – Children's harnesses, reins and similar articles

The standard EN 13210 (2004) deals with children's harnesses, reins and similar types of articles. Harnesses are defined as products designed to fit around a child's torso with the intention to restrain the child, when used with specific attachment points on a child care article or with a walking rein. The only chemical requirements listed in EN 13210 (2004) are:

- Migration of certain elements
- Content and migration of nickel

The migration of elements from plastic, any coatings of paint, varnish, lacquer or similar substances and parts consisting of dyed materials, leather and textiles shall be made by use of products, which in their soluble compound shall comply with the limit values listed for the eight metals in EN 71-3.

It is stated in the standard that the sample shall be taken down to the substrate where a surface is coated with a multi-layer of paint or similar coating. The test procedure shall be as defined in EN 71-3.

There is no specific dated reference for EN 71-3 which means that the latest edition of EN 71-3 applies, i.e. EN 71-3:2013, meaning that the requirements for the extended list of 18 different elements apply.

For the requirement regarding content and migration of nickel, the following limit values are set which are similar to the requirement as listed in REACH Annex XVII entry no. 27:

- Migration of nickel shall not exceed $0.5 \mu\text{g}/\text{cm}^2/\text{week}$ when tested in accordance with EN 1811:2011 (release of nickel from products intended to come into direct and prolonged contact with the skin).
- Migration of nickel shall not exceed $0.5 \mu\text{g}/\text{cm}^2/\text{week}$ when tested in accordance with EN 12472:2005+A1:2009 (detection of nickel from coated items).

4.2.12 EN 14036:2003 – Baby bouncers

The standard EN 14036 (2003) deals with baby bouncers which are products that suspend a child in a vertical position with the child's feet in contact with the floor to activate a bouncing action. The only chemical requirement listed in EN 14036 (2003) is that migration of elements from any coatings of paint, varnish, lacquer or similar substances and parts consisting of dyed materials, leather and textiles shall be made by use of products, which in their soluble compound shall comply with the limit values listed for the eight metals in EN 71-3.

It is stated in the standard that the sample shall be taken down to the substrate where a surface is coated with a multi-layer of paint or similar coating.

There is no specific dated reference for EN 71-3 which means that the latest edition of EN 71-3 applies, i.e. EN 71-3:2013, meaning that the requirements for the extended list of 18 different elements apply.

The standard also includes a requirement for flammability. The requirement is that no part of the baby bouncer can give rise to surface flash when tested in accordance with EN 71-2. This requirement could be fulfilled by the use of chemical flame retardants, but the requirements are not demanding the use of such flame retardants. Other solutions may be used as well.

4.2.13 EN 14344:2004 – Child seats for cycles

The standard EN 14344 (2004) deals with child seats for cycles and the only chemical requirements listed in EN 14344 (2004) are:

- Requirements according to EN 71-3
- Content and migration of nickel

It is stated in the standard EN 14344 (2004) that the seats shall comply with the requirements of EN 71-3. There is no specific dated reference for EN 71-3 which means that the latest edition of EN 71-3 applies, i.e. EN 71-3:2013, meaning that the requirements for the extended list of 18 different elements apply. There is no reference to which materials that the requirement applies for. Therefore this indicates that the requirement of EN 71-3 applies for any materials.

For the requirement regarding content and migration of nickel, the following limit value is set which is similar to the requirement as listed in REACH Annex XVII entry no. 27:

- Nickel shall not be used in parts of the seat which may come into direct contact with the skin, if the rate of nickel release from these parts is greater than $0.5 \mu\text{g}/\text{cm}^2/\text{week}$ when tested in accordance with

EN 1811:2011 (release of nickel from products intended to come into direct and prolonged contact with the skin).

4.2.14 EN 14350-2:2004 – Drinking equipment

The standard EN 14350-2 (2004) deals with chemical requirements for drinking equipment for children. Drinking equipment is defined as a container with a teat or any other device than a feeding teat which permits a child to obtain fluid from a container. The standard contains several chemical requirements for the following types of chemicals:

- Elements – migration
- N-nitrosamines and N-nitrosatable substances – release
- 2-Mercaptobenzothiazole (MBT) – release
- Antioxidants – release
- Bisphenol A – release
- Volatile compounds – content

The standard contains an overview of the types of materials that should be tested for the chemicals listed above. This overview is taken directly from the standard and is reproduced in Table 5. It is mentioned in the standard that the materials used in the manufacture of components of drinking equipment shall be subjected to the tests marked with an “x” in the table.

Table 5: Requirements and tests for different materials in drinking equipment according to EN 14350-2 (2004), Table 1.

Material	Migration of certain elements (see 5.2)	N-Nitrosamines and N-Nitrosatables release (see 5.3)	MBT release (see 5.4)	Anti-oxidants release (see 5.4)	BPA release (see 5.5)	Volatile compounds content (see 5.6)
Vulcanised rubber	x	x	x	x		
Silicone rubber	x	x				x
Thermoplastic elastomers (TPEs)	x	x				
Glass	x					
Thermoplastics	x				x ^a	

^a Only thermoplastics containing polycarbonate or polysulfone shall be tested for Bisphenol A release

4.2.14.1 Requirements for elements in EN 14350-2

The requirement for elements in EN 14350-2 (2004) refers to EN 71-3 (undated reference) for test methods; however, the migration limits that are listed differ from the migration limits in EN 71-3 (2013). In Table 6 below the migration limits in EN 71-3 (2013) is listed for comparison as well as the migration limits listed in EN 14350-2 (2004) for drinking equipment. In general much lower limit values apply compared to the EN 71-3 (2013a) limit values for plastic or glass bottles.

Table 6: Comparison of migration limits for elements listed in EN 71-3 (2013) and EN 14350-2 (2004) for drinking equipment. All migration limits are measured in mg/kg.

Element	EN 71-3 (based on TSD 2009/48/EC)			EN 14350-2 (2004)
	Category I Dry, brittle, powder-like or pliable toy material (mg/kg)	Category II Liquid or sticky toy material (mg/kg)	Category III Scraped-off toy material (mg/kg)	Limits of elements migration from drinking equipment (mg/kg)
Aluminium	5,625	1,406	70,000	
Antimony	45	11.3	560	15
Arsenic	3.8	0.9	47	10
Barium	1,500	375	18,750	100
Boron	1,200	300	15,000	
Cadmium	1.3	0.3	17	20
Chromium (III)	37.5	9.4	460	10
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	25
Manganese	1,200	300	15,000	
Mercury	7.5	1.9	94	10
Nickel	75	18.8	930	
Selenium	37.5	9.4	460	100
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	

4.2.14.2 N-nitrosamines and N-nitrosatable substances limit values in EN 14350-2

The requirement for N-nitrosamines and N-nitrosatable substances in EN 14350-2 (2004) refers to EN 12868 (undated reference) for test methods. The limit values for N-nitrosamines and N-nitrosatable substances are as listed in Directive 93/11/EEC concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats:

- 0.01 ppm (mg/kg) in total of N-nitrosamines released (of the parts of teat or soother made of elastomer or rubber).
- 0.1 ppm (mg/kg) in total of N-nitrosatable substances (of the parts of teat or soother made of elastomer or rubber).

4.2.14.3 Requirements for MBT release in EN 14350-2

The following migration limit value for MBT (2-mercaptobenzothiazole, CAS 149-30-4) is listed in EN 14350-2 (2004) and is valid for the vulcanised rubber components of the drinking equipment:

- MBT: 8 mg/kg (ppm)

The test method is specified in the standard (EN 14350-2, 2004).

4.2.14.4 Requirements for antioxidant release in EN 14350-2

The following release limit values for certain antioxidants are listed in EN 14350-2 (2004) and are valid for the vulcanised rubber components of the drinking equipment:

- BHT (CAS 128-37-0): 30 µg/100 ml or 60 µg/dm²
- Antioxidant 2246 (CAS 119-47-1): 15 µg/100 ml or 30 µg/dm²

4.2.14.5 Requirements for Bisphenol A migration in EN 14350-2

The following migration limit value for Bisphenol A (CAS 80-05-7) is listed in EN 14350 (2004) and is valid for the thermoplastic parts of the drinking equipment:

- Bisphenol A (CAS 80-05-7): 0.03 µg/ml

4.2.14.6 Requirements for content of volatile compounds in EN 14350-2

According to EN 14350-2 (2004) the content of volatile compounds shall not exceed 0.5% (5000 ppm) based on the test method listed in the standard. This limit value only applies for silicone rubber components.

4.2.15 EN 14372:2004 – Cutlery and feeding utensils

The standard EN 14372 (2004) deals with cutlery (such as knives, forks, spoons and food pushers) and feeding utensils (containers such as plates and bowls) for babies and young children. The standard contains several chemical requirements for the following types of chemicals:

- Elements – migration
- Phthalates - content
- Volatile compounds – content
- Formaldehyde – migration
- Nickel - release
- Bisphenol A – release

The standard contains an overview of the types of materials that should be tested for the chemicals listed above. This overview is taken directly from the standard and is reproduced in Table 7. It is mentioned in the standard that materials used in the manufacturing of components of cutlery and feeding utensils shall be subjected to the tests marked with an “x” in the table.

Table 7: Requirements and tests for different materials in cutlery and feeding utensils according to EN14372 (2004), Table 1.

Material	Tests					
	Migration of certain elements (see 6.3.1)	Phthalate content (see 6.3.2)	Volatile compounds content (see 6.3.3)	Formaldehyde release (see 6.3.4)	Nickel release (see 6.3.5)	Bisphenol A release (see 6.3.6)
Silicone rubber	x		x			
Thermoplastic elastomers (TPEs)	x					
Glass, ceramics, glass-ceramics, vitreous enamels and other enamels	x					
Thermoplastics	x	x				x ^a
Thermosetting plastics	x			x		
Metals / Alloys	x				x	
Wood	x			x		

^a Only thermoplastics containing polycarbonate or polysulfone shall be tested for Bisphenol A release

4.2.15.1 Requirements for elements in EN 14372

The requirement for elements in EN 14372 (2004) refers to EN 71-3 (undated reference) for test methods; however, the migration limits that are listed differ from the migration limits in EN 71-3 (2013). It is stated in the EN 14372 (2004) standard (in Table 2) that “the limits have been set based

on the limit of detection for each element using commonly available analytical techniques”. Therefore the limit values are of quite different nature than the limits set in the toy standard (EN 71-3 (2013)) which are based on exposure and a fraction of the TDI value for each element. Instead the EN 14372 (2004) standard simply reduces the limit values to the possible detection limits.

In Table 8 below the migration limits in EN 71-3 (2013) are listed for comparison as well as the migration limits listed in EN 14372 (2004) for cutlery and feeding utensils. The migration limit values set for the elements in EN 14372 (2004) are in general lower than the limit values in the toy standard (EN 71-3 (2013)) because the detection limits of commonly available analytical techniques for the elements have been used.

Table 8: Comparison of migration limits for elements listed in EN 71-3 (2013) and EN 14372 (2004) for cutlery and feeding utensils. All migration limits are measured in mg/kg.

Element	EN 71-3 (based on TSD 2009/48/EC)			EN 14372 (2004)
	Category I Dry, brittle, powder-like or pliable toy material (mg/kg)	Category II Liquid or sticky toy material (mg/kg)	Category III Scraped-off toy material (mg/kg)	Limits of elements migration from soothers (mg/kg)
Aluminium	5,625	1,406	70,000	
Antimony	45	11.3	560	15
Arsenic	3.8	0.9	47	10
Barium	1,500	375	18,750	100
Boron	1,200	300	15,000	
Cadmium	1.3	0.3	17	20
Chromium (III)	37.5	9.4	460	10
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	25
Manganese	1,200	300	15,000	
Mercury	7.5	1.9	94	10
Nickel	75	18.8	930	
Selenium	37.5	9.4	460	100
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	

4.2.15.2 Phthalate limit values in EN 14372

The requirement for phthalates in EN 14372 (2004) is that the total content of the following phthalates shall not exceed 0.1% (or 1000 ppm) in thermoplastic components of cutlery and feeding utensils:

- DINP (CAS 28553-12-0)
- DEHP (CAS 117-81-7)
- DNOP (CAS 117-84-0)
- DIDP (CAS 26761-40-0)
- BBP (CAS 85-68-7)

- DBP (CAS 84-74-2)

However, it is not clear whether the total content refers to the sum of all six phthalates or for the six phthalates individually.

It is the same six phthalates which are restricted by REACH Annex XVII. However, REACH only restricts three of the phthalates (DEHP, DBP and BBP) in all child care articles and the three other phthalates (DINP, DIDP and DNOP) in child care articles which can be placed in the mouth by children. The restriction in the standard EN 14372 (2004) is therefore more strict than the restriction in REACH Annex XVII.

The test method to be used is described in the EN 14372 (2004) standard.

4.2.15.3 Requirements for content of volatile compounds in EN 14372

According to EN 14372 (2004) the content of volatile compounds shall not exceed 0.5% (5000 ppm) based on the test method listed in the standard. This limit value only applies for silicone rubber components of cutlery and feeding utensils.

4.2.15.4 Requirements for formaldehyde release in EN 140372

The following migration limit value for formaldehyde (CAS 50-00-0) is listed in EN 14372 (2004) and is valid for the thermosetting plastic or wood components of cutlery and feeding utensils:

- Formaldehyde (CAS 50-00-0): Release shall not exceed 15 mg/kg migration liquid

The test method is specified in EN ISO 4614.

4.2.15.5 Requirements for nickel release in EN 140372

According to EN 14372 (2004), the release of nickel shall not exceed 0.5 µg/cm²/week based on the test method listed in the standard EN 1811. This limit value only applies for all metal or alloys components. This limit value is similar to the requirement as listed in REACH Annex XVII entry no. 27.

4.2.15.6 Requirements for Bisphenol A migration in EN 14372

The following migration limit value for Bisphenol A (CAS 80-05-7) is listed in EN 14372 (2004) and is valid for polycarbonate and polysulfone containing thermoplastic components of cutlery and feeding utensils:

- Bisphenol A (CAS 80-05-7): 0.03 µg/ml aqueous food simulant

The limit is expressed as amount of substance per millilitre of food simulant. The test method is specified in EN 14372 (2004).

4.2.16 EN 16120:2012 – Chair mounted seat

The standard EN 16120 (2012) deals with chair mounted seats, i.e. chairs that are intended to be mounted on adult chairs. The only chemical requirement listed in EN 16120 (2012) is that the migration of elements from coatings of paint, varnish, lacquer, polymer and similar coatings on exterior surfaces shall comply with the limit values listed for the eight metals in EN 71-3. The limit values shall be verified in accordance with the test method given in EN 71-3:1994.

It is stated in the standard that the test sample shall not include the base material where a surface is coated with a multi-layer of paint or similar coating. A separate sample may be used for these tests.

A specific reference to the EN 71-3:1994 version is made, i.e. it is the 'old' migration limits that apply for the eight metals and not the 'new' migration limits for the 18 elements as listed in EN 71-3:2013.

4.2.17 EN 16232:2013 – Infant swings

The standard EN 16232 (2013) deals with infant swings, i.e. products with a stationary unit with a frame and mechanism that enable a child unable to sit up unaided to be swung. The only chemical requirement listed in EN 16232 (2013) is that the migration of synthetic or natural elements from coatings of paint, varnish, lacquer, polymer and similar coatings on exterior surfaces shall comply with the limit values listed for the eight metals in EN 71-3. The limit values shall be verified in accordance with the test method given in EN 71-3:1994.

It is stated in the standard that the test sample shall not include the base material where a surface is coated with a multi-layer of paint or similar coating. A separate sample may be used for these tests.

A specific reference to the EN 71-3:1994 version is made, i.e. it is the 'old' migration limits that apply for the eight metals and not the 'new' migration limits for the 18 elements as listed in EN 71-3:2013.

4.3 Conclusions on chemical requirements for child care articles

In the following tables (Table 9 and Table 10), the above mentioned standards (listed in Table 1 and Table 2) are described and the chemical requirements in the standards are listed. The chemical requirements have been described in more details in section 4.2.1 to section 4.2.17. The standards are only listed in the tables below if chemical requirements are present.

Table 9: Overview of the chemical requirements in existing published standards

Chemical/ group of chemicals	Requirement	Product	Test methods/comments
Metals	For surfaces of the materials: migration limits in EN 71-3:1994 apply	Table mounted chairs (EN 1272)	Specific reference (to 1994 version), i.e. the new version does not apply.
	For any surface, plastics, coatings or finishes: migration limits in EN 71-3 apply	Baby walking frames (EN 1273)	No specific reference, i.e. the new (2013) version applies. Castors and wheels are excluded.
	Inside surfaces of parts accessible to the child: migration limits in EN 71-3 apply	Carrycots and stands (EN 1466)	No specific reference, i.e. the new (2013) version applies.
	For any coating and any other accessible surfaces: migration limits in EN71-3 apply	Safety barriers (EN 1930)	No specific reference, i.e. the new (2013) version applies.
	For any coating, leather, textiles and plastic materials accessible to the child: migration limits in EN 71-3 apply	Changing units (EN 12221-1)	No specific reference, i.e. the new (2013) version applies.

Chemical/ group of chemicals	Requirement	Product	Test methods/comments
	For any material used: specific (lower) migration limits in EN 1400:2013 apply	Soothers (EN 1400)	No specific reference, but specific migration limit values are listed in the standard.
	For any material used: specific (lower and/or higher) migration limits in EN 1400:2013 apply	Drinking equipment (EN 14350-2)	No specific reference, but specific migration limit values are listed in the standard.
	For any material used: specific (lower) migration limits in EN 1400:2013 apply	Cutlery and feeding utensils (EN 14372)	No specific reference, but specific migration limit values are listed in the standard.
	For any parts, plastic coatings or finishes: migration limits in EN 71-3 apply	Reclined cradles (EN 12790)	No specific reference, i.e. the new (2013) version applies.
	For any coating and any other accessible surfaces: migration limits in EN 71-3:1994 apply	Wheeled child conveyances (EN 1888)	Specific reference (to 1994 version), i.e. the new version does not apply.
	For any coating and any other materials: migration limits in EN 71-3 apply	Framed back carriers (EN 13209-1)	No specific reference, i.e. the new (2013) version applies.
	For any coating and any other materials: migration limits in EN 71-3 apply	Soft carriers (EN 13209-2)	No specific reference, i.e. the new (2013) version applies.
	For any coating, leather, textiles and plastic materials: migration limits in EN 71-3 apply	Harnesses, reins and similar articles (EN 13210)	No specific reference, i.e. the new (2013) version applies.
	For any coating, leather and textiles materials: migration limits in EN 71-3 apply	Baby bouncers (EN 14036)	No specific reference, i.e. the new (2013) version applies.
	For any material and coating: migration limits in EN 71-3 apply	Child seats for cycles (EN 14344)	No specific reference, i.e. the new (2013) version applies.
	For any coating on exterior surfaces: migration limits in EN 71-3:1994 apply	Chair mounted seat (EN 16120)	Specific reference (to 1994 version), i.e. the new version does not apply.
	For any coating on exterior surfaces: migration limits in EN 71-3:1994 apply	Infant swings (EN 16232)	Specific reference (to 1994 version), i.e. the new version does not apply.
Nickel	For any material: migration limit value of 0.5 µg/cm ² /week	Harnesses, reins and similar articles (EN 13210)	Test method described in EN 1811 and EN 12472.
	For parts in direct contact with skin: migration limit value of 0.5 µg/cm ² /week	Child seats for cycles (EN 14344)	Test method described in EN 1811.
	For metal and alloys: the release of nickel may not exceed 0.5 µg/cm ² /week	Cutlery and feeding utensils (EN 14372)	Test method described in EN 1811.
N-nitrosamines and N-nitrosatable substances	For rubber and thermoplastic elastomers (TPEs): migration as in Directive 93/11/EEC on soothers (0.01 and 0.1 ppm respectively)	Soothers (EN 1400)	Test method described in EN 12686.
		Drinking equipment (EN 14350-2)	Test method described in EN 12686.
MBT	Migration from vulcanised rubber components must not exceed 8 ppm	Soothers (EN 1400)	Test method described in EN 1400.
		Drinking equipment (EN 14350-2)	Test method described in EN 14350-2.
Certain antioxidants	Release from vulcanised rubber components: release limits in EN 1400:2013 apply Limit values for six antioxidants	Soothers (EN 1400)	Test method described in EN 1400.
	Release from vulcanised rubber components: release limits in EN 14350-2 apply Limit values for two antioxidants	Drinking equipment (EN 14350-2)	Test method described in EN 14350-2.
Formaldehyde	Migration from vulcanised rubber and silicone rubber components must not exceed 0.375 mg/l simulat	Soothers (EN 1400)	Test method described in EN 71-11.

Chemical/ group of chemicals	Requirement	Product	Test methods/comments
	Release from thermosetting plastic or wood components must not exceed 15 mg/kg migration liquid	Cutlery and feeding utensils (EN 14372)	Test method described in EN ISO 4614.
Bisphenol A	Migration from thermoplastics (polycarbonates) must not exceed 0.125 mg/l simulant	Soothers (EN 1400)	Test method described in EN 71-11.
	Migration from thermoplastics must not exceed 0.03 µg/ml (= 0.03 mg/l)	Drinking equipment (EN 14350-2)	Test method described in EN 14350-2.
	Migration from polycarbonate and polysulfone containing thermoplastic components must not exceed 0.03 µg/ml (= 0.03 mg/l) into aqueous food simulant	Cutlery and feeding utensils (EN 14372)	Test method described in EN 14372.
Volatile compounds	Content in silicone rubber components must not exceed 0.5%	Soothers (EN 1400)	Test method described in EN 1400.
		Cutlery and feeding utensils (EN 14372)	Test method described in EN 14372.
Phthalates	Total content in thermoplastics: the six phthalates (DEHP, BBP, DBP, DINP, DNOP and DNOP) shall not exceed 0.1% (1000 ppm)	Cutlery and feeding utensils (EN 14372)	Test method described in EN 14372.

Table 10: Overview of the chemical requirements in standards under development

Chemical	Requirement	Product	Comment
Metals	Inside surfaces of parts accessible to the child: EN 71-3:1994	Carrycots and stands (Draft prEN 1466)	Specific reference (to 1994 version), i.e. the new version does not apply.
	For any coating and any other materials: migration limits in EN 71-3:1994 apply	Soft carriers (Draft prEN 13209-2)	Specific reference (to 1994 version), i.e. the new version does not apply.

The tables show that for 17 of the published standards listed in Table 1, a chemical requirement concerning the migration of metals is included in the standards. It is actually almost all of the standards that contain this requirement for migration of elements as a few of the standards listed in Table 1 only deal with test methods or translation of warnings or similar.

However, as it can be seen from Table 9 it is only a few other standards that go further and include other chemical requirements besides the migration of elements requirement:

- Nickel is only restricted in three standards.
- N-nitrosamines and N-nitrosatable substances are restricted in the two standards dealing with soothers and baby bottles.
- MBT is restricted in the two standards dealing with soothers and baby bottles.
- Certain antioxidants are restricted in the two standards dealing with soothers and baby bottles.
- Formaldehyde is restricted in the two standards dealing with soothers and cutlery/feeding utensils.
- Bisphenol A is restricted in the three standards dealing with soothers, baby bottles and cutlery/feeding utensils.
- Volatile compounds are only restricted in the two standards dealing with soothers and cutlery/feeding utensils.
- Phthalates are only restricted in the standard dealing with cutlery and feeding utensils.

To conclude, in general it is only requirements concerning migration of elements that are included in the standards for child use and care articles unless the child use and care articles are used directly in the mouth of babies and young children, i.e. products such as soothers, baby bottles, and cutlery and feeding utensils. In this case other chemicals are restricted as well. Of course it makes perfect sense to restrict more chemicals for products that are intended to be placed in the mouth of babies. However, it may also be relevant to restrict other groups of chemicals such as CMR substances, allergenic substances etc. in line with the Toy Safety Directive for child use and care articles where the main exposure is through skin (i.e. for child seats, baby carriers etc.).

5 Examples of chemicals identified in child use and care articles

This chapter describes examples of hazardous substances found in child use and care articles. The different examples are listed and followed by a short description.

Some of the examples are repeated from the report “Chemical requirements for consumer products – Proposals for regulatory measures to improve chemical safety for consumers” (Poulsen et al., 2010) but the list of examples has been updated with new examples from 2010 and forward.

The examples are summarised in a table (Table 12) at the end of this chapter.

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

5.1 Sources used

The examples found regarding chemicals in child use and care articles have mainly been found by use of the following sources:

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

The Danish EPA has published over 100 surveys of chemicals in consumer products during the past 10 years. Hazardous substances have been identified in all surveys. In many of the surveys a risk assessment has been made as well in order to determine whether the hazardous substances found constitute a risk to human health when looking at the exposure of the substances individually from these products. Generally the hazardous substances found do not result in risks to human health when looking at the products examined individually. A risk to human health was only found in a very few cases such as use of phthalates in eraser.

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

Of **other authorities** can be mentioned the Norwegian Climate and Pollution Agency (former called SFT) and the Swedish Chemicals Agency (Kemi).

Surveys from the following **NGOs** have been listed:

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

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

The **German magazine “Öko-test” magazine** and the **Danish magazine “Tænk”** often test child use and care articles for the content of hazardous substances. Some of their most recent tests are included as examples.

Others than the above **searches on the Internet** have been performed.

5.2 Examples of chemicals in child use and care articles

This chapter lists a number of examples of problematic chemicals found in consumer products. The list, which is not an exhaustive list, covers the examples as listed in Table 11.

The list primarily covers examples of problematic chemicals found in child use and care articles that are not “illegal”, meaning that there are no restrictions on these substances for the described products, which are not complied with. However, some of the examples mentioned may have resulted in a withdrawal of the products from the market as a potential health risk (as calculated in a risk assessment) is in violation with the EU General Product Safety Directive.

Table 11: Examples of problematic chemicals found in child use and care articles

Example	Source	Year
<i>Products for mouthing</i>		
Chemicals in silicone dummies	Öko-Test	2012
Chemicals in toothbrushes for children	Öko-Test	2012
Chemicals in baby drinking bottles	Öko-Test	2011
Bisphenol A in baby bottles	Öko-Test	2011
Bisphenol A in baby dummies	Danish EPA	2011
PAHs in toothbrushes for children	Öko-test	2008
<i>Products for transportation</i>		
Chemicals in running bikes	Danish Consumer Council Tænk	2013
Child safety seats	Danish Consumer Council Tænk	2013
Dangerous chemical in safe child safety seat	Politiken.dk	2013

Example	Source	Year
Combination prams	Danish Consumer Council	2012
Chemicals in baby harnesses	Öko-Test	2011
Chemicals in child safety seats	FDM	2011
Chemicals in folding pushchairs	Öko-Test	2011
Hazardous substances in prams	Test (German magazine)	2009
PAHs in running bikes	Öko-test	2008
<i>Clothes/textiles and shoes</i>		
Baby sleeping bags	Öko-Test	2013
NP and NPE in textiles for children	Danish EPA	2013
NPE in children jeans	Test Fakta Sweden	2013
Chemicals in baby bibs	Öko-Test	2012
Thiourea in neoprene rubber products	Danish EPA	2012
Chemicals in children rainwear	Test Fakta Sweden	2012
Chemicals in textile crib protectors	Öko-Test	2012
Chemicals in baby lambskins	Öko-Test	2012
Chemicals in nursing pillows	Öko-Test	2011
Chemicals in baby crawling blankets	Öko-Test	2011
Chemicals in textiles	Danish EPA	2011
Chromium in leather shoes	Danish EPA	2011
Phthalates in plastic sandals	Danish EPA	2010
Phthalates in ski mittens	Norwegian Climate and Pollution Agency	2010
Hazardous substances in jackets and mittens	Danish EPA	2009
Children bed linens and football T-shirts	Öko-test	2009
Hazardous chemicals in plastic shoes	Swedish Society for Nature Conservation and Danish EPA	2009
PAHs in rain proof clothes	Öko-test	2008
Chemicals in bath towels	Swedish Society for Nature Conservation and Danish EPA	2007
Fluorinated pollutants in all-weather clothing	Friends of the Earth Norway	2006
Toxic children's wear	Greenpeace	2004
<i>Furniture</i>		
Beanbags	Öko-test	2013
Flame retardants in children's furniture	Center for Environmental Health	2013
Chemicals in travelling beds for children	Öko-Test	2012
Chemicals in children mattresses	Öko-Test	2012
Flame retardants in children mattresses	Chicago Tribune	2012
Chemicals in baby high chairs	Öko-Test	2011
<i>Electronics</i>		
Hazardous substances in games console components	Greenpeace	2008
<i>Personal protection equipment</i>		
Children ski helmets	Austrian Standards Institute	2006
<i>Indoor climate</i>		
Indoor climate	Danish EPA	2006
<i>Other relevant examples</i>		
Children's heating pads	Öko-Test	2013
Chemicals in nursing pillows	Öko-Test	2013
Bisphenol A in child care articles	Swedish Chemicals Agency	2012
PAH in child care products	Danish EPA	2011
Chemicals in felt tip pens and crayons	Danish Consumer Council	2011
Phthalates in products for children	Danish EPA	2010
Endocrine disrupting substances that two-year-old children are exposed to	Danish EPA	2009
Phthalates in products for children	Danish Information Centre for Environment and Health	2009
Hazardous substances in baby products	Danish EPA	2008
Erasers	Danish EPA and Öko-test	2007

Each of the above examples is described shortly in the text below.

5.2.1 Products for mouthing

5.2.1.1 Chemicals in silicone dummies (2012) – Öko-Test

The German magazine Öko-Test has tested 17 different silicone dummies for children and found PAH in 6 of them in higher amounts, i.e. above 100 µg/kg (Öko-Test No. 8, 2012).

5.2.1.2 Chemicals in toothbrushes for children (2012) – Öko-Test

The German magazine Öko-Test has tested 13 different toothbrushes for children and found PAH in 5 of them and chlorinated organic compounds in 8 of the toothbrushes. No concentrations are listed (Öko-Test No. 9, 2012).

5.2.1.3 Chemicals in baby drinking bottles (2011) – Öko-Test

The German magazine Öko-Test has tested 12 different baby drinking bottles and has found PAHs in one of the baby drinking bottles. No concentrations are listed. In two of the baby drinking bottles the printing on the outside of the bottles was based on PVC or chlorinated hydrocarbons (Öko-Test No. 10, 2011b).

5.2.1.4 Bisphenol A in baby bottles (2011) – Öko-Test

The German magazine Öko-Test has tested 16 different baby bottles and found Bisphenol A in the two baby bottles based on polycarbonate. No concentrations are listed (Öko-Test No. 1, 2011).

5.2.1.5 Bisphenol A in baby dummies (2011) – Danish EPA

The Danish EPA has investigated the content of Bisphenol A in baby dummies (pacifiers). The investigation shows that 10-20% of the baby dummies on the market are made of polycarbonate which can contain small quantities of Bisphenol A. However, the part of polycarbonate based baby dummies on the market is decreasing.

A total of 8 baby dummies was analysed for the migration of Bisphenol A. In 2 out of the 8 baby dummies the migration of Bisphenol A to artificial sweat and saliva was above the detection limit. A risk assessment carried out in the project showed that there is no health risk to children because of the exposure to Bisphenol A in baby dummies (Danish EPA No. 110, 2011).

5.2.1.6 PAHs in children toothbrushes (2008) – Öko-test

Öko-test has tested children toothbrushes and found Polycyclic Aromatic Hydrocarbons (PAHs) that are known for their carcinogenic, mutagenic, and teratogenic properties in amounts between 100 and 1000 µg/kg (0.1-1 ppm) (Öko-test 4, 2008).

5.2.2 Products for transportation

5.2.2.1 Chemicals in running bikes (2013) – Danish Consumer Council

The Danish Consumer Council has tested 10 running bikes for small children for content of phthalates, PAHs and flame retardants. No PAHs were found in handles or the saddles. However, phthalates were found in the saddles (maximum concentration of 15.5% DPHP) in two products or in the handles (maximum concentration of 0.18% DEHP and 0.05% DIDP) in one product. The flame retardant TCPP was found in the foam padding of the saddle in two running bikes (Danish Consumer Council Tænk, 2013a).

5.2.2.2 Child safety seats (2013) – Danish Consumer Council

In cooperation with ICRT (International Consumer Research & Testing), the Danish Consumer Council has tested in total 12 child safety seats for children in all age groups. The following chemicals were found in some of the child safety seats (Danish Consumer Council Tænk, 2013b):

- PAH was found in 4 of 12 child safety seats – maximum concentration was 26 mg/kg.
- Phthalates were found in one of the 12 child safety seats.

5.2.2.3 Dangerous chemical in safe child safety seat (2013) – Politiken.dk

The Danish newspaper Politiken refers to a test that FDM (the Danish association for motor owners) carried out on child safety seats. Most tested child safety seats are for children up to 13 kg and for children from 9-18 kg, i.e. for the age group up to 4 years. However, some of the tested child safety seats also cover the age group 1 to 12 years. In this test it turns out that the most safe child safety seat contains a high content of the carcinogenic substance naphthalene in the textile fabric which the child is in contact with (Politiken, 2013).

5.2.2.4 Combination prams (2012) – Danish Consumer Council

The Danish Consumer Council has tested 8 different combination prams for babies and small children, i.e. prams that can be used as a pram and a push chair/stroller at the same time. In one of the 8 combination prams the phthalate DNIP was found in the imitation leather on the front of the pram and in the shoulder straps (Danish Consumer Council Tænk, 2012).

5.2.2.5 Chemicals in baby harnesses (2011) – Öko-Test

The German test magazine Öko-Test has tested 9 different baby harnesses for different problematic chemicals. Chemicals found in one or more of the baby harnesses were optical brighteners, halogenated organic compounds, dispersive dyes, and in one baby harness p-chloroaniline was found (Öko-Test No. 4, 2011).

5.2.2.6 Chemicals in child safety seats (2011) - FDM

FDM (the Danish association for motor owners) carried out a test on child safety seats. Most tested child safety seats are for children up to 13 kg and for children from 9-18 kg, i.e. for the age group up to 4 years. However, some of the tested child safety seats also cover the age group 1 to 12 years. This test also included a test for chemicals in the textiles of the child safety seats. Flame retardants were found in one third of the child safety seats, and two different phthalates were found in small concentrations close to the REACH limit value in a few of the child safety seats. The phthalates were found in the padding and in the upholstery fabric (FDM, 2012).

5.2.2.7 Chemicals in folding pushchairs (2011) – Öko-Test

The German test magazine Öko-Test has tested 9 different folding pushchairs for small children for different problematic chemicals. PAHs were found in almost all of the pushchairs and in some cases in highly increased concentrations. Furthermore, halogenated organic compounds, phthalate (DEHT), perfluorinated compounds and phosphorous flame retardant (TCEP), (Öko-Test No. 6, 2011) were found.

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

The German magazine Test tested in 2009 14 different prams and pushchairs for babies and small children. The test included a test for PAHs (polyaromatic

hydrocarbons), phthalates (DEHP, DBP, BBP, DINP, DIDP, DNOP), chlorinated paraffines, flame retardants, organostannic compounds, nonylphenol and formaldehyde. None of the 14 prams/pushchairs was without all these groups of hazardous substances. Some prams/pushchairs only tested positive for formaldehyde, others tested positive for PAHs and flame retardants or for phthalates and flame retardants. The concentrations of the chemicals found in the tested products are not listed (Test No. 9, 2009).

5.2.2.9 PAHs in running bikes (2008) – Öko-test

The German magazine Öko-test has tested (the handles of) running bikes for small children and found Polycyclic Aromatic Hydrocarbons (PAHs) which are known for their carcinogenic, mutagenic, and teratogenic properties in amounts between 1,000 and 10,000 µg/kg (1-10 ppm). In 4 of the running bikes the amount was higher than 10,000 µg/kg. (Öko-test 4, 2008).

5.2.3 Clothes/textiles and shoes

5.2.3.1 Baby sleeping bags (2013) – Öko-Test

The German magazine Öko-Test has tested 14 sleeping bags for babies. The following chemicals were found (Öko-Test No. 2, 2013):

- Halogenated organic compounds
- Elements – antimony

5.2.3.2 NP and NPE in textiles for children (2013) – Danish EPA

The Danish EPA has investigated the content of nonylphenols (NP) and nonylphenoletoxylates (NPE) in 15 pieces of textiles for 2-year old children (bed linen, mittens, underwear, jeans and T-shirts). The highest concentration of NPE measured in the purchased children's wear was 310 mg NPE/kg textile, and the average concentration was 96 mg NPE/kg textile. No pattern was found regarding the types of textile (cotton or polyester, organic or non-organic) containing elevated concentrations of NP and NPE. Textiles with a higher concentration of NPE also tend to have one or more bright colours. Generally, the textiles from China - except a naturally coloured sweater - had higher concentrations of NPE (Danish EPA no. 120, 2013).

The report concludes that children can be exposed to NP and NPE in concentrations which can be problematic – however, if the textiles are washed before use, the content of NP and NPE is reduced considerably and the health risk is as well (Danish EPA no. 120, 2013).

5.2.3.3 NPE in children jeans (2013) – Test Fakta Sweden

The Swedish organisation Test Fakta has tested 10 children's jeans and found nonylphenolethoxylat in three of the jeans in concentrations up to 140 mg/kg. The jeans tested were in sizes between 98 and 134 cm, i.e. 2 years to 9 years old. Furthermore, the jeans were tested for the content of aniline (decomposition product of azo dyes). Nine of the ten jeans contained aniline and the highest measure concentration was 26 mg/kg (Test Fakta, 2013).

5.2.3.4 Chemicals in baby bibs (2012) – Öko-Test

The German magazine Öko-Test has tested 18 different baby bibs for content of hazardous chemicals. They found PAHs in 3 of the baby bibs, nonylphenolethoxylate in 3 of the bibs, halogenated organic compounds in 3 of the bibs and the organostannic compound DBT in one of the bibs.

Furthermore, they found optical brighteners in several of the bibs (Öko-Test No. 7, 2012a).

5.2.3.5 Thiourea in neoprene rubber products (2012) – Danish EPA

The Danish EPA has investigated the content and migration of thiourea compounds in different neoprene rubber (chloroprene rubber) products for children and adults. The specific age for the products for children investigated is not mentioned. In four of six products for children (wetsuits, rubber socks and bathing shoes) diethyl thiourea (DETU) was found in concentrations ranging from 33 to 720 mg/kg. Migration of DETU was measured to be between 0.9 and 1.8 µg/cm²/hour in these products. The content of DETU in the products was higher than the concentration which has been known to cause allergic reactions (192-251 mg/kg), (Danish EPA no. 118, 2012).

5.2.3.6 Chemicals in children rainwear (2012) – Test Fakta Sweden

The Swedish organisation Test Fakta has tested 12 rain wear sets for children and found phthalates and heavy metals (lead and cadmium) in two of the 12 rain wear sets. The specific age for the children rainwear products investigated is not mentioned. The concentration of phthalates was as high as 9% and 5.6% in the strip used for pulling the zipper. This strip is often chewed on by children when wearing the rain wear sets. The highest concentration of lead found in buttons in one of the rain wear sets was 0.2% (Test Fakta, 2012).

5.2.3.7 Chemicals in textile crib protectors (2012) – Öko-Test

The German magazine Öko-Test has tested 16 crib protectors of textiles (a broad textile boarder to put up in the crib near the mattress all the way round inside the crib). Öko-Test found the organostannic compound DBT in one of the crib protectors and found a phthalate in another crib protector. Aniline was also found in one of the crib protectors. Seven of the crib protectors contained antimony, and most of the crib protectors contained optical brighteners (Öko-Test No. 2, 2012).

5.2.3.8 Chemicals in baby lambskins (2012) – Öko-Test

The German magazine Öko-Test has tested 12 baby lambskins for content of problematic chemicals. The following chemicals were found (Öko-Test No. 10, 2012):

- Halogenated organic compounds were found in all of the baby lambskins.
- Formaldehyde was found in 3 of the 12 baby lambskins.
- Chromium was found in 4 of the 12 baby lambskins.
- Pesticide residues were found in 2 of the 12 baby lambskins.

5.2.3.9 Chemicals in nursing pillows (2011) – Öko-Test

The German magazine Öko-Test has tested 16 nursing pillows and 16 covers for nursing pillows. The following hazardous substances were found (Öko-Test No. 5, 2011):

- Organostannic compounds, TBT and DBT
- Elements – antimony
- Organic compounds – styrene
- Halogenated organic compounds
- Antibacterial and antifungal compounds
- Optical brighteners

5.2.3.10 Chemicals in baby crawling blankets (2011) – Öko-Test

The German magazine Öko-Test has tested 17 baby crawling blankets. Some of the baby crawling blankets are activity blankets that contain toys sowed into the top of the blankets. Öko-Test found the following hazardous chemicals in one or more of the baby crawling blankets (Öko-Test No. 12, 2011):

- Phthalates – DEHP
- PAHs
- Elements – antimony
- Formaldehyde
- Optical brighteners
- Aniline
- Disperse dyes
- Organostannic compounds
- Halogenated organic compounds
- p-aminoazobenzol

5.2.3.11 Chemicals in textiles (2011) – Danish EPA

In this survey the Danish EPA has made a review of several different surveys concerning chemicals in textiles. This survey is a general survey for textiles in general and does not only cover textiles for children. The survey concludes that the following chemicals can be found in textiles to a greater or lesser extent:

- Antibacterial agents (Triclosan, nano-silver)
- Anti-mould agents (DMF)
- Dyes (azo dyes, other dyes, optical brighteners)
- Phthalates
- Brominated flame retardants
- Various metals (As, Sb, Pb, Cd, Cr, Co, Cu, Ni, V, Zn, Ag)
- Impregnation agents (per- or polyfluor compounds, silicone compounds)
- Organostannic compounds
- Various other organic compounds (such as formaldehyde, nonylphenol/nonylphenoxyethoxylates (NP/NPE), aliphatic hydrocarbons etc.)

The study concludes that these chemical residues are caused by the large use of chemicals in the production of the textiles. However, many of these chemicals can be washed out of the textiles when washed in the washing machine. Especially phthalates, some heavy metals and antibacterial agents are not washed out of the textiles during wash, but phthalates and to some degree also the heavy metals can be avoided by buying eco-labelled or health-labelled textiles (Danish EPA No. 113, 2011).

5.2.3.12 Chromium in leather shoes (2011) – Danish EPA

The Danish EPA investigated the content of chromium (VI) in 60 pairs of leather shoes – 20 of these were children's shoes (no specific age group). The typical content of chromium in the shoes was around 1 to 3%. Chromium (VI) content was investigated in 18 pairs of shoes. In 8 pairs (or 44% of the analysed shoes) the release of Cr(VI) was higher than the detection limit of 3 ppm indicating a risk of allergic effects as patients with Cr(VI) allergy may react to exposures in the range of 1 to 3 ppm. The shoe with the highest levels of Cr(VI) release was a children's sandal (> 10 ppm), (Danish EPA No. 112, 2011).

5.2.3.13 Phthalates in plastic sandals (2010) – Danish EPA

The Danish EPA has investigated the content of four specific phthalates (DEHP, BBP, DBP and DIBP) in 60 different plastic sandals and foam clogs/foam shoes – 20 of these were shoes for the age group 2 year-olds. A content of the phthalates DIBP, DBP and DEHP was detected in several of the analysed plastic sandals and foam clogs/foam shoes and for all age groups. Several plastic sandals for children contained phthalates in the sole or strap in the order of magnitude of 10-46% (weight percent). BBP was only detected in a few sandals and in low concentrations.

Migration of the phthalates was measured as well and showed a maximum migration value of 53 ppm for DBP. Supplementary tests were performed to evaluate the influence of dynamic conditions (corresponding to movement of the food) and use of sun lotion. These results show that dynamic conditions together with sun lotion can increase the migration of the phthalates by a factor 3 to 149 depending on the water solubility of the different phthalates. These results indicate that use of plastic sandals for a long time each day in combination with sun lotion contributes significantly to the total phthalate exposure for consumers, especially for 2 year-olds and children (Danish EPA No. 107, 2010).

5.2.3.14 Phthalates in ski mittens (2010) – NCPA

The Norwegian Climate and Pollution Agency has found the phthalate DEHP in 22 % (w/w) in some black rubber material of three different types of ski mittens on the Norwegian market. The survey does not mention if only children ski mittens were investigated or if the investigation also covers ski mittens for adults. One ski mitten for children is depicted but the specific age group is not listed. According to an assessment from the Norwegian Climate and Pollution Agency, the content is considered as a health risk as DEHP is toxic to the reproduction and is embryotoxic. The ski mittens have been withdrawn from the market. (Norwegian Climate and Pollution Agency, 2010).

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

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

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

Other hazardous substances found in most jackets and mittens were styrene, fluorinated compounds (used for impregnation), phthalates, formaldehyde, and isocyanates. (Danish EPA No. 102, 2009).

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

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

- Seven out of eight of the children bed linens contained optical brighteners, half of the tested children bed linens contained

halogenated hydrocarbons, and one bed linen contained formaldehyde.

- All of the 18 tested children football T-shirts contained optical brighteners. Dibutyltin, antimony, and organic phosphor compounds were found in several of the 18 T-shirts. Finally, phthalates, triclosan, and chlorinated organic compounds were found in some of the T-shirts. (Öko-test No. 12, 2009).

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

Both the Danish EPA and the Swedish Society for Nature Conservation have tested plastic shoes for content of hazardous chemicals. The Danish EPA (No. 102, 2009) has tested plastic clogs for the content of phthalates in the report “Two-year-old children’s exposure to chemical substances” (in Danish) and the Swedish Society for Nature Conservation (2009) has tested a long range of plastic shoes for the content of phthalates, tin organic compounds, PAHs, and heavy metals.

The survey from the Danish EPA

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

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

- The migration of DIBP from the plastic clog was not a risk in itself, but contributed to the total exposure of endocrine disrupting chemicals that two-year-old children are exposed to through different consumer products. The total exposure of endocrine disrupting chemicals constitutes a clear risk for two-year-old children.
- The migration of DBP from the plastic clog was in itself so high that use of the clog 4 hours a day (with bare feet) constitutes a risk of endocrine disrupting effects of the two-year-old children.

The survey from the Swedish Society for Nature Conservation

The Swedish Society for Nature Conservation tested 27 different pairs of plastic shoes from all over the world for different hazardous chemicals. 25% of the shoes were children shoes and the rest for adults. 18 of the shoes were tested for content of different phthalates. The analyses showed that 17 of the 18 shoes which were tested contained one or more of the tested phthalates. The phthalate DEHP was present in various amounts in all 17 of these products. The highest content, 23.2%, was found in a pair of flip-flops from South Africa.

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

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

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

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

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

5.2.3.19 Chemicals in bath towels (2007) – SSNC

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

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

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

Four windbreakers/jackets for children were analysed for the content of fluorinated chemicals such as perfluorooctanyl sulfonate, PFOS, fluortelomer alcohols (FTOH), and perfluorocarboxylic acids (PFCA). The compounds are widely used as impregnating agents, but in recent years their problematic properties have been identified and investigated. The substances are extremely stable in the environment and the levels in the environment are now close to the levels that have been proven to produce harmful effects in laboratory experiments. The substances accumulate in wild life and humans, and they have been linked to health effects such as metabolic disorders (thyroid diseases)⁶, higher levels of cholesterol⁷, lowering of semen quality in men⁸, and impairment of the fertility of women⁹. (Friends of the Earth Norway, 2006).

⁶ Association between Serum Perfluorooctanoic Acid (PFOA) and Thyroid Disease in the NHANES study. Environmental Health Perspectives.
<http://ehsehplp03.niehs.nih.gov/article/fetchArticle.action?articleURI=info%3Adoi%2F10.1289%2Fehp.0901584>

⁷ Exposure to Polyfluoroalkyl Chemicals and Cholesterol, Body Weight, and Insulin Resistance in the General US Population. Environmental Health Perspectives.
<http://ehp03.niehs.nih.gov/article/fetchArticle.action?articleURI=info:doi/10.1289/ehp.0901165>

⁸ Do Perfluoroalkyl Compounds Impair Human Semen Quality? Environmental Health Perspectives.
<http://ehp03.niehs.nih.gov/article/fetchArticle.action?articleURI=info:doi/10.1289/ehp.0800517>

These results have been confirmed by the analysis carried out in the project for the Danish EPA No. 102 (2009) which focused on the total exposure to endocrine disrupting substances for two-year-old children. In this project fluorinated compounds were also found in children jackets and mittens (see description above).

5.2.3.21 Toxic children's wear (2004) – Greenpeace

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

The test showed that:

- All of the tested textiles contained phthalates. The sum of all phthalates ranged from 1.4 ppm to 320,000 ppm (i.e. 32 % by weight). The textiles with the very content of phthalates suggest that they have been printed with PVC-based plastisol prints.
- Alkylphenoethoxylates were found in all of the tested textiles in concentrations between 34 and 1,700 ppm.
- Organostannic compounds were found in 10 of the 17 tested textiles in concentrations between 4 and 474 µg/kg (as a sum of all organostannic compounds).
- Lead was found in all of the 19 tested textiles in concentrations between 0.14 and 2,600 µg/kg.
- Cadmium was found in 14 of the 19 tested textiles in concentrations between 0.0069 and 38 ppm (mg/kg).
- Formaldehyde was found in 8 of the 15 textiles tested in concentrations between 23 ppm and 1,100 ppm. (Greenpeace, 2004).

5.2.4 Furniture

5.2.4.1 Beanbags (2013) – Öko-Test

The German magazine Öko-Test has tested 12 beanbags for children for content of different hazardous chemicals. The following chemicals were found (Öko-Test No. 9, 2013):

- Brominated flame retardants – HBCDD
- Organic phosphorous compounds (could be a sign of phosphorous based flame retardants)
- Phthalates – DEHP, DINP, DIDP, DPHP
- Volatile organic compounds – styrene
- Polycyclic aromatic hydrocarbons (PAH)
- Organostannic compounds – DBT
- Benzidine
- Optical brighteners

⁹ Maternal levels of perfluorinated chemicals and subfecundity. Human reproduction. <http://www.oxfordjournals.org/eshre/press-release/freepdf/den490.pdf>

Four of the 12 tested bean bags contained the brominated flame retardant HBCDD and two other bean bags contained organic phosphorous compounds which could be a sign of a content of a phosphorous based flame retardant. The phthalates were found in two products in concentration higher than 1,000 ppm.

5.2.4.2 Flame retardants in children's furniture (2013) – CEH

The American Center for Environmental Health (CEH) has investigated the content of flame retardants in 42 different pieces of children's furniture. All but 4 of the 42 pieces of children's furniture contained one or more flame retardants. The flame retardants identified were (CEH, 2013):

- Firemaster 550 (a mixture of different flame retardants) was found in 22 pieces of children's furniture.
- TCPP was found in 15 pieces of children's furniture.
- TDCPP was found in 2 pieces of children's furniture.
- Butylated triphenyl phosphate was found in 1 piece of children's furniture.

5.2.4.3 Chemicals in travelling beds for children (2012) – Öko-Test

The German magazine Öko-Test has tested 9 different travelling beds for children for content of different hazardous chemicals. Antimony, which can be used as flame retardant, was found in four of the travelling beds and organic phosphorous compounds, which also could be a sign of use of phosphorous flame retardants, were found in two of the travelling beds. PAHs were found in four of the travelling beds. Other chemicals found were halogenated organic compounds, dispersive dyes and the organostannic compound DBT.
(Öko-Test No. 7, 2012b)

5.2.4.4 Chemicals in children mattresses (2012) – Öko-Test

The German magazine Öko-Test has tested 13 children mattresses for content of different hazardous chemicals. Antimony was found in 8 of the 13 children mattresses, which could be a sign of use of antimony compounds as a flame retardant. Furthermore, silver was found in 2 of the mattresses and optical brighteners were found in 8 of the 13 children mattresses (Öko-Test No. 4, 2012).

5.2.4.5 Flame retardants in children mattresses (2012) – Chicago Tribune

In a test conducted for the Chicago Tribune, 27 baby crib mattresses were tested for the content of flame retardants. The flame retardant TDCPP was found in 11 of the mattresses in significant amounts – these 11 mattresses were all made in China or imported from China (Chicago Tribune, 2012).

5.2.4.6 Chemicals in baby high chairs (2011) – Öko-test

The German magazine Öko-Test has tested 10 wooden baby high chairs and has found the following chemicals: formaldehyde, phthalates, chlorocresole, medium chained chloroparaffines, o-phenylphenol and chromium (in the leather parts). In general, formaldehyde was found in the back rest of all baby high chairs (Öko-Test No. 10, 2011a).

5.2.5 Electronics

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

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

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

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

5.2.6 Personal Protection Equipment

5.2.6.1 Children ski helmets (2006) – Austrian Standards Institute

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

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

5.2.7 Indoor climate

5.2.7.1 Indoor climate (2006) – Danish EPA

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

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

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

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

5.2.8 Other relevant examples

5.2.8.1 Chemicals in children's heating pads (2013) – Öko-Test

The German magazine Öko-Test has tested 12 different heating pads for children. The following hazardous substances were found (Öko-Test No. 11, 2013):

- Elements – antimony
- Halogenated organic compounds
- Polycyclic aromatic hydrocarbons (PAH)
- Optical brighteners

5.2.8.2 Chemicals in nursing pillows (2013) – Öko-Test

The German magazine Öko-Test has tested 15 nursing pillows. The following hazardous substances were found (Öko-Test No. 3, 2013):

- Phthalates – DINP (diisononylphthalate), DCHP (dicyclohexylphthalate), DPHP (dipropylheptylphthalate)
- Chloroparaffine
- Organic phosphorous compounds (could be a sign of phosphorous based flame retardants)
- Elements – antimony, cadmium, lead

- Halogenated organic compounds
- Optical brighteners

5.2.8.3 Bisphenol A in child care articles (2012) – Swedish Chemicals Agency

The Swedish Chemicals Agency has investigated the content of Bisphenol A in more than 80 pieces of toys and child care articles. The highest concentration measured was 600 mg/kg. The highest concentrations measured were found in products such as drinking bottles, CD's with children's music and in different plastic toys. The conclusion from the investigation is that the content of Bisphenol A in the toys and child care articles does not constitute a health risk for the children (KEMI, 2012).

5.2.8.4 PAH in child care products (2011) – Danish EPA

The Danish EPA has investigated the content of PAHs in different toys and child care products. The child care products investigated were a toothbrush, plastic clogs, bathing shoes, bicycle (tyres and grip), scooters (grip), eraser, rubber ducks, teething rings, goggles, baby bibs, balloons, and a pen. The sum of 16 different PAHs measured was in 55% of the samples below 1 mg/kg, in 40% of the samples between 1-10 mg/kg and in one sample (5%) between 100-1,000 mg/kg.

Germany suggests a limit value of 0.2 mg/kg for 8 PAHs in consumer products. It is stated in the report that 2 out of 20 products (bicycle tyre and scooter grip) would not have met this suggested limit value. (Danish EPA No. 114, 2011).

5.2.8.5 Chemicals in felt tip pens and crayons (2011) – Danish CC

The Danish Consumer Council has tested 10 sets of felt tip pens and 10 sets of crayons for content of problematic chemicals. PAH was found in two black crayons in concentrations of 5.7 and 2.3 mg/kg. The phthalate DBP was found in high amounts in one crayon. The metal barium was found in small amounts in three crayons (Danish Consumer Council Tænk, 2011).

5.2.8.6 Phthalates in products for children (2010) – Danish EPA

The Danish EPA has investigated the content of the four phthalates (DEHP, BBP, DBP and DIBP) in products that children are in direct contact with, i.e. plastic bags (sponge bags, rucksacks), swimming equipment, swimming pools, textiles with prints, tablecloths and dinner mats, shower curtains that appeal to children, and balance balls. A total of 72 products for 2 year-olds and 6/7 year-olds was analysed for the content of the four phthalates.

High concentrations of DEHP and DIBP were detected in a number of products. DIBP was primarily detected in balance balls in concentrations between 11-35%, whereas DEHP was measured in all types of the investigated products in concentrations between 2-44%. BBP was not detected in the analysed products and DBP was only detected in concentrations less than 0.1%. Ten T-shirts were analysed and all detected phthalates were in concentrations less than 0.05%. A high content of DINP and isophthalate was detected in a wide range of products which were not quantified in this project.

In the light of the quantitative analysis results, 10 products were selected for 18 migration analyses with artificial sweat and saliva to simulate the exposure of skin and mouth contact of a child with the products. The migration analyses detected the migration of DEHP in concentrations less than 0.0005%

in the products, while the migration of DIBP was detected in a concentration of 0.02% in one product (Danish EPA No. 109, 2010).

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

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

As new research has shown that a dose-addition approach can be used for assessing the risk of exposure to phthalates and other antiandrogene¹⁰ substances; this approach was used in the risk assessment in the project. In other words, it is assumed that if two different substances both have the same effect on humans (in this case blocking the action of androgens (the hormones responsible for male characteristics)), the dose or the exposure to these types of chemicals can be added.

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

The conclusion of the project was that a health risk is definitely involved when looking at the worst case exposure to endocrine disrupting chemicals for two-year-old children. Some single exposures are critical in this respect: For example, exposure to phthalates in plastic clogs, exposure to PCBs through the indoor climate and food, exposure to DEHP through indoor climate and food, and exposure to parabens through cosmetic products. (Danish EPA No. 102, 2009).

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

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

The phthalates DEHP (26 %), DINP (3.2 %), and DIBP (6.2 %) were found in the maximum concentrations as listed. The highest concentration of DEHP was found in a shower curtain and a children's leather jacket. (Danish Information Centre for Environment and Health, 2009).

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

In 2005, the Danish EPA investigated different products intended for baby use. The products were: pillows for baby feeding, nursing pads, baby foam mattresses, disposable foam wash cloths, baby carriers and textile cover on prams. All products were analysed for the content of hazardous substances

¹⁰ An antiandrogen is a substance that blocks the action of androgens, the hormones responsible for male characteristics.

and all baby products contained measurable amounts of more than one compound classified as hazardous to health and/or the environment. However, no substances with hazardous health risks were found in the products but the exposure from this type of products contributes to the total exposure from other consumer products.

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

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

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

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

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

Furthermore, four products with high amounts of lead and cadmium were found (lead: 475 ppm to 4,600 ppm (the legal limit in Denmark is 100 ppm), cadmium: 250 ppm to 400 ppm (the legal limit in Denmark is 75 ppm)). (Danish EPA No. 84, 2007).

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

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

5.3 Summary of chemicals found in child care articles

The examples in this chapter illustrate that problematic chemicals in consumer products such as child use and care articles are common and support the criticism regarding the current European regulatory framework on chemicals in consumer products being insufficient.

In Table 12 below, the different chemicals identified in the listed examples are summarised. It should be mentioned that not all the performed tests have analysed for all the listed groups of chemicals. For instance, all-weather clothing was only tested for content of fluorinated compounds. This product may very well contain phthalates, heavy metals, flame retardants, formaldehyde, aromatic amines, DBT, TBT, or other organostannic compounds as well as other problematic substances.

Furthermore, it should be mentioned that even though the different chemicals are found in the different child use and care products, they may not necessarily be found in high amounts or in amounts that would result in health effects when performing a risk assessment on the individual consumer products. Children are, however, exposed to small amounts of many different chemicals from many different consumer products, indoor air, outdoor air, food and water. For this reason, it will be necessary to limit or restrict problematic chemicals in child use and care articles to lower the total chemical burden of children today.

Table 12: Examples of problematic chemicals found in child use and care articles. The table represents an overview of what has been identified. Not all products have been tested for all the mentioned groups of chemical compounds.

Example	Year	Phthalates	PAHs	Heavy metals	Flame retardants	Formaldehyde	Halogenated hydrocarbons	Fluorinated compounds, PFOS	DBT, TBT organostannic compounds	Other problematic substances
<i>Products for mouthing</i>										
Chemicals in silicone dummies	2012		x							
Chemicals in toothbrushes for children	2012		x				x			
Chemicals in baby drinking bottles	2011									
Bisphenol A in baby bottles	2011									x
Bisphenol A in baby dummies	2011									x
PAHs in children toothbrushes	2008	x								
<i>Products for transportation</i>										
Chemicals in running bikes	2013	x			x					
Child safety seats	2013	x	x	x	x	x			x	x
Dangerous chemical in safe child safety seat	2013									x
Combination prams	2012	x								
Chemicals in baby harnesses	2011						x			x
Chemicals in folding pushchairs	2011	x	x		x		x	x		x
Chemicals in child safety seats	2011	x			x					
Hazardous substances in prams	2009	x	x		x		x		x	x
PAHs in running bikes	2008	x								
<i>Clothes/textiles and shoes</i>										
Baby sleeping bags	2013			x			x			
NP and NPE in textiles for children	2013									x
NPE in children jeans	2013									x
Chemicals in bibs	2012		x						x	x

Example	Year	Phthalates	PAHs	Heavy metals	Flame retardants	Formaldehyde	Halogenated hydrocarbons	Fluorinated compounds, PFOS	DBT, TBT organostannic compounds	Other problematic substances
Thiourea in neoprene rubber products	2012									x
Chemicals in children rainwear	2012	x		x						
Chemicals in textile crib protectors	2012	x		x					x	x
Chemicals in baby lambskins	2012			x		x	x			x
Chemicals in nursing pillows	2011			x			x		x	x
Chemicals in baby crawling blankets	2011	x	x	x		x	x		x	x
Chemicals in textiles	2011	x		x	x	x		x	x	x
Chromium in leather shoes	2011			x						
Phthalates in plastic sandals	2010	x								
Phthalates in ski mittens	2010	x								
Hazardous substances in jackets and mittens	2009	x				x		x		x
Children bed linens and football T-shirts	2009	x		x		x	x		x	x
Hazardous chemicals in plastic shoes	2009	x	x	x					x	
PAHs in rain proof clothes	2008		x							
Chemicals in bath towels	2007			x						x
Fluorinated pollutants in all-weather clothing	2006							x		
Toxic children's wear	2004	x		x		x			x	x
Furniture										
Bean bags for children	2013	x	x		x		x		x	x
Flame retardants in children's furniture	2013				x					
Chemicals in travelling beds for children	2012		x	x	x		x		x	x
Chemicals in children mattresses	2012			x						x
Flame retardants in children mattresses	2012				x					
Chemicals in baby high chairs	2011	x		x		x				x
Electronics										
Hazardous substances in games console components	2008	x		x	x					x
Personal protection equipment										
Children ski helmets	2006			x						x
Indoor climate										
Indoor climate	2006	x			x	x		x		x
Other relevant examples										
Children's heating pads	2013		x	x			x			x
Chemicals in nursing pillows	2013	x		x			x			x
Bisphenol A in child care articles	2012									x
PAH in child care products	2011		x							
Chemicals in felt tip pens and crayons	2011	x	x	x						
Phthalates in products for children	2010	x								
Endocrine disrupting substances that two-year-old children are exposed to	2009	x								x
Phthalates in products for children	2009	x								
Hazardous substances in baby products	2008	x				x				x
Erasers	2007	x	x	x						

Some of the specific examples show that child use and care articles should as a minimum be restricted in the same way as toys (the existing Toy Safety Directive). The examples with the plastic sandals show that these products contain high amounts of the endocrine disrupting phthalates, but these phthalates are not restricted in plastic sandals as sandals are not defined as child care articles, but as child use articles.

This is just one example that illustrates that all products for children, i.e. all child use and child care articles should be restricted for the content of problematic chemicals in line with toys. A discussion is, however, needed whether the chemical requirements for toys should be directly transferred to all child use and care articles or if a differentiation should be made for mouthed products (dummies etc.) compared to products not possible to put in the mouth (children bicycle seats etc.). This and other aspects will be discussed in the next chapters.

6 Suggestion of chemical requirements for child use and care articles

The review of the chemical requirements in present legislation and standards (chapter 4) illustrates that chemical requirements set for child care articles are few and for child use articles even less chemical requirements are set. Furthermore, the examples of chemicals identified in child use and care articles (chapter 5) illustrate that several problematic chemicals can be found in child use and care articles. Sparse legislation on the area and the presence of problematic chemicals in these products strongly suggest the need for a stronger regulation of chemicals in both child use and care articles.

In this chapter, the aspects listed below are discussed and finally a suggestion for chemical requirements will be made based on the chemical requirements suggested for toys in the former ASI Consumer Council study “Chemical requirements for toys” (Poulsen, 2013):

- Definition and coverage of child use and care products
- Exposure aspects concerning the requirements
- Material specific requirements

6.1 Definition and coverage of child use and care products

As described in chapter 3, the definition of child use and care articles in this project is:

“Child use and care articles include any product designed or obviously intended to safely ensure and facilitate seating, bathing, changing and general body care, feeding, sleeping, sucking, (dressing,) transportation and protection of children up to four (or 14) years”

This means that any product which may be used by a child is covered as long as the product is designed for or intended to be used by a child for the given purposes. The reason for using this broader definition than the existing definition used in REACH Annex XVII is to ensure that all relevant products designed to be used by children are covered. Examples such as the following are not covered by the existing child care articles definition:

- appendages to zippers on children jackets, which young children may chew or suck on (phthalates have been observed),
- plastic sandals (clogs) which children walk in with bare feet during summer or indoor (phthalates have been observed),
- T-shirts and other clothes that young children may chew or suck on (phthalates and NPEs have been observed),
- children bean bags (flame retardants have been observed).

In principle, it could be relevant to expand the child use and care articles definition to all children up to the age of 14 similar to what is done for toys and for the REACH Annex XVII restriction on phthalates. All children should irrespective of age be protected against hazardous chemicals in the consumer products they use; however, the youngest children are the most vulnerable, i.e. they have a higher exposure per kg bodyweight due to a lower bodyweight and because of their tendency to put products in their mouth. For this reason the age limit of 'up to the age of 4 years' – similar to the definition used by CEN/TC 252 – has been used and suggested for child use and care articles in this report, but an expansion of the age limit should be taken into consideration.

6.2 Exposure aspects

The starting point for this project has been to use the chemical requirements suggested for use in toys (from the former ASI Consumer Council study "Chemical requirements for toys" (Poulsen, 2013)). In order to do this it is, however, necessary to discuss whether the requirements set for child use and care articles should be as strict as the chemical requirements suggested for toys.

Many toys – but not all – are used by the hands, and especially the youngest children will – if possible – put the products into their mouth, as this is their way of 'investigating' products. Similarly, child use and care articles may be used by the hands, but many child use and care articles are not necessarily intended to be used by the hands most of the time. Such examples are nursing pillows, mattresses, high chairs, bicycle helmets etc. For this reason, there can be differences in the exposure scenario for child use and care articles compared to toys.

Some child use and care articles will have a minimum of skin contact and thereby a minimum of exposure, e.g. high chairs, bicycle helmets, bicycles, whereas other child use and care articles will have a much higher exposure, e.g. soothers. Therefore, it is obvious that the chemical requirements should be stricter in those child use and care articles which have a higher exposure, whereas e.g. bicycles seats and high chairs are not in need of the same strict level of chemical requirements even though the migration through sweat on a warm summer day may be relevant as well. For this reason, it seems necessary to differentiate between different exposure situations or the accessibility of the chemicals in the articles. Different approaches have been used so far:

- For phthalates in the REACH Annex XVII restriction for child care articles the concept of articles which "can be placed in the mouth" has been applied.
- For elements in the Toy Safety Directive, the approach is based on accessibility: "These limit values shall not apply to toys or components of toys, which due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin".
- For several categories of substances in the CEN/TC 252 document, an approach based on accessibility has been used (listed here for elements): "...the migration of elements from any parts which due to their accessibility, function, volume or mass, can reasonably lead to exposure due to sucking, licking, swallowing, or prolonged contact with skin shall..."

Using a definition based on accessibility instead of the “can be placed in the mouth” approach for the phthalates is broader as it would also include licking from surfaces where none of the dimensions is smaller as 5 cm as used as the definition by the REACH Annex XVII restrictions of phthalates in toys and child care articles. Therefore, it is suggested to use the broader term based on ‘accessibility’ of the chemicals in the articles in general for the child use and care articles.

The chemical requirements set for toys will therefore be discussed in the following section with respect to these exposure relevant aspects.

6.3 Material specific requirements

The chemical requirements suggested for toys in the former ASI Consumer Council study “Chemical requirements for toys” (Poulsen, 2013) were set without going into details about specific materials, i.e. looking more closely whether the chemical requirements may only be relevant for certain materials. As this is a relevant aspect, a discussion of the relevant materials will therefore be briefly introduced in this project and will be discussed in the section below where the chemical requirements are discussed one by one.

6.4 Discussion of suggested chemical requirements for child use and care articles

In this section, the chemical requirements suggested for toys in the former ASI Consumer Council study “Chemical requirements for toys” (Poulsen, 2013) will be discussed in order to evaluate whether the suggested requirements for toys should be used directly for child use and care articles as well or whether a modification concerning materials and/or exposures (i.e. mouthed products) is needed. The requirements will be discussed one by one as they are listed in the “Chemical requirements for toys” report and in Appendix 1: Suggested chemical requirements for toys. In general the requirements suggested for toys have been modified for use for child use and care articles.

6.4.1 CMRs, PBTs, vPvBs and others (e.g. EDCs)

This group of substances includes substances which are CMR (carcinogenic, mutagenic and/or toxic to reproduction), PBT (persistent bioaccumulative and toxic substances), vPvB (substances that are very persistent and very bioaccumulative) and other e.g. EDC (endocrine disrupting chemicals). Such substances may be included on the Candidate list of REACH (and are then referred to as substances of very high concern (SVHC) and may later on be subject for the authorisation process of REACH. As it is expected that very few of the SVHCs will be granted authorisation to be used in the manufacturing of child use and care articles in Europe, it is proposed that the suggested chemical requirement regarding these substances for toys is used directly for all child use and care articles as well – irrespective of the exposure situation and irrespective of the materials used as these substances could be present in all types of materials. As an option the requirement could be limited to parts accessible to children (as described above where the accessibility can lead to exposure due to sucking, licking, swallowing or prolonged contact with

skin). This option is, however, broader than the term used for the restriction of the phthalates in REACH Annex XVII ‘can be placed in the mouth’.

It is suggested to set this chemical requirement regarding CMRs, PBTs, vPvBs and others (e.g. EDCs) for child use and care articles for several reasons:

- First of all because these substances should not be present in products for children.
- When these substances become subject for authorisation, the use of the substances will be restricted. However, this authorisation process may take several years for which reason it will be necessary to restrict the chemicals in child use and care articles sooner.
- Finally, these substances which are subject for authorisation will not automatically be restricted in imported products. Substances subject for authorisation will in principle only be restricted for use (use in production of articles) in the EU whereas import of articles containing substances subject for authorisation will not be covered by the authorisation process.

Table 13: Suggested chemical requirement for CMRs, PBTs, vPvBs and others (e.g. EDCs) for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
<p>CMRs PBTs vPvBs and others (e.g. EDCs)</p>	<p>All materials</p>	<p>Type of limit value: Migration or content based limit values depending on the material and the nature of the substances:</p> <p><u>Non-volatile substances:</u></p> <ul style="list-style-type: none"> • Solid: Migration based <p><u>Volatile substances:</u></p> <ul style="list-style-type: none"> • All child use and care articles: Evaporation based <p>Limit value CMRs (category 1A, 1B and 2) and EDCs (proposed category 1A and 1B): <u>Migration based limit value:</u> Must not be detectable, i.e. 0.01 mg/kg (10 ppb) in all child use and care articles (possibly limited to parts accessible to children).</p> <p><u>Content and evaporation based limit value:</u> Need to be discussed.</p> <p>Exemptions can be made, but only on the basis of a full risk assessment and a positive opinion by SCHER.</p> <p>Limit value PBTs and vPvBs: PBTs and vPvBs must not be present in all child use and care articles (possibly limited to parts accessible to children) in a content above 0.1 %.</p> <p>Test method: <u>Content:</u> None suggested. Dependant on the substance.</p> <p><u>Migration:</u> 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.</p>

It is suggested that the requirement concerning CMRs, PBTs, vPvBs and others (e.g. EDCs) are limited in all child use and care articles. Another option could be to limit the requirement to parts accessible children instead. However, this approach should be used with exceptions, as the existing legal requirement on phthalates (reproductive substances) on child care articles (REACH Annex XVII) is limited to products that ‘can be placed in the mouth’.

6.4.2 PAHs

PAHs are a group of organic substances of which most of them are CMR substances (carcinogenic). CMR substances may be included or are intended to be included on the Candidate list of REACH and may later on be subject for the authorisation process of REACH. As it is expected that very few SVHCs will be granted authorisation to be used in the manufacturing of child use and care articles in Europe, it is therefore proposed that the suggested chemical requirement for toys on PAHs is used directly for child use and care articles as well.

A new regulation concerning PAHs has been adopted (Regulation 1272, 2013). In this regulation, PAHs (8 PAHs) are restricted in a concentration of 0.5 mg/kg in child care articles that ‘come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use’. However, the suggested chemical requirement for toys is set even lower as a lower detection limit is possible.

It should be emphasised that this new regulation only concerns 8 PAHs, but more PAHs may be of potential concern. The US EPA operates with 16 PAHs, whereas the Oekotex 100 lists 24 PAH substances. It should be investigated further if the requirement ought to cover more than the 8 PAHs.

PAHs are found in materials made of rubber or elastomers (BfR No. 51, 2009). For this reason the specific requirement for PAHs will only be relevant for these types of materials.

It is suggested to use the suggested chemical requirement suggested for toys but adding the accessibility definition as used in the new PAH regulation.

Table 14: Suggested chemical requirements for PAHs for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
PAHs	Rubber Elastomer materials	<p>Type of limit value: Content based</p> <p>Limit value: 0.2 mg/kg as for each of the 8 carcinogenic PAHs in all child use and care articles which come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal and foreseeable conditions of use.</p> <p>However, a further lowering of the limit value should be possible when validated test methods with lower detection limit values are developed.</p> <p>Test method: Test method used for the German GS (certified safety) mark.</p>

6.4.3 Phthalates and other plasticizers

Phthalates are mostly found in soft plastic materials (mostly PVC, but also other plastics like polyvinyl acetate and polyurethane (PU)). Furthermore, phthalates are used in elastomers, coatings, adhesives, and sealants (CPSC, 2010). In RAPEX notifications, phthalates have also been identified in imitation leather (which is also made of PVC or PU) and rubber. For this reason, the chemical requirements for phthalates should only apply for these types of materials.

Some phthalates are classified as reprotoxic (CMR substances) and for this reason 12 phthalates are (as of December 2013) on the Candidate list of REACH and some of the phthalates are already subject for the authorisation process of REACH. It is expected that very few of the SVHCs will be granted authorisation to be used in the manufacturing of child use and care articles in Europe. Therefore, it is proposed that the suggested chemical requirement for toys on phthalates and other plasticizers is used directly for child use and care articles as well. Whether the ban should be general or limited to accessible parts or for 'products that can be mouthed' should be discussed further.

Table 15: Suggested chemical requirements for phthalates for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
Phthalates and other plasticizers	Plastic materials (PVC, PU) Elastomer materials Adhesives Rubber Imitation leather	<p>Type of limit value: Content based</p> <p>Limit value:</p> <ul style="list-style-type: none"> No phthalates (esters of o-phthalic acid) are allowed in <u>child use and care article</u>. Limit value: 0.05% (500 ppm). <i>Up to debate whether the ban is general or limited to accessible parts.</i> 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 plasticizers that have been approved by SCHER on the basis of a full risk assessment (= positive list of other plasticizers that can be used in specific concentrations). <p>Test method: None suggested. Dependant on the substance.</p>

6.4.4 Formaldehyde

Formaldehyde is used as a preservative and biocide in textile products and can be found naturally in wood and therefore also in paper products. Formaldehyde is carcinogenic and therefore also considered to be a substance of very high concern. Substances of very high concern are included or are intended to be included on the Candidate list of REACH and later on they may be subject for the authorisation process of REACH. As it is expected that very few of the SVHCs will be granted authorisation to be used in the manufacturing of child use and care articles in Europe, it is therefore proposed that the suggested chemical requirement for toys on formaldehyde is used directly for accessible parts of child use and care articles as well.

Table 16: Suggested chemical requirements for formaldehyde for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
Formaldehyde	Textiles Wood Paper	<p>Type of limit value: Dependant on the material</p> <p>Limit value:</p> <ul style="list-style-type: none"> • Textiles: Accessible textile components of child use and care article 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 child use and care article 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 child use and care article 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. <p>Test method: Use of existing test methods, but to be discussed further.</p>

6.4.5 Phenol

Phenol is used, amongst others, in the production of plastics and dyes. Phenol is mutagenic and therefore also considered to be a substance of very high concern. Substances of very high concern are included or are intended to be included on the Candidate list of REACH and may later on be subject for the authorisation process of REACH. As it is expected that very few of the SVHCs will be granted authorisation to be used in the manufacturing of child use and care articles in Europe, it is therefore proposed that the suggested chemical requirement for toys on phenol is used directly for accessible parts of child use and care articles as well.

Table 17: Suggested chemical requirements for phenol for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
Phenol	Plastics Dyes	<p>Type of limit value: Migration</p> <p>Limit value:</p> <ul style="list-style-type: none"> • As a monomer: 4 mg/l in aqueous migrate <p>Test method: Use of existing test methods (in EN 71-9 (2007) and EN 71-11 (2005)).</p>

6.4.6 Elements

Elements may be present in all materials as elements may be used in metals, leather, plastics and in colours and dyes used on any material. The suggested limit values are therefore relevant for all materials.

The elements are usually bound in the materials in which they are used, but may migrate from the products. For this reason, the exposure to elements will

mainly be relevant for the parts of the articles that are accessible to the child. It is proposed that the suggested chemical requirement for toys on elements is used for accessible parts of child use and care articles, as also defined in the Toy Safety Directive: “These limit values shall not apply to toys or components of toys, which due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin”.

Table 18: Suggested chemical requirements for elements for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements																																																																																			
Elements	All materials	<p>Type of limit value: Migration limit values split into three depending on the material:</p> <ul style="list-style-type: none"> Scraped-off <p>Limit value: Migration limit values (in mg/kg) for <u>accessible parts of child use and care articles</u> as listed in the table below.</p> <table border="1"> <thead> <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> </thead> <tbody> <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> </tbody> </table> <p>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/WG5, 2013).</p>				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
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6.4.7 Fragrances

Fragrances can be used in different products to give scent to the products; e.g. in plastics, in scented erasers or in heating bags camouflaged as e.g. a teddy bear. Many fragrances are sensitising substances that are volatile. It is therefore proposed that the suggested chemical requirement for toys on fragrances is used for all scented child use and care articles.

Table 19: Suggested chemical requirements for fragrances for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
Fragrances	All scented materials	<p>Type of limit value: Content based</p> <p>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 scented child use and care articles in non-detectable amounts (alternatively in an amount of 10 ppm).</p> <p>Test method: No suggestions</p>

6.4.8 Sensitising substances

Substances that are sensitising can be present in all types of materials and are therefore suggested to be restricted in all types of materials. Sensitising substances can be sensitising by skin contact and/or by inhalation. It is proposed to use the suggested chemical requirement for toys on sensitising substances for accessible parts of child use and care articles.

Table 20: Suggested chemical requirements for sensitising substances for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
Sensitising substances	All materials	<p>Type of limit value: Content based</p> <p>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 accessible parts of child use and care articles in a concentration higher than 100 ppm.</p> <p>If substances are sensitising in lower concentrations than 100 ppm, the sensitisation level of the specific substances must not be exceeded.</p> <p>Test method: Dependant on the substance</p>

6.4.9 The flame retardants TCEP, TCPP and TDCP

The flame retardants TCEP, TCPP and TDCP are classified as carcinogenic/reprotoxic, acutely toxic and carcinogenic respectively and a ban of these flame retardants in toys (which are intended for children under 36 months and in other toys intended to be placed in the mouth) has therefore been adopted (Directive 2014/79/EU). For this reason, it is proposed to use this chemical requirement for toys on TCEP, TCPP and TDCP for all child use and care articles made of combustible materials such as textiles, plastics etc.

Table 21: Suggested chemical requirements for TCEP, TCPP and TDCP for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
TCEP, TCPP and TDCP	All combustible materials	<p>Type of limit value: Content based</p> <p>Limit value: Use of TCEP, TCPP and TDCP in all child use and care articles is not allowed (non-detectable), i.e. 5 ppm (5 mg/kg).</p> <p>Test method: No suggestions</p>

6.4.10 Flame retardants in general

Some flame retardants are classified as carcinogenic and/or reprotoxic. For this reason, it is proposed to use the suggested chemical requirement for toys on flame retardants in general for [all child use and care articles](#) made of combustible materials such as textiles, plastics etc.

Table 22: Suggested chemical requirements for flame retardants for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
Flame retardants	All combustible materials	<p>Type of limit value: Content based and based on migration</p> <p>Limit value:</p> <ol style="list-style-type: none"> 1. It is only allowed to use flame retardants in child use and care articles 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 child use and care articles (non-detectable content, i.e. detection level of 5 mg/kg): <ul style="list-style-type: none"> • 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 <p>Test method: Depends on the substance</p>

6.4.11 Colourants and primary aromatic amines

Some colourants can break down to certain carcinogenic primary aromatic amines and therefore they are not wanted in products for children. Furthermore, some colourants are considered to be sensitizers. Colourants and primary aromatic amines are primarily used in textile and leather and may primarily migrate from these materials. Colourants and primary aromatic amines are therefore suggested to be restricted in these materials only.

Exposure of colourants and primary aromatic amines takes place at skin contact or mouthing of products containing these substances. It is proposed to

use the suggested chemical requirement for toys on colourants and primary aromatic amines as a starting point. However, this is a large area and an area that needs further review and probably an extension of colourants and aromatic amines that should be limited compared to the colourants and aromatic amines listed in the table below.

It is suggested that the chemical requirement is set for accessible parts of child use and care articles. The requirement should only be valid for products made of textiles and leather.

Table 23: Suggested chemical requirements for colourants and primary aromatic amines for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
Colourants and primary aromatic amines	Textiles Leather	<p>Type of limit value: Content based</p> <p>Limit value:</p> <ul style="list-style-type: none"> • The use of the following colorants shall not be present in <u>accessible parts of child use and care articles</u> – action limit 10 mg/kg for all colourants below: <ul style="list-style-type: none"> ○ 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 • The use of the following primary aromatic amines shall not be present in <u>accessible parts of child use and care articles</u> – action limit 5 mg/kg for all primary aromatic amines below: <ul style="list-style-type: none"> ○ Benzidine ○ 2-Naphthylamine ○ 4-Chloroaniline ○ 3,3'-Dichlorobenzidine ○ 3,3'-Dimethoxybenzidine ○ 3,3'-Dimethylbenzidine ○ o-Toluidine ○ 2-Methoxyaniline (o-Anisidine) ○ Aniline <p>Test method: As described in EN 71-11</p>

6.4.12 Monomers

Free monomers may be present in plastic products at low levels. As monomers are very reactive they are therefore also likely to have hazardous properties. Free monomers may migrate from the products during contact. Therefore, it is proposed to use the suggested chemical requirement for toys on monomers for accessible parts of child use and care articles. The requirement should only be valid for plastic materials.

Table 24: Suggested chemical requirements for monomers for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
Monomers	Plastic materials	<p>Type of limit value: Based on migration</p> <p>Limit value: For <u>accessible parts of child use and care articles</u>: 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.</p> <p>Test method: Dynamic migration method as described in EN71-10.</p>

6.4.13 Solvents

Typically solvents are not constituents of the child use and care products, but residues from materials production. Therefore solvents will typically not be present in large quantities, but solvents may be reactive and therefore they are also likely to have hazardous properties. Solvents may migrate or may evaporate from the products. It is suggested to restrict migration from the accessible parts of child use and care articles. Evaporation will be most relevant from products which can surround children for example a rain cover. For other products, evaporation may happen indoor in a large room resulting in an indoor concentration; however, the total exposure will be small. Concerning evaporation it is therefore suggested only to restrict the evaporation of solvents for products which can surround the child.

Therefore it is proposed to use the suggested chemical requirement for toys on solvents for accessible parts of child use and care articles when it comes to migration of solvents, and for child use and care articles that can surround the child when it comes to evaporation of solvents.

Table 25: Suggested chemical requirements for solvents for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
Solvents	All materials	<p>Type of limit value: Based on migration and inhalation</p> <p>Limit value:</p> <ol style="list-style-type: none"> 1. For child use and care articles that can surround the child: Adoption of the already proposed limit values for certain solvents in EN 71-9 (2007) standard (table 2F inhalation). 2. For accessible parts of child use and care articles: Adoption of the already proposed limit values for certain solvents in EN 71-9 (2007) standard (table 2E migration). 3. 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. <p>Test method: Dependant on the specific solvent. Some test methods are described in EN 71-10 (2005) and EN 71-11 (2005).</p>

6.4.14 Preservatives and biocides

No requirement is proposed regarding preservatives and biocides. The reason for this is that preservatives are not considered to be relevant for child use and care articles and that biocides are covered by the biocidal product regulation (Regulation No. 528/2012).

6.4.15 N-nitrosamines and N-nitrosatable substances

Nitrosamines are chemical compounds that may be present as contaminants in a number of product including rubber products. Some of these nitrosamines are classified as carcinogenic and therefore N-nitrosamines and N-nitrosatable substances are today already restricted in elastomer or rubber teats and soothers (Directive 93/11/EEC). However, it is suggested that the same limit values should be used for all accessible parts of child use and care products containing rubber. It is therefore proposed to use the suggested chemical requirement for toys on N-nitrosamines and N-nitrosatable substances for accessible parts of child use and care articles. The requirement should be valid for products made of rubber or elastomer materials.

Table 26: Suggested chemical requirements for N-nitrosamines and N-nitrosatable substances for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
N-nitrosamines and N-nitrosatable substances	Rubber materials Elastomer materials	<p>Type of limit value: Based on migration</p> <p>Limit value: For accessible parts of child use and care articles:</p> <ul style="list-style-type: none"> • 0.01 ppm in total of N-nitrosamines released. • 0.1 ppm in total of N-nitrosatable substances. <p>Test method: As described in EN 71-12 (2013), but with dynamic migration. Migration time should be discussed further.</p>

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

This group covers substances with hazardous properties not dealt with in the previous sections. In the former ASI Consumer Council study “Chemical requirements for toys” (Poulsen, 2013), this group of chemical was not discussed much in detail and it was emphasised that perhaps only very toxic and toxic substances should be restricted. At least this aspect should be discussed in further details.

For child use and care articles, it is proposed to use the suggested chemical requirement toys on substances classified as very toxic, toxic, harmful, corrosive, irritating etc. for accessible parts of child use and care articles. The requirement should be valid for all materials as these substances may be present in all materials.

Table 27: Suggested chemical requirements for substances classified as very toxic, toxic, harmful, corrosive, irritating etc. for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
Substances classified as very toxic, toxic, harmful, corrosive, irritating etc.	All materials	<p>Type of limit value: Based on content</p> <p>Limit value: For <u>accessible parts of child use and care articles</u>: Only chemicals <u>not</u> fulfilling the following hazard criteria shall be used in materials for accessible parts of child use and care articles:</p> <ul style="list-style-type: none"> • “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), • “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). <p>Test method: None suggested. Perhaps based on SDS on used chemicals.</p>

6.4.17 Nanomaterials

As described in the former ASI Consumer Council study “Chemical requirements for toys” (Poulsen, 2013), 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. For products accessible to children a potential risk may therefore be present. It is proposed to use the suggested chemical requirement toys on nanomaterials for accessible parts of child use and care articles. The requirement should be valid for all materials as these substances may be present in all materials.

Table 28: Suggested chemical requirements for nanomaterials for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
Nanomaterials	All materials	<p>Type of limit value: Content based</p> <p>Limit value:</p> <ol style="list-style-type: none"> 1. Nanomaterials shall not be actively added to accessible parts of child use and care articles (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. <p>Test method: Depends on the substance</p>

6.4.18 Use of Food Contact Materials Regulation for child use and care articles

As described in the former ASI Consumer Council study “Chemical requirements for toys” (Poulsen, 2013), organisations such as BfR and ANEC suggest using the principles behind the Food Contact Materials (FCM) Regulation on plastic materials for toys. The same principles could also be relevant to transfer to the parts of child use and care articles which are accessible to children. Therefore it is proposed to use the suggested chemical requirement toys on FCM legislation for plastic materials for [accessible parts of child use and care articles](#).

It is suggested for simplicity reasons to use the suggested chemical requirement for child use and care articles as defined in this report.

Table 29: Suggested chemical requirements concerning FCM legislation for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
Use of FCM legislation	Plastic materials	<p>Type of limit value: Migration based limit values as used in the FCM Regulation for plastic materials in accessible parts of child use and care articles.</p> <p>Limit value: A combination of the following limit values should be used as used in the FCM Regulation for plastic materials:</p> <ul style="list-style-type: none"> • Only substances on the positive list of authorised materials may be used for manufacturing of plastic materials for child use and care articles. • 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)). <p>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)):</p>

Group of chemicals	Relevant materials	Suggested chemical requirements
		<ul style="list-style-type: none"> • 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 article. • Use of repeated extraction with several hours pause. Calculation of average migration. • Use of dynamic migration.

7 Suggested chemical requirements

This chapter contains a total list of the suggested chemical requirements based on the review and discussions made in this report and in the former project – the ASI Consumer Council study: “Chemical requirements for toys” (Poulsen, 2013).

Table 30: Suggested chemical requirements for child use and care articles

Group of chemicals	Relevant materials	Suggested chemical requirements
<p>CMRs PBTs vPvBs and others (e.g. EDCs)</p>	<p>All materials</p>	<p>Type of limit value: Migration or content based limit values depending on the material and the nature of the substances:</p> <p><u>Non-volatile substances:</u></p> <ul style="list-style-type: none"> • Solid: Migration based <p><u>Volatile substances:</u></p> <ul style="list-style-type: none"> • All child use and care articles: Evaporation based <p>Limit value CMRs (category 1A, 1B and 2) and EDCs (proposed category 1A and 1B): <u>Migration based limit value:</u> Must not be detectable, i.e. 0.01 mg/kg (10 ppb) in all child use and care articles (possibly limited to parts accessible to children).</p> <p><u>Content and evaporation based limit value:</u> Need to be discussed.</p> <p>Exemptions can be made, but only on the basis of a full risk assessment and a positive opinion by SCHER.</p> <p>Limit value PBTs and vPvBs: PBTs and vPvBs must not be present in all child use and care articles (possibly limited to parts accessible to children) in a content above 0.1 %.</p> <p>Test method:</p> <p><u>Content:</u> None suggested. Dependant on the substance.</p> <p><u>Migration:</u> 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.</p>

Group of chemicals	Relevant materials	Suggested chemical requirements
PAHs	Rubber Elastomer materials	<p>Type of limit value: Content based</p> <p>Limit value: 0.2 mg/kg as for each of the 8 carcinogenic PAHs in all child use and care articles which come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal and foreseeable conditions of use.</p> <p>However, a further lowering of the limit value should be possible when validated test methods with lower detection limit values are developed.</p> <p>Test method: Test method used for the German GS (certified safety) mark.</p>
Phthalates and other plasticizers	Plastic materials (PVC, PU) Elastomer materials Adhesives Rubber Imitation leather	<p>Type of limit value: Content based</p> <p>Limit value:</p> <ul style="list-style-type: none"> No phthalates (esters of o-phthalic acid) are allowed in child use and care article. Limit value: 0.05% (500 ppm). <i>Up to debate whether the ban is general or limited to accessible parts.</i> 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 plasticizers that have been approved by SCHER on the basis of a full risk assessment (= positive list of other plasticizers which can be used in specific concentrations). <p>Test method: None suggested. Dependant on the substance.</p>
Formaldehyde	Textiles Wood Paper	<p>Type of limit value: Dependant on the material</p> <p>Limit value:</p> <ul style="list-style-type: none"> <u>Textiles:</u> Accessible textile components of child use and care article shall not contain free and hydrolyzed formaldehyde in excess of 30 mg/kg when tested in accordance with EN ISO 14184-1. <u>Paper:</u> Accessible paper components of child use and care article shall not contain formaldehyde in excess of 30 mg/kg when tested in accordance with EN 645 and EN 1541. <u>Wood:</u> Accessible resin-bonded wood components of child use and care article 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 simulatant. <p>Test method: Use of existing test methods, but to be discussed further.</p>
Phenol	Plastics Dyes	<p>Type of limit value: Migration</p> <p>Limit value:</p> <ul style="list-style-type: none"> As a monomer: 4 mg/l in aqueous migrate. <p>Test method: Use of existing test methods (in EN 71-9 (2007) and EN 71-11 (2005)).</p>

Group of chemicals	Relevant materials	Suggested chemical requirements																																																																																
Elements	All materials	<p>Type of limit value: Migration limit values split into three depending on the material:</p> <ul style="list-style-type: none"> Scraped-off <p>Limit value: Migration limit values (in mg/kg) for accessible parts of child use and care articles as listed in the table below.</p> <table border="1" data-bbox="730 450 1442 1249"> <thead> <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> </thead> <tbody> <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> </tbody> </table> <p>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/WG5, 2013).</p>	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
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Fragrances	All scented materials	<p>Type of limit value: Content based</p> <p>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 scented child use and care articles in non-detectable amounts (alternatively in an amount of 10 ppm).</p> <p>Test method: No suggestions.</p>																																																																																

Group of chemicals	Relevant materials	Suggested chemical requirements
Sensitising substances	All materials	<p>Type of limit value: Content based</p> <p>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 accessible parts of child use and care articles in a concentration higher than 100 ppm.</p> <p>If substances are sensitising in lower concentrations than 100 ppm, the sensitisation level of the specific substances must not be exceeded.</p> <p>Test method: Dependant on the substance.</p>
TCEP, TCPP and TDCP	All combustible materials	<p>Type of limit value: Content based</p> <p>Limit value: Use of TCEP, TCPP and TDCP in all child use and care articles is not allowed (non-detectable), i.e. 5 ppm (5 mg/kg).</p> <p>Test method: No suggestions.</p>
Flame retardants	All combustible materials	<p>Type of limit value: Content based and based on migration</p> <p>Limit value:</p> <ol style="list-style-type: none"> 1. It is only allowed to use flame retardants in child use and care articles that have been approved by SCHER on the basis of a full risk assessment (= positive list of flame retardants which 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 child use and care articles (non-detectable content, i.e. detection level of 5 mg/kg): <ul style="list-style-type: none"> • 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 <p>Test method: Depends on the substance.</p>
Colourants and primary aromatic amines	Textiles Leather	<p>Type of limit value: Content based</p> <p>Limit value:</p> <ul style="list-style-type: none"> • The use of the following colorants shall not be present in accessible parts of child use and care articles – action limit 10 mg/kg for all colourants below: <ul style="list-style-type: none"> ○ Disperse Blue ○ Disperse Blue 3 ○ Disperse Blue 106 ○ Disperse Blue 124 ○ Disperse Yellow 3 ○ Disperse Orange 3

Group of chemicals	Relevant materials	Suggested chemical requirements
		<ul style="list-style-type: none"> ○ 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 <ul style="list-style-type: none"> • The use of the following primary aromatic amines shall not be present in accessible parts of child use and care articles – action limit 5 mg/kg for all primary aromatic amines below: <ul style="list-style-type: none"> ○ Benzidine ○ 2-Naphthylamine ○ 4-Chloroaniline ○ 3,3'-Dichlorobenzidine ○ 3,3'-Dimethoxybenzidine ○ 3,3'-Dimethylbenzidine ○ o-Toluidine ○ 2-Methoxyaniline (o-Anisidine) ○ Aniline <p>Test method: As described in EN 71-11.</p>
Monomers	Plastic materials	<p>Type of limit value: Based on migration</p> <p>Limit value: For accessible parts of child use and care articles: 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.</p> <p>Test method: Dynamic migration method as described in EN71-10.</p>
Solvents	All materials	<p>Type of limit value: Based on migration and inhalation</p> <p>Limit value:</p> <ol style="list-style-type: none"> 1. For child use and care articles that can surround the child: Adoption of the already proposed limit values for certain solvents in EN 71-9 (2007) standard (table 2F inhalation). 2. For accessible parts of child use and care articles: Adoption of the already proposed limit values for certain solvents in EN 71-9 (2007) standard (table 2E migration). 3. However, a review needs to be made if other solvents should be restricted as well; more research and validation of the test methods and limit values are needed. <p>Test method: Dependant on the specific solvent. Some test methods are described in EN 71-10 (2005) and EN 71-11 (2005).</p>

Group of chemicals	Relevant materials	Suggested chemical requirements
N-nitrosamines and N-nitrosatable substances	Rubber materials Elastomer materials	<p>Type of limit value: Based on migration</p> <p>Limit value: For accessible parts of child use and care articles:</p> <ul style="list-style-type: none"> • 0.01 ppm in total of N-nitrosamines released. • 0.1 ppm in total of N-nitrosatable substances. <p>Test method: As described in EN 71-12 (2013), but with dynamic migration. Migration time should be further discussed.</p>
Substances classified as very toxic, toxic, harmful, corrosive, irritating etc.	All materials	<p>Type of limit value: Based on content</p> <p>Limit value: For accessible parts of child use and care articles: Only chemicals <u>not</u> fulfilling the following hazard criteria shall be used in materials for accessible parts of child use and care articles:</p> <ul style="list-style-type: none"> • “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), • “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). <p>Test method: None suggested. Perhaps based on SDS on used chemicals.</p>
Nanomaterials	All materials	<p>Type of limit value: Content based</p> <p>Limit value:</p> <ol style="list-style-type: none"> 1. Nanomaterials shall not be actively added to accessible parts of child use and care articles (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. <p>Test method: Depends on the substance.</p>

Group of chemicals	Relevant materials	Suggested chemical requirements
Use of FCM legislation	Plastic materials	<p>Type of limit value: Migration based limit values as used in the FCM Regulation for plastic materials in accessible parts of child use and care articles.</p> <p>Limit value: A combination of the following limit values should be used as used in the FCM Regulation for plastic materials:</p> <ul style="list-style-type: none"> • Only substances on the positive list of authorised materials may be used for manufacturing of plastic materials for child use and care articles. • 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)). <p>Test method: Must be further discussed, but broadly in line with EN 71-10, but modified (e.g. with principles from SCHER (2010b) and ANEC proposal (2011b)):</p> <ul style="list-style-type: none"> • 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 article. • Use of repeated extraction with several hours pause. Calculation of average migration. • Use of dynamic migration.

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Appendix 1: Suggested chemical requirements for toys

This appendix contains a total list of the suggested chemical requirements based on the review in the ASI Consumer Council study “Chemical requirements for toys” (Poulsen, 2013).

Table 31: Suggested chemical requirements for toys

Group of chemicals	Suggested chemical requirements
<p>CMRs PBTs vPvBs and others (e.g. EDCs) (all materials)</p>	<p>Type of limit value: Migration or content based limit values depending on the toy material and the nature of the substances:</p> <p><u>Non-volatile substances:</u></p> <ul style="list-style-type: none"> • Dry, brittle, powder-like or pliable: Content based • Liquid or sticky: Content based • Solid: Migration based <p><u>Volatile substances:</u></p> <ul style="list-style-type: none"> • All toys: Evaporation based <p>Limit value CMRs (category 1A, 1B and 2) and EDCs (proposed category 1A and 1B): <u>Migration based limit value:</u> Must not be detectable, i.e. 0.01 mg/kg (10 ppb) in all toys.</p> <p><u>Content and evaporation based limit value:</u> Need to be discussed.</p> <p>Exemptions can be made, but only on the basis of a full risk assessment and a positive opinion by SCHER.</p> <p>Limit value PBTs and vPvBs: PBTs and vPvBs must not be present in all toys in a content above 0.1 %.</p> <p>Test method:</p> <p><u>Content:</u> None suggested. Dependant on the substance.</p> <p><u>Migration:</u> 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.</p>

Group of chemicals	Suggested chemical requirements
<p>PAHs</p> <p>(in rubber and elastomer materials)</p>	<p>Type of limit value: Content based</p> <p>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.</p> <p>Test method: Test method used for the German GS (certified safety) mark.</p>
<p>Phthalates and other plasticizers</p> <p>(in plastic materials)</p>	<p>Type of limit value: Content based</p> <p>Limit value:</p> <ul style="list-style-type: none"> • 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 plasticizers that have been approved by SCHER on the basis of a full risk assessment (= positive list of other plasticizers that can be used in specific concentrations). <p>Test method: None suggested. Dependant on the substance.</p>
<p>Formaldehyde</p> <p>(in textiles, wood, paper, as preservative and monomer)</p>	<p>Type of limit value: Dependant on the material</p> <p>Limit value:</p> <ul style="list-style-type: none"> • <u>Textiles:</u> 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. • <u>Paper:</u> 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. • <u>Wood:</u> 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%. <p>Test method: Use of existing test methods, but to be discussed further.</p>
<p>Phenol</p>	<p>Type of limit value: Migration and content based</p> <p>Limit value:</p> <ul style="list-style-type: none"> • As a monomer: 4 mg/l in aqueous migrate • As preservative: 10 mg/kg in toy material (content based) <p>Test method: Use of existing test methods (in EN 71-9 (2007) and EN 71-11 (2005)).</p>

Group of chemicals	Suggested chemical requirements																																																																																
Elements (in all materials)	<p>Type of limit value: Migration limit values split into three depending on the toy material:</p> <ul style="list-style-type: none"> • Dry, brittle, powder-like or pliable • Liquid or sticky • Scraped-off <p>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.</p> <table border="1" data-bbox="730 546 1433 1346"> <thead> <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> </thead> <tbody> <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> </tbody> </table> <p>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).</p>	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
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Fragrances (in all materials)	<p>Type of limit value: Content based</p> <p>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).</p> <p>Test method: No suggestions</p>																																																																																
Isothiazolinones (in “chemical” toys)	<p>Type of limit value: Content based</p> <p>Limit value: Use of isothiazolinones in toys is not allowed (non-detectable).</p> <p>Test method: HPLC, detection limit 2 ppm.</p>																																																																																

Group of chemicals	Suggested chemical requirements
Sensitising substances (in all materials)	<p>Type of limit value: Content based</p> <p>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.</p> <p>If substances are sensitising in lower concentrations than 100 ppm, the sensitisation level of the specific substances must not be exceeded.</p> <p>Test method: Dependant on the substance</p>
TCEP, TCPP and TDCP (in all materials)	<p>Type of limit value: Content based</p> <p>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.</p> <p>Test method: No suggestions</p>
Flame retardants (in all materials)	<p>Type of limit value: Content based and based on migration</p> <p>Limit value:</p> <ol style="list-style-type: none"> 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): <ul style="list-style-type: none"> • 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 <p>Test method: Depends on the substance</p>

Group of chemicals	Suggested chemical requirements
<p>Colourants and primary aromatic amines</p> <p>(in all materials)</p>	<p>Type of limit value: Content based</p> <p>Limit value:</p> <ul style="list-style-type: none"> • The use of the following colorants shall not be present in all toys – action limit 10 mg/kg for all colourants below: <ul style="list-style-type: none"> ○ 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 • 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: <ul style="list-style-type: none"> ○ Benzidine ○ 2-Naphthylamine ○ 4-Chloroaniline ○ 3,3'-Dichlorobenzidine ○ 3,3'-Dimethoxybenzidine ○ 3,3'-Dimethylbenzidine ○ o-Toluidine ○ 2-Methoxyaniline (o-Anisidine) ○ Aniline <p>Test method: As described in EN 71-11</p>
<p>Monomers</p> <p>(in plastic materials)</p>	<p>Type of limit value: Based on migration</p> <p>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.</p> <p>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.</p>

Group of chemicals	Suggested chemical requirements
<p>Solvents (in all materials)</p>	<p>Type of limit value: Based on migration and inhalation</p> <p>Limit value:</p> <ol style="list-style-type: none"> 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. <p>Test method: Dependant on the specific solvent. Some test methods are described in EN 71-10 (2005) and EN 71-11 (2005).</p>
<p>Preservatives and biocides (in all materials)</p>	<p>Type of limit value: Based on content</p> <p>Limit value:</p> <ol style="list-style-type: none"> 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. <ul style="list-style-type: none"> • But excluding preservatives that are restricted in the Cosmetic Products Directive with the following statements: <ul style="list-style-type: none"> ○ 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. <p>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.</p>
<p>N-nitrosamines and N-nitrosatable substances (in rubber materials)</p>	<p>Type of limit value: Based on migration</p> <p>Limit value: For all toys:</p> <ul style="list-style-type: none"> • 0.01 ppm in total of N-nitrosamines released. • 0.1 ppm in total of N-nitrosatable substances. <p>Test method: As described in EN 71-12 (2013), but with dynamic migration. Migration time should be further discussed.</p>

Group of chemicals	Suggested chemical requirements
<p>Substances classified as very toxic, toxic, harmful, corrosive, irritating etc. (in all materials)</p>	<p>Type of limit value: Based on content</p> <p>Limit value: For all toys: Only chemicals <u>not</u> fulfilling the following hazard criteria shall be used in toy materials:</p> <ul style="list-style-type: none"> • “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). <p>Test method: None suggested. Perhaps based on SDS on used chemicals.</p>
<p>Nanomaterials (in all materials)</p>	<p>Type of limit value: Content based</p> <p>Limit value:</p> <ol style="list-style-type: none"> 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. <p>Test method: Depends on the substance</p>

Group of chemicals	Suggested chemical requirements
<p>Use of FCM legislation (in plastic materials)</p>	<p>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.</p> <p>Limit value: A combination of the following limit values should be used as used in the FCM Regulation for plastic materials:</p> <ul style="list-style-type: none"> • 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)). <p>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)):</p> <ul style="list-style-type: none"> • 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.