



CEN GUIDE 16

**Guide for addressing chemicals in
standards for consumer-relevant
products**

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Foreword

In March 2010, CEN adopted a guidance document entitled “CEN approach on addressing environmental issues in product and service standards”. The key objective of this approach was to establish a general framework to promote and ensure better inclusion of environmental aspects in European Standards. The document acknowledged that in addition to generic instruments in support of the incorporation of environmental considerations into European product and service standards, tailored environmental programmes for Technical Committees addressing specific issues may be needed.

Subsequently, it was decided to initiate a project with the aim to address chemicals in product standards and a project proposal was developed by the project partners: ASI, DS, ECOS and UNE. CEN’s Strategic Advisory Body on Environment (CEN/SABE) approved the project proposal in March 2013 (Decision 03/2013) and financial support was granted by the European Commission in December 2014.

In the context of the project, “product” is understood as “article”, as defined in the REACH Regulation. The main aim of the project is to ensure that chemicals are adequately addressed in standards for articles (i.e. products other than chemical mixtures) which are intended for consumers, which are likely to be used by consumers even if not intended for them, or to which consumers may be exposed (e.g. in the context of a service).

The project supports the EU objectives to minimize the health and environmental impacts of chemicals most recently repeated in the 7th Environmental Action Programme, and can contribute to the development of a “Union strategy for a non-toxic environment” envisaged for 2018.

The project consists of 3 key activities:

- Setting up of a multi-stakeholder panel of experts;
- Development of a guidance document including the preparation of a literature review report;
- Development of a strategy for the implementation of the guidance document.

The stakeholder panel consulted in the development of the Guide was made up of representatives from consumer organisations, industry, research and testing institutes, the European Commission, the European Chemicals Agency and public authorities.

This “Guide for addressing chemicals in standards for consumer-relevant products” includes a framework and recommendations for normative provisions relating to chemicals which should be taken into consideration when developing standards for consumer-relevant articles.

A separate background information to the Guide provides information including regulatory provisions for chemical substances, for specific articles, and related standards, as well as internet links where most up-to-date information can be found. Information is also provided for voluntary instruments and policy developments in the EU and in some Member States. This information aims to put into a wider context issues relating to chemicals that could be addressed in standards for consumer-relevant articles.

Publication of a Guide by CEN requires approval by simple majority of the national bodies casting a vote.

Introduction

This Guide is intended for use by anyone involved in drafting standards for consumer-relevant products other than chemical mixtures (i.e. the Guide covers “articles” as defined in REACH) with the aim of minimizing exposure to chemicals which may constitute a health risk while also bearing in mind environmental burdens.

Establishing standards provisions on chemicals is a complex task requiring specialist knowledge. Not all standards writers have expertise in scientific disciplines such as chemistry and (eco)toxicology but, by using this Guide, they are encouraged to:

- identify and understand basic principles that need to be considered when thinking about incorporation of chemicals provisions into standards for consumer-relevant articles;
- identify and understand the regulatory and political background as well as existing voluntary initiatives and tools relevant to chemicals in articles;
- assess the relevance of existing information sources with respect to a particular group of articles;
- identify and consult with competent and experienced chemistry and (eco)toxicology experts from a broad range of stakeholders;
- integrate chemicals provisions in standards for consumer-relevant articles, where appropriate.

The need for external expertise will vary depending on the availability of experts familiar with monitoring and establishing chemicals provisions in articles. In any case it may be useful to establish specific Working Groups (or Task Groups) composed of experts possessing the necessary skills with the aim to develop chemicals related (parts of) standards addressing chemicals in articles.

Naturally a broad Guide like this can only constitute a starting point for the development of article-specific requirements. It cannot provide article-specific solutions which can be copied and pasted into standards. Consequently, the adequacy of any particular recommendation in the Guide including referenced sources for a specific article and/or material needs to be checked by the Technical Committee in charge of preparing a standard for a specific article, particularly when making use of requirements developed for other sectors or articles. The data quality needs and scientific rigour of assessments to derive limit values may vary in the specifications presented in the Guide. It should also be borne in mind that the level of ambition in certain approaches (e.g. the European Ecolabel) is higher compared to others which aim to set baseline criteria. Hence, the final responsibility of the Technical Committee to assess the scientific validity of limits to be used in a standard and to determine the chemical provisions appropriate for a specific article and/or material is underlined.

Normally some information is readily available when identifying chemicals of concern which are or may be present in a specific article. The compilation of available data sources (regulatory provisions, voluntary instruments, test reports, scientific literature and assessments, etc.) will be begun at the start of any normative project. The separate background information to this Guide provides information including references to many data sources and may be of help in this regards.

In some areas there are already sector-specific approaches (e.g. guidelines and certification schemes) available and should be considered in addition to the present Guide.

1 Scope

This document provides guidance on addressing chemicals in the development of standards for consumer-relevant articles. The aim is to minimize the impacts of chemicals of concern on human health and the environment by complying with, complementing or going beyond legal obligations for

these chemicals. Emphasis is given to chemicals in articles posing risks to human health during use. The environmental dimension is considered, where feasible and where appropriate, for instance by addressing environmental exposure or persistent or bio-accumulative chemicals.

The Guide is intended to assist in the development of normative provisions for chemicals, particularly in those areas where specific regulatory provisions (e.g. limit values) for chemicals are absent and are not envisaged to be implemented in the foreseeable future such as articles covered by the General Product Safety Directive (2001/95/EC). In so doing, the Guide aims to facilitate the placing on the market of safe products. In addition, these guidelines can assist those with a general professional interest in consumer safety.

The Guide including the associated background information document presents a comprehensive overview of approaches taken on chemicals in various legislative and voluntary tools. It is not intended to override legal obligations. Both documents reflect the status as of April 2017.

Electrical and electronic equipment, and ICT products, are excluded from the scope as these products fall under the lead of CENELEC and ETSI, respectively. Food contact materials, materials used in the supply of drinking water, medical devices, and construction products are also excluded. This is because comprehensive, detailed and specific regulation on chemicals in these products is either already available or subject to consideration and debate; because specific approaches are required; or because performance requirements are supposed to be addressed at national level; or a combination of all these. Nonetheless, some of the guidance may be useful in areas excluded from the scope of the Guide.

It is envisaged that sector specific guides or standards dealing with chemical hazards in standards for consumer-relevant articles, where available, should be used in conjunction with the present Guide.

NOTE The Bibliography includes relevant CEN sector guidance documents.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1 article

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

[SOURCE: REACH, Article 3.3]

2.2 consumer-relevant article

an article which is intended for consumer use, is likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them or to which consumers may be exposed (e.g. in the context of a service)

3 Regulatory, normative and policy background

3.1 General

In Europe consumer-relevant articles are covered by a wide range of regulatory requirements addressing the use of chemical substances in their production, the content of chemical substances in them, and the release of chemical substances from such products. In addition, national, European and international standards and other voluntary specifications which include chemical provisions are available.

In determining the need for, the kind of and the specific characteristics of any envisaged chemical provision it is essential to investigate the existing regulatory provisions including related standards for

the article in question as well as applicable voluntary specifications. In addition, it is advisable to include further subjects in the research including European and national policy developments, envisaged legislative measures, scientific opinions, and identified concerns.

The following clauses provide a brief overview of some of the most relevant information sources which should be investigated prior to establishing chemical requirements for consumer-relevant articles.

Recommendation:

The background information to this Guide provides documentation and a more comprehensive description of some of the issues covered in this Guide including links to important reference documents on the internet and may provide useful additional information. Readers of the Guide are recommended to review and make use of the information included in this complementary document.

NOTE A list of all recommendations is provided in Annex A.

3.2 Chemicals legislation

3.2.1 REACH Regulation

The EU's horizontal chemicals management legislation is known as REACH - Registration, Evaluation, Authorization and Restriction of Chemicals (Regulation (EC) No 1907/2006). It aims to improve the protection of human health and the environment through better and earlier identification of the intrinsic properties of chemical substances, and to enhance innovation and competitiveness of the EU chemicals industry.

Through REACH, all chemical substances on their own or in mixtures manufactured or imported in quantities of at least 1 tonne per year per manufacturer or importer must be registered with the European Chemicals Agency (ECHA) unless they are exempted from the scope of registration. The registration obligations for substances in articles (when the chemical substance is intended to be released) apply to quantities totalling over 1 tonne per producer or importer per year. Registration requirements include the provision of information about the chemical's physicochemical, toxicological and ecotoxicological properties.

Chemical substances in articles do not need to be registered under REACH, except chemical substances intended to be released from articles (e.g. a scented eraser), and then only if the annual substance production levels are greater than 1 tonne per manufacturer/importer. Chemical substances unintentionally released during use are not in the scope of registration, such as plasticizers migrating from a product over time.

Chemicals with certain hazardous properties may be identified as "substances of very high concern" (SVHC) and may be subject to authorization before being allowed to be manufactured or used in the European Union. These properties are carcinogenic, mutagenic and toxic for reproduction (CMRs), persistent, bio-accumulating and toxic/very persistent and very bio-accumulating (PBTs/vPvBs), and chemical substances identified as causing serious and irreversible effects to humans or the environment equivalent to the effects mentioned earlier. As a first step, such chemical substances are incorporated in a "candidate list" of SVHCs, and may eventually be included in an Authorization list (Annex XIV list). These chemical substances cannot be placed on the market or used for manufacturing in Europe after a given date, unless an authorization is granted for their specific use, or the use is exempted from authorization.

If articles including articles in complex products (consisting of several articles) contain chemical substances on the "candidate list" (SVHC list) in a concentration above 0,1 % (w/w), the supplier or importer must provide sufficient information (as a minimum the name of the chemical substance) to the recipient of the article to allow for its safe use. For consumers the information about these chemical substances in the article must only be given upon request and within 45 days of the request (Article 33).

This requirement is independent of the total tonnage of the chemical substance. No such requirement exists for other chemical substances in articles.

If a SVHC is present in a concentration above 0,1 % in the article including articles in complex products, and its import or manufacturing quantities are above 1 tonne per year per company, EU producers or importers of articles must notify the European Chemicals Agency (ECHA) of the presence of the SVHC unless exposure during normal and reasonably foreseeable conditions of use and disposal can be excluded (Article 7). Such notification requirement does not exist for other chemical substances in articles.

Chemical substances can be restricted where there is an unacceptable risk to health or the environment, and these limits also apply to imported products. By April 2017 the REACH Restricted Substance list (Annex XVII list) contained 67 entries including specific restrictions on 62 chemical substances or groups of substances (5 entries have been deleted: 33, 39, 42, 44, 53). These may apply to all uses of the substance or more specifically to certain product types or types of uses. In some cases, the REACH restrictions are complemented by European standards which provide test methods. Some “harmonised” standards address test methods for the release of nickel. Appendix 8 of Annex XVII includes a list of test methods for determination of certain aromatic amines derived from azo colorants.

Recommendation:

The relevant REACH provisions including ongoing developments and how they apply to the concerned product category should be taken into account. This particularly applies to restrictions contained or envisaged to be included in the list of restricted substances (Annex XVII).

When establishing normative chemical provisions for consumer-relevant articles substances covered by Annex XVII relating to the articles and/or materials in question normally do not need to be addressed (since the legal requirements apply anyway) unless there are exceptionally specific reasons to do so, e.g. if only a specific risk or material is addressed in the REACH restriction or lower limits seem preferable in line with sector-specific considerations and established practices and based on a sound scientific assessment in accordance with the state-of-the art of chemical safety assessment. In any case a proper justification should be given where such requirements are established.

3.2.2 CLP Regulation

The Classification, Labelling and Packaging of substances and mixtures Regulation (Regulation EC/1272/2008) also known as the CLP Regulation sets out chemical substance classification criteria and labelling rules. These criteria and rules are based on the United Nations Globally Harmonized System of classification and labelling of chemicals (GHS), providing an internationally harmonized approach.

The main purpose of the CLP Regulation is to identify and communicate the hazardous properties of chemicals to manufacturers, workers and consumers through classification and labelling of chemicals. To this end the Regulation provides a standardized system for classification of substances and mixtures in accordance with identified hazards as well as standardized hazard statements and pictograms. Manufacturers, importers and downstream users of substances or mixtures are responsible for classification (“self-classification”).

In some cases, classification of a chemical is harmonized and obligatory at Community level (“harmonised classification”). In any case, self-classification of a substance must be performed for those hazard classes not covered by the harmonized classification. Of particular importance is Part 3 of Annex VI which includes a list of harmonized classification and labelling of hazardous substances (Table 3.1). An unofficial updated table of harmonized entries in Annex VI to CLP is available on the ECHA website: <http://echa.europa.eu/information-on-chemicals/annex-vi-to-clp>

Information on the classification of substances covering harmonized classification and self-classification is available in an inventory of classification and labelling (the “C&L Inventory”) accessible on the ECHA

website. The inventory includes classification information from REACH registrations and CLP notifications: <http://echa.europa.eu/information-on-chemicals/cl-inventory-database>

It should be noted that self-classification may not always be backed by adequate data (e.g. required in a REACH registration dossier) and, therefore, may not always be correct. Also substances may be classified differently by different manufacturers.

The classification of a substance is not only a relevant parameter in a chemical safety assessment, it may also be an important reference for a product-related provision (e.g. banning of CMRs). However, absence of a classification (especially in the case of self-classified substances) does not guarantee that a given substance may not receive a classification e.g. due to improved data availability in the future.

NOTE ECHA offers more comprehensive information on chemicals in a database structured in three layers: infocard, brief profile and detailed source data: <http://echa.europa.eu/information-on-chemicals>

Recommendation:

Standards writers should include experts that are familiar at least with the basic principles of the CLP Regulation, hazard classification and related standardized hazard statements and pictograms. Of particular importance is Part 3 of Annex VI which includes a list of substances subject to a harmonized classification and labelling of hazardous substances (Table 3.1) and information on classification of substances by industry (self-classification). This and other substance related information is accessible via the ECHA website. Ongoing developments concerning new or amended classifications should be monitored.

3.2.3 Other relevant chemicals legislation

The Regulation on Persistent Organic Pollutants (POP, Regulation (EC) No 850/2004) restricts production, placing on the market and use of chemical substances listed in Annex I of the Regulation whether on their own, in preparations or as constituents of articles. The Regulation is mainly important to identify specific substances which do not need to be addressed in developing standards.

The Biocidal Products Regulation (BPR, Regulation (EU) No 528/2012) is covered in 5.16.8.2.

Recommendation:

The substances covered by Annex I of the Regulation on Persistent Organic Pollutants (POPs) apply to articles and normally do not need to be addressed (since the legal requirements apply anyway) unless there are exceptionally specific reasons to do so, e.g. if lower limits seem preferable in line with sector-specific considerations and established practices and based on a sound scientific assessment in accordance with the state-of-the art of chemical safety assessment. In any case a proper justification should be given where such requirements are established.

3.3 Relevant EU regulation for articles and associated standards

3.3.1 General considerations

European product-specific legislation covers a broad range of articles including: toys, food contact materials, packaging, electrical and electronic equipment, batteries, energy-related products, personal protective equipment, construction products, medical devices, gas appliances, pyrotechnic articles, recreational craft as well as machinery and motor vehicles. In addition, articles not covered in any of the specific laws are addressed by the provisions of the General Product Safety Directive (GPSD) which provides a generic definition of a safe product and applies when no specific regulations exist for a given product. The background information to this Guide contains a summary of the relevant pieces of legislation and associated standards covering articles focusing on chemical provisions. It includes articles beyond the scope of this Guide as the related information may be of use in the present context. For instance, test methods developed for measuring emissions from construction products can be used in other areas such as furniture. Standardization committees addressing chemicals in specific articles

will need to be familiar with the relevant provisions included in the applicable legislation. In addition, it may be useful to understand how chemicals are addressed in legislation in other product areas, particularly where similar materials and/or chemicals are used or exposure situations are comparable.

In this section two directly relevant Directives are briefly described: the General Product Safety Directive (GPSD) and the Toy Safety Directive (TSD). The GPSD covers a broad range of articles and will be relevant for many products which could be covered by normative chemical requirements. The TSD is one of the few examples of legislation for consumer-relevant articles establishing chemical provisions which may also be relevant for a range of articles which are not toys, particularly for children.

Recommendation:

Standardization bodies should include experts that are familiar with the chemicals-related regulatory provisions and developments applicable to the articles in question. It is also useful to look at areas where similar materials and/or chemicals are used or exposure situations are comparable. As an example, chemical requirements for toys may be a useful reference in determining requirements applicable to other articles, particularly to articles for children.

3.3.2 General Product Safety Directive (GPSD) and related standards

The General Product Safety Directive (GPSD, Directive 2001/95/EC) contains a general safety requirement and does not address chemical substances in particular. However, Article 13 provides for the opportunity to adopt temporary “emergency” measures which may include limit values for chemical substances in consumer products. Such measures had been adopted for certain phthalates in toys and childcare articles and for dimethylfumarate (DMF) in consumer products. Both have later been incorporated into REACH. In addition, Member States can impose actions on products found unsafe. So a manufacturer should be able to demonstrate that the chemicals included in a product do not constitute an unacceptable risk.

The Directive is complemented by approximately 60 harmonized standards developed following “standardisation requests” (formerly called “mandates”) issued by the European Commission which are based on safety requirements published in the form of Commission decisions. In some cases, references to “existing” standards (i.e. standards developed before the entry into force of the GPSD) were published in the Official Journal without mandates.

A limited number of those – particularly in the field of child use and care articles - include chemical requirements. In most cases only requirements for elements/metals are covered which correspond to limits applicable to toys. Few standards include more far reaching chemical provisions including other substances.

CEN Technical Committee (CEN/TC) 252 “Child use and care articles” developed safety guidelines to be used by its Working Groups when preparing standards, and the second part of these guidelines addresses chemicals. CEN/TR 13387-2:2015 “Child use and care articles - General safety guidelines - Part 2: Chemical hazards” includes recommendations for chemical provisions to be considered which are strongly based on regulatory and normative provisions applicable to toys. These guidelines seem relevant for a broader range of articles, particularly articles for children, and have been used as a starting point for the preparation of the current CEN Guide.

3.3.3 Toy Safety Directive (TSD) and related standards

The Toy Safety Directive (TSD, Directive 2009/48/EC) sets out the safety criteria that toys must meet before they can be placed on the EU market. The essential safety requirements address general risks - the health and safety of children, and other people such as parents or caregivers; and particular risks - physical, mechanical, flammability, chemical, electrical, hygiene and radioactivity. Toys must also comply with any other EU legislation applicable to them. The chemical requirements contained in the Directive cover:

- chemical substances classified as carcinogenic, mutagenic or toxic to reproduction (CMR);

- allergenic fragrances;
- migration of elements; and
- N-nitrosamines and N-nitrosatable substances.

In addition, the European Commission may adopt specific limit values for chemical substances used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth (Article 46), taking into account food contact material legislation (Regulation (EC) No 1935/2004). These specific limit values are listed in Appendix C of Annex II. By April 2017 limits for the following substances were included: tris (2-chloroethyl) phosphate (TCEP), tris-monochloro-propyl phosphate (TCPP), tris(1,3-dichloropropyl-2) phosphate (TDCPP), bisphenol A (BPA), formamide, benzisothiazolinone, chloromethyl-isothiazolinone and methylisothiazolinone.

The following harmonized standards whose references have been published in the Official Journal deal with chemical substances in toys which may be relevant for other articles, particularly for children:

- EN 71-3:2013+A1:2014, “Safety of toys - Part 3: Migration of certain elements”;
- EN 71-12:2016, “Safety of toys - Part 12: N-Nitrosamines and N-nitrosatable substances”.

The following harmonized standards whose references have not been published in the Official Journal deal with chemical substances in toys which may be relevant for other articles, particularly for children:

- EN 71-9:2005+A1:2007, “Safety of toys - Part 9: Organic chemical compounds – Requirements”;
- EN 71-10:2005, “Safety of toys - Part 10: Organic chemical compounds - Sample preparation”;
- EN 71-11:2005, “Safety of toys - Part 11: Organic chemical compounds - Method of analysis”.

The standards EN 71-9, EN 71-10 and EN 71-11 which do not provide a presumption of conformity to essential requirements of the TSD include limit values and test methods for certain organic chemical compounds such as flame retardants, colorants, primary aromatic amines, monomers (migration), solvents (migration and inhalation), wood preservatives, preservatives and plasticizers (migration).

It should be noted, however, that EN 71-9, EN 71-10 and EN 71-11 are partly outdated and are under review.

3.4 EU policy developments, discussions, scientific opinions and tools relevant to chemicals

Several ongoing developments in the European Union potentially affect chemicals legislation as well as chemical provisions in specific regulations addressing consumer-relevant products. This includes not only the implementation, review and revision of current legislative frameworks but also issues such as strategic policy approaches, risk assessments of specific chemicals in articles or further development of risk assessment methodologies. It is important to monitor these developments including those not directly related to the products in question. Below there is a list of policy programmes and activities of particular relevance to chemical related issues.

The background information to this Guide provides key details on the following policy areas and tools, ranging from high-level strategies, to developments in elements of chemicals legislation and on specific aspects or classes of substances or materials, to scientific opinion bodies assisting in the development and implementation of existing legislation relevant to chemicals (see background information, Clause 2):

- 7th Environmental Action Programme;

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- Circular Economy;
- Banning CMR substances in consumer products based on Article 68 (2) of REACH;
- REACH SVHC roadmap;
- Endocrine Disrupting Chemicals;
- Combination effects of chemicals;
- Exposure to single substances via different routes and from different sources;
- Nanomaterials;
- Food contact materials;
- Materials in contact with drinking water;
- Emissions to indoor air;
- EU Scientific Committees;
- EU Export Helpdesk Database.

NOTE While some of the items listed above are beyond the scope of the current Guide, the associated information may provide a wider policy and regulatory context for chemicals aspects relevant for certain articles.

Recommendation:

Standards writers should include experts that are familiar with ongoing developments and discussions in the European Union related to implementation, review and revision of current legislative frameworks addressing chemicals in articles to be standardized, as well as relevant strategic policy approaches, risk assessments of specific chemicals in articles or further development of risk assessment methodologies.

3.5 Relevant national product regulation and policy developments

In some cases, familiarity with legislative instruments, normative provisions and policy developments in the EU Member States is useful not only to avoid potential discrepancies between standards and national regulations but also as a source of inspiration for the setting of normative requirements. Often national initiatives pave the way for the adoption of European measures.

The background information to this Guide addresses the following subjects, initiatives and national implementation decisions of EU legislation which can provide more detail of relevance to chemicals aspects relating to consumer-relevant products (see background information, Clause 3):

- General strategies;
- Endocrine Disrupting Chemicals (EDCs);
- Nanomaterials;
- Food contact materials;
- Materials in contact with drinking water;
- Emissions to indoor air;

- Textiles;
- Information on chemicals in articles.

NOTE While some of the items listed above are beyond the scope of the current Guide, the associated information may be relevant for certain articles.

Recommendation:

Standards writers should include experts that are familiar with the most relevant legislative instruments, normative provisions and policy developments, initiatives and discussions in pioneering Member States (e.g. Member States with benchmark legislation) related to chemicals in articles to be standardized.

3.6 Voluntary specifications (ecolabel criteria, industry initiatives and standards)

Chemical provisions are also found in various kinds of voluntary specifications which can be a valuable source of information when establishing normative requirements for consumer-relevant articles. Often these voluntary tools are much ahead of regulatory frameworks as they are on a voluntary basis and can be produced in the context of environmental excellence that goes beyond existing legislation.

This includes, for example, the chemical requirements contained in many European Ecolabel product criteria. These provisions are often drawn from national ecolabels or other voluntary instruments and have been agreed in a multi-stakeholder process.

The key elements of the European Ecolabel Regulation relevant for chemicals in consumer-relevant articles as well as a brief description of the chemical requirements included in the product specific European Ecolabel criteria are summarized in the background information to this Guide (see background information, subclause 4.1) which also identifies articles covered by selected national or regional ecolabel criteria, namely the German Blue Angel and the Nordic Swan (see background information, subclause 4.2).

NOTE Voluntary ecolabel criteria (which may be based on legislation) are supposed to award the best performing products on the market and, therefore, many requirements are more demanding than those included in obligatory legislation. It is worth keeping this in mind when making use of ecolabel criteria to set standard requirements which are typically supposed to provide basic level substance limits. Further, ecolabel criteria make more extensive use of hazard-based provisions compared to regulatory approaches covering chemicals in products. In the latter case hazard-based exclusions are mainly related to CMR substances.

A further clause of the background information addresses several activities in the field of textiles and leather, including the well-known Oeko-Tex® Standard 100 and the industry-led initiatives “Zero Discharge of Hazardous Chemicals (ZDHC) Programme”, both of which focus on production-related elements. Similarly, the product-related criteria established by the “Apparel & Footwear International RSL Management Group (AFIRM)”, a joint initiative of major apparel brands, are also addressed (see background information, subclause 4.3).

In addition, CEN/TR 16741:2015 “Textiles and textile products - Guidance on health and environmental issues related to chemical content of textile products intended for clothing, interior textiles and upholstery”, CEN ISO/TR 16178:2012 “Footwear - Critical substances potentially present in footwear and footwear components (ISO/TR 16178:2012)”, CEN/TR 16417:2016: “Footwear -Footwear industry guideline for substances of very high concern (Annex XIV of REACH)” and EN ISO 20137 “Leather - Chemical tests - Guidelines for testing critical chemicals in leather” are briefly summarized.

Activities of stakeholders other than industry are also covered in the background information (see background information, subclause 4.4), in particular, by the environmental NGO, the International Chemical Secretariat (ChemSec). ChemSec issues a list of chemicals that, according to its interpretation,

satisfy the REACH criteria for Substances of Very High Concern (SVHC). The list, called the “SIN List” (Substitute It Now!), is developed by ChemSec in close collaboration with an NGO advisory committee.

Recommendation:

Chemical provisions in existing voluntary initiatives including EU and national ecolabels, product standards and industry or NGO led initiatives establishing criteria for chemicals in articles should be reviewed. It should be kept in mind that the level of ambition varies in different approaches and, therefore, the aspiration level in European standards may be different from other specifications. Similarly, the validity and scientific foundation may vary among initiatives and should be considered. Finally, it should be borne in mind that ecolabel criteria make more extensive use of hazard-based provisions compared to obligatory regulatory approaches.

3.7 International developments

The United Nations Environment Programme (UNEP) oversees international efforts to ensure that by 2020 chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health. Under UNEP's auspices, the Strategic Approach to International Chemicals Management (SAICM) is a policy framework to foster the sound management of chemicals. A specific project on chemicals in products (CiP) aims at improving information provision on chemicals along the supply chain, and of particular relevance is a pilot project on the textiles sector. SAICM's work described briefly in the background information to this Guide (see background information, Clause 5).

4 Basics of Chemical Safety Assessment (CSA)

When developing chemical provisions for consumer-relevant articles it is essential to evaluate the risks to human health and the environment associated with the exposure to chemicals. This process has been called chemical risk assessment. Within REACH this is designated as chemical safety assessment (CSA) and is linked to the specific requirements of this particular legislation (e.g. tonnage thresholds). However, the CSA basic principles and procedures required for the purpose of REACH are equally valid for the assessment of any chemical produced in any amount and used in any product in any regulatory context though certain sectors may have detailed rules for the chemical risk assessment of their products. Nevertheless, REACH guidance documents for chemical safety assessment are a useful reference for establishing limit values for articles in standards.

In most cases, however, standardisers establishing chemical provisions in standards for consumer-relevant articles will rely on available risk assessments carried out by competent bodies and/or existing limits for other (similar) products or materials and will adapt them to the specific needs of the articles in question. Nevertheless, it is important to understand the key aspects of a chemical safety assessment.

CSA is the process that identifies and describes the conditions under which the use and/or presence of a chemical substance is considered safe. A more comprehensive description of the CSA including links to the relevant REACH guidance documents is provided in the background information to this Guide (see background information, subclause 1.1.1.6). Here we summarize briefly the three major steps in the CSA process as described in the REACH guidance documents. These are:

Hazard assessment requires the collection and evaluation of all available and relevant information on the intrinsic properties of a chemical substance. The objective of the hazard assessment is to identify the hazards of the substance, assess their potential effects on human health and the environment, and determine, where possible, the threshold levels for exposure considered as safe (the so-called Derived No-Effect Level, DNEL).

Exposure assessment is the process of measuring or estimating the dose or concentration of a chemical substance to which humans and the environment are or may be exposed, depending on the use of the chemical substance and the use of products in which it is present. Within the exposure assessment, the definition of the conditions under which the chemical substance is used and present, as

well as how a product or product group containing the chemical substance is used, is critical in order to determine the potential level of exposure. The information on the conditions under which a chemical substance and the product or product group containing the chemical substance is used is called the **exposure scenario**. For each exposure scenario, the potential exposure levels of humans and if relevant the environment need to be determined.

Risk characterization compares levels of exposure with the threshold levels for each relevant effect. Risks are regarded as controlled when the potential exposure levels to the chemical substance are below the threshold levels considered as safe. For effects with no threshold levels, emissions and exposures must be minimized or avoided for risks to be considered to be controlled.

Recommendation:

Standards writers should include experts that are familiar with the basic principles of chemical risk assessment or chemical safety assessment. Even though, in most cases, standardisers will not conduct a full assessment and will rely on available risk assessments carried out by competent bodies and/or existing limits for other (similar) products or materials and will adapt them to the specific needs of the articles in question.

5 Chemical requirements for consumer-relevant articles

5.1 General aspects

Several existing processes provide potential inspiration for approaches to different groups of chemicals which could be covered in standards for consumer-relevant articles. The basic philosophy of this Guide is to build upon existing chemical provisions in regulatory and voluntary specifications for certain articles and to suggest considering their application in standards for consumer-relevant articles, possibly adapted to the needs of the materials and/or sector concerned.

In a general guidance document like this, covering a broad range of consumer-relevant articles, the given recommendations cannot be more than a starting point for further in-depth assessment and discussion. The referred sources and possibly others should be reviewed to identify possible provisions for chemicals in consumer-relevant articles which might need adjustment when applied to a particular article (addition or subtraction of substances, or different limit values) depending on the article in question. The scientific validity of the information as well as the level of ambition of specifications may vary and should be assessed. Chemical requirements in standards for consumer-relevant articles should be based on sound scientific assessments. Available source documents may be subject to change which needs to be kept in mind when work is underway on how to address chemicals for any given consumer-related products. In addition, recommended thresholds for consumer-relevant articles should be checked regularly and other values should be considered as new scientific evidence can suggest that limits need to be updated.

Similarly, the scope of application of any limit may have to be adjusted to specific user groups, exposure situations and/or materials. Where appropriate a more in-depth chemical risk assessment or chemical safety assessment may be required rather than using the suggested default categories. In such cases the assistance of specialists (e.g. toxicologists) may be required.

Standardization bodies should not only define requirements but also identify or develop related test methods that are validated to ensure accurate, reproducible and repeatable results. However, to limit the amount of testing for compliance purposes it may be useful to make use of alternative approaches such as the presentation of safety data sheets of substances or mixtures used in the production (widely practiced in EU and national ecolabel schemes) and/or a manufacturer's compliance declaration, where appropriate.

Recommendation:

The substance specific recommendations of this Guide should be considered as a starting point for further in-depth assessment and discussion to adapt the provisions to the specific product needs. Related test methods should be identified or developed to ensure accurate, reproducible and repeatable results. Validated test methods should be given preference. Alternative approaches to testing such as the presentation of safety data sheets and/or a manufacturer's compliance declaration should be also considered, where appropriate.

5.2 Substances of Very High Concern (SVHC) included in Annex XIV of REACH

It is a goal of the European chemicals regulation REACH to minimize or phase out the use of SVHCs in the long run where possible. However, the process of identification and authorization of SVHCs will take many years and, most importantly, substances subject to authorization may still be present in imported articles.

It is advisable and beneficial from a precautionary perspective as well as from a business sustainability perspective to minimize or eliminate such chemical substances in consumer-relevant articles as soon as possible once included in the "candidate list". However, it would be difficult to establish normative requirements in this regard as compliance would be expected from the day of publication of any new substance onto the candidate list unless a transitional period is defined in the standard. Furthermore not all substances of the candidate list are necessarily included in the authorization list (Annex XIV of REACH). However, at the latest any SVHC in Annex XIV should no longer be present in an article by the sunset date given for the substance. An exception should be considered for the holder of an authorization where an authorization is granted for the use of an SVHC in the production of the articles concerned. It is advisable to include a requirement including a threshold concentration for the substance (0,1 %) for its practical implementation. However, lower specific thresholds may be necessary for certain SVHCs in Annex XIV where suggested by a risk assessment. Lower limits defined for specific SVHCs take precedence over the generic threshold.

NOTE Non-authorized SVHCs in Annex XIV are not allowed to be placed on the market or used in the EU. Therefore such substances should normally not be found in articles produced in the EU, except for trace levels. Bearing in mind the challenge to verify the absence of SVHCs in consumer-relevant articles and their components in the value chain a general limit of 0,1 %, seems appropriate, particularly as it is coherent with the triggering of communication in the supply chain (defined in REACH Article 33).

Recommendation:

A requirement should be considered to ensure that substances included in Annex XIV of REACH generally do not exceed 0,1 % in the article in question or its components by the sunset date given for that substance. An exception should be considered for the holder of an authorization where the authorization is granted for the use of an SVHC in the production of the articles concerned. In addition, checks should be made on the basis of available risk assessments whether lower thresholds are warranted for specific SVHCs. Lower limits defined for specific SVHCs take precedence over the generic threshold.

5.3 Carcinogenic, mutagenic and toxic to reproduction (CMR) substances – generic provisions

Several regulations and voluntary specifications include generic, non-substance specific exclusions of chemicals classified as carcinogenic, mutagenic or toxic to reproduction (CMR) without identifying specific substances following a hazard-based approach. These provisions may relate to all categories of CMR substances or only to categories 1A and 1B.

NOTE The hazard classes and categories are defined in Part 3 of Annex I of the CLP Regulation.

In some cases, the restriction pertains to harmonized and self-declared classifications, or only to the CLP Regulation substances with harmonized classification (listed in Table 3.1 in Part 3 of Annex VI).

There are CMR restrictions relating to all chemicals contained in a product or its components, and CMR exclusions relating to certain families of chemicals such as colourants or flame retardants, as well as substance thresholds indicated. In addition, a CMR exclusion may relate to the entire product or only to accessible parts. Finally, more stringent limits for specific CMR substances and derogations may apply.

For example, the generic limits for CMR substances in the Toy Safety Directive (TSD) are the CLP Regulation's generic concentration limits for the classification of mixtures are as follows:

- for carcinogenic and mutagenic substances 0,1 % (cat. 1A), 0,1 % (cat. 1B) and 1 % (cat. 2);
- for substances toxic to reproduction 0,3 % (cat. 1A) 0,3 % (cat. 1B) and 3 % (cat. 2).

These generic concentration limits are superseded by the specific concentration limits included in Annex VI, Table 3.1 of Part 3 of the CLP Regulation.

The provision applies to substances in toys, in toy components or in micro-structurally distinct parts of toys which are accessible in any form, including inhalation. Derogations apply.

It should be noted that the EU Scientific Committee SCHER (Scientific Committee on Health and Environmental Risks) suggested that CMRs without a threshold (i.e. typically cat. 1A and 1B) should not be intentionally used in toys and their absence should be verified using a sensitive analytical method whilst specific limits for other CMRs should be set based on a risk assessment. However, this would mean a substance-by-substance approach which is time and resource consuming. Hence, it is suggested to consider an approach for certain consumer-relevant articles (other than toys) which keeps the concept of a generic restriction but complements it by substance-specific provisions, i.e. to screen the product category in question for the occurrence of CMR compounds and to identify priority substances for establishing specific normative limits based on chemical risk assessment. Any specific limit for a CMR substance included in a standard for consumer-relevant articles should, of course, prevail over the generic exclusion.

Often the ALARA ("As Low as Reasonably Achievable") principle has been applied by advisory bodies and regulatory agencies to keep the exposure of certain substances (particularly non-threshold substances) to the lowest achievable level, considering technological feasibility and economic considerations. This approach seems relevant for CMRs, particularly mutagenic carcinogens.

NOTE Further sections of this document provide additional guidance on specific CMR substances.

Recommendation:

A requirement should be considered to ensure that substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under the CLP Regulation ((EC) No 1272/2008) are not used in any part of consumer-relevant articles which, due to their accessibility, function, volume or mass, can reasonably lead to an exposure due to sucking, licking, swallowing, prolonged contact with skin or inhalation exceeding the following limits:

- for carcinogenic and mutagenic substances 0,1 % (cat. 1A), 0,1 % (cat. 1B) and 1 % (cat. 2);
- for substances toxic to reproduction 0,3 % (cat. 1A), 0,3 % (cat. 1B) and 3 % (cat. 2).

In addition, a requirement should be considered that these generic concentration limits are superseded by the specific limits included in Annex VI, Table 3.1 of Part 3 of the CLP Regulation, where such limits are available.

Where more specific limits for CMR substances are stipulated in the standard to be prepared such limits should prevail over the generic ones.

In addition, standardisers should seek to identify as a matter of priority specific CMR substances which have been associated with the relevant product category. CMRs without a threshold (i.e. typically cat. 1A and 1B) should not be intentionally used in consumer-relevant articles and their absence should be

verified using a sensitive analytical method with a low limit of detection. Limits for other CMR substances should be set using a risk assessment approach. Derogations may be set where any risk for the consumer can be excluded.

The standard could also contain a general recommendation to reduce the levels of CMR substances as far as technically feasible following the ALARA (As Low As Reasonably Achievable) principle.

5.4 Generic provisions for other hazard classes in the CLP Regulation

Generic exclusions of substances falling in other (categories of) hazard classes in the CLP Regulation have been included in voluntary specifications such as ecolabel criteria. For example, the European Ecolabel criteria for textiles excludes hazardous substances used in dyeing, printing and finishing if they meet certain hazard criteria, unless they have been specifically derogated and subject to derogation conditions. In addition to CMR substances this includes substances falling in (some or all categories of) the hazard classes “acute toxicity”, “specific target organ toxicity”, “respiratory and skin sensitisation”, “hazardous to the aquatic environment” and “hazardous to the ozone layer”.

Similar exclusions can be found in other EU and national and regional ecolabel criteria. Such hazard-based exclusions could also be introduced in standards for consumer-relevant articles complemented, where appropriate, by more specific substance limits as well as derogations under specified conditions. As in the case of CMR substances a practical enforcement limit seems warranted. This could also be the CLP thresholds for the classification of mixtures. However, it should be considered whether a risk-based approach is feasible and more appropriate to address the concern relating to a specific substance. It should be also noted that such hazard-based exclusions for other hazard classes according to the CLP Regulation are rather uncommon in regulatory and normative contexts.

Recommendation:

Other hazard-based exclusions such as for substances satisfying the criteria for “acute toxicity”, “specific target organ toxicity”, “respiratory and skin sensitisation”, “hazardous to the aquatic environment” and “hazardous to the ozone layer” could be considered as is already the case for European Ecolabel criteria. The exclusion could be limited to certain kinds of articles or families of chemicals (such as dyes) or to accessible parts of articles. The maximum concentrations could be linked to the CLP thresholds for the classification of mixtures (as in case of CMR substances). Alternatively, a risk-based approach for such substances could be used.

5.5 Generic provisions for other hazard properties not covered by the CLP Regulation

5.5.1 Endocrine disrupting chemicals (EDCs)

Although provisions on Endocrine Disrupting Chemicals (EDCs) are in force in some sectoral EU legislation (such as the Plant Protection Product Regulation (EC) 1107/2009 (PPPR) and the Biocidal Products Regulation (EU) 528/2012 (BPR)), no formal criteria have been adopted yet for unambiguously identifying or classifying such substances. However, in June 2016 the Commission presented scientific criteria to identify endocrine disruptors in the pesticides and biocides areas based on a WHO definition (“an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations”) and on a weight-of-evidence approach. In view of the negative reactions to the proposals it is unclear when a final decision will be taken. Irrespective of this, for the time being only a substance-by-substance approach based on expert judgement is possible and hazard-based exclusions resting upon classification in accordance with the CLP Regulation as in case of e.g. CMR substances are not possible. A screening for relevant EDCs in the product category in question should be conducted prior to establishing normative requirements. The background information to this Guide provides additional information on the subject including lists of identified or suspected EDCs.

Recommendation:

In the absence of a classification system for Endocrine Disrupting Chemicals (EDCs) such as the one for CMR substances hazard-based exclusions for EDCs are not useful for the time being. It is recommended to screen for the occurrence of substances with EDC properties meeting the WHO definition identified in scientific literature (peer-reviewed journals, recognized scientific bodies, opinions of scientific committees etc.) which are associated with the product category in question and to stipulate, where appropriate, substance specific limits where relevant exposure can be expected.

5.5.2 Persistent, bio-accumulative and toxic (PBT) and very persistent and very bio-accumulative (vPvB) substances

Persistent, bio-accumulative and toxic (PBT) as well as very persistent and very bio-accumulative (vPvB) substances are resistant to degradation and unwanted in the environment as they may accumulate in parts of the environment, enter the food chain and may exhibit unpredictable (not yet known) effects in the long term. Criteria for these substances are given in Annex XIII of REACH. PBTs and vPvBs should be avoided in consumer-relevant articles. However, it may be difficult for a standards user to identify substances which satisfy the PBT and vPvB criteria specified. Therefore it may be helpful to identify such substances based on existing lists of substances of concern.

Recommendation:

When setting requirements for chemicals in consumer-relevant articles and their components a requirement could be considered to ensure that the article does not contain any persistent, bioaccumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) substances based on the criteria listed in Annex XIII of REACH in amounts exceeding 0,1 % by weight if relevant amounts can be released during the life cycle of the product. The restriction could be generic or (preferably) include substances identified from existing lists of substances of concern.

5.6 Nanomaterials

Particles in the nano range (1 nm equals 1 billionth of a metre) exhibit different properties compared to bulk materials such as titanium dioxide, or show unique features in synthesized chemicals such as those found in quantum dots, as a result of the increased relative surface area (increased surface area to volume ratio) and the increased importance of quantum effects which may affect reactivity, strength, optical, magnetic and electrical characteristics of the materials. These specific material characteristics are the very reason for the great interest in these materials. As a consequence, there is a range of possible interactions with biological systems which may result in health and environmental effects. Nano-forms of traditional “bulk” substances may have different toxicological and ecotoxicological properties from the bulk form, and gaps in hazard information still exist. Some procedures for assessing the potential risks of manufactured nanomaterials are still under development and existing test results may not provide all the information deemed necessary for safety assessment.

Scientific committees have concluded that it is not possible to make general statements about the risks of nanomaterials. With current knowledge, some materials appear to raise no concern, while research on some others shows significant potential risks, so nanomaterials cannot be considered hazardous simply due to their size. Hence, a case by case approach for the risk assessment of nanomaterials has been advocated for.

Despite years of work by the European Commission to more explicitly integrate nanomaterials and specific information requirements for these materials into REACH, an official proposal for amending REACH Annexes is still awaited. Hence, REACH covers nanomaterials in the same way as all other chemical substances, but does not to date specify any additional, nano-form specific information requirements for registration.

Some European regulations include specific provisions for nanomaterials. For example, the EU Regulation on plastic materials and articles to come into contact with food materials (Commission Regulation (EU) No 10/2011) provides that substances in nanof orm shall only be used if explicitly

authorized and mentioned in the specifications in Annex I (i.e. the approval of the bulk substance does not imply that the nanoform is accepted). Similarly, the Cosmetic Products Regulation (Regulation (EC) No 1223/2009) includes specific requirements for nanomaterials including notification and labelling obligations. Approved colourants, preservatives and UV-filters listed in Annexes IV and VI include nanoforms only when specifically mentioned.

Nanomaterials should only be used where sufficient data and adequate risk assessments are available demonstrating the high likelihood of the absence of health and environmental risks. Risk assessments carried out for the bulk form of the chemical substance indicating the absence of risk cannot be taken as evidence that the nanoform is safe. Hence, it is recommended to review available risk assessments for the nanoforms of chemicals potentially included in articles, particularly related opinions of EU Scientific Committees (e.g. dealing with food contact materials or cosmetics). Where risk assessments indicate that nanoforms of substances show different toxic effects and/or exposure this should be taken into account when setting limits in standards for consumer-relevant articles.

The background information to this document provides more detail on nanomaterials including the Commission Recommendation on the definition of nanomaterial, originally adopted in 2011 (see background information, 2.8).

Recommendation:

The occurrence of nanomaterials associated with the particular article in question should be investigated. Relevant nanomaterials should be assessed case-by-case taking into account risk assessments made by bodies such as EU Scientific Committees. Where toxic effects and/or exposure of nanoforms differ from their bulk counterparts this should be taken into account when establishing limits for such substances.

5.7 Certain elements (metals)

Almost 80 % of the elements in the periodic table are metals or metalloids (such as arsenic and antimony). Some of these elements are essential (such as zinc or copper), others are of great toxicological concern (such as cadmium, lead or mercury), not least because they and their compounds have been spread in the human environment and, in some cases, exposure exceeds tolerated thresholds.

5.7.1 REACH restrictions for consumer-relevant articles

The following restrictions for elements/metals in Annex XVII of REACH seem to be of particular relevance when determining the need for addressing chemicals in consumer-relevant articles (entry numbers in Annex XVII indicated):

Mercury (entry 18a) is not allowed to be used in fever thermometers and other measuring devices intended for the general public.

Organostannic compounds (entry 20) including tri-substituted organostannic compounds such as tributyltin (TBT) compounds and triphenyltin (TPT), dibutyltin (DBT) compounds and dioctyltin (DOT) compounds shall not be used in articles where the concentration in the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin.

Cadmium (entry 23) shall not be used in articles manufactured from certain plastic materials including e.g. PVC, PUR, LD PE, PP. A limit of 0,01 % applies. In addition, painted articles shall not be placed on the market if the concentration of cadmium is equal to or greater than 0,1 % by weight of the paint on the painted article. A limit of 0,01 % applies to metal parts of jewellery and imitation jewellery articles and hair accessories including bracelets, necklaces and rings, piercing jewellery, wrist-watches and wrist-wear and brooches and cufflinks.

Nickel (entry 27) shall not be used in any post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than 0,2 µg/cm² /week (migration limit).

Nickel shall not be used in products intended to come into direct and prolonged contact with the skin (examples include e.g. rivet buttons, zippers, and tighteners) if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than $0,5 \mu\text{g}/\text{cm}^2/\text{week}$.

Nickel shall not be used in articles intended to come into direct and prolonged contact with the skin where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin will not exceed $0,5 \mu\text{g}/\text{cm}^2/\text{week}$ for a period of at least two years of normal use of the article.

An ECHA Guidance Document is available to clarify the term “prolonged contact with skin”. http://echa.europa.eu/documents/10162/13641/nickel_restriction_prolonged_contact_skin_en.pdf

It defines the term as “more than 10 minutes on three or more occasions within two weeks, or 30 minutes on one or more occasions within two weeks”.

Test methods are included in:

- EN 1811 “Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin”;
- EN 12472 “Method for the simulation of wear and corrosion for the detection of nickel release from coated items”;
- EN 16128 “Reference test method for release of nickel from those parts of spectacle frames and sunglasses intended to come into close and prolonged contact with the skin”.

NOTE The limit for nickel addresses only induced sensitization by skin contact but not systemic toxicity.

Chromium VI (entry 47) provides that leather articles or articles containing leather parts coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than $3 \text{ mg}/\text{kg}$ ($0,0003 \%$ by weight) of the total dry weight of the leather or leather part.

NOTE The limit for chromium VI only addresses the risk of induction of skin sensitization related to direct or indirect skin contact but not systemic toxicity.

Phenylmercury compounds listed (entry 62) contained in articles or any parts thereof shall not be placed on the market after 10 October 2017 if the concentration of mercury in the articles or any part thereof is equal to or greater than $0,01 \%$ by weight.

Lead (entry 63) shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than $0,05 \%$ by weight (exceptions apply).

In addition, it shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than $0,05 \%$ by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children (exceptions apply). That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed $0,05 \mu\text{g}/\text{cm}^2$ per hour (equivalent to $0,05 \mu\text{g}/\text{g}/\text{h}$), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article. For the purposes of this paragraph, it is considered that an article or accessible part of an article may be placed in the mouth by children if it is smaller than 5 cm in one dimension or has a detachable or protruding part of that size. A guideline on the scope of the entry 63 (paragraphs 7 to 10) of Annex XVII to REACH on “Lead and its compounds in articles supplied to the

general public that can be mouthed by children” is available here:

http://echa.europa.eu/documents/10162/13563/lead_guideline_information_en.pdf

5.7.2 Other regulatory provisions for articles and related standards

The limits for elements in the Toy Safety Directive (TSD) are applicable to toys or components of toys for children up to 14 years. They have been derived with a focus on oral exposure by small children (see background information, 1.6.1). The migration limits for elements from scraped-off toy material in the Toy Safety Directive are shown in Table 1.

Table 1 — TSD migration limits for elements from scraped-off toy materials

Element	mg/kg
Aluminium	70 000,00
Antimony	560,00
Arsenic	47,00
Barium	18 750,00
Boron	15 000,00
Cadmium	17,00
Chromium (III)	460,00
Chromium (VI)	0,20
Cobalt	130,00
Copper	7 700,00
Lead	160,00
Manganese	15 000,00
Mercury	94,00
Nickel	930,00
Selenium	460,00
Strontium	56 000,00
Tin	180 000,00
Organic tin	12,00
Zinc	46 000,00

These limit values do 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 when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

NOTE 1 The Council has backed a Commission proposed limit of 23 mg/kg toy for lead in scraped-off toy materials.

NOTE 2 SCHER has recommended a limit of 0,009 4 mg/kg toy for chromium VI in scraped-off toy materials. The Commission has proposed a limit of 0,053 mg/kg toy in view of limitations of currently available analytical methods.

NOTE 3 Limits for dry, brittle, powder-like or pliable or liquid or sticky toy material are also included in the TSD but are not considered relevant for typical consumer-relevant articles.

Test methods for elements in Table 1 are included in EN 71-3 “Safety of toys - Part 3: Migration of certain elements ” covering a range of materials including coatings, polymeric and similar materials, paper and paper board, textiles, glass, ceramic and metallic materials, wooden materials and leather. The basic principle is extraction of a sample in acidic solution (pH 1,2) for 2 h (with 1 h agitation) at 37°C. The standard also provides a list of organic tin compounds for which the method has been validated and another one for which it has not. The lists include more substances than the REACH restriction mentioned above.

Nickel (classified CMR cat. 2) included in toys and toy components made of stainless steel and in toy components which are intended to conduct an electric current is excluded from the general ban of CMR substances (and related derogation rules).

The Packaging and Packaging Waste Directive (Directive 94/62/EC) establishes that the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components shall not exceed 100 ppm by weight. This does not apply to packaging entirely made of lead crystal glass. The Commission may grant derogations from this requirement. The CEN Report CR 13695-1 “Packaging – Requirements for measuring and verifying the four heavy metals and other dangerous substances present in packaging and their release into the environment – Part 1: Requirements for measuring and verifying the four heavy metals present in packaging” provides guidance on the measurement of the metals.

5.7.3 Voluntary specifications for consumer-relevant articles

The Oeko-Tex® 100 Standard is applicable to textile products and articles of all levels of production, including textile and non-textile accessories. It stipulates limits for extractable heavy-metals and content based limits for heavy metals in digested samples. The limits for extractable heavy-metals and for heavy metals in digested sample in the Oeko-Tex® Standard 100 are shown in Tables 2 and 3.

Table 2 — Limits for extractable heavy-metals in the Oeko-Tex® Standard 100

Element	I Baby, mg/kg	II in direct contact with skin, mg/kg	III with no direct contact with skin, mg/kg	IV Decoration material, mg/kg
Antimony	30,00	30,00	30,00	-
Arsenic	0,20	1,00	1,00	1,00
Cadmium	0,10	0,10	0,10	0,10
Chromium	1,00	2,00	2,00	2,00
Chromium (VI)	0,50*	0,50*	0,50*	0,50*
Cobalt	1,00	4,00	4,00	4,00
Copper	25,00**	50,00**	50,00**	50,00**
Lead	0,20	1,00***	1,00***	1,00***
Mercury	0,02	0,02	0,02	0,02
Nickel	1,00****	4,00*****	4,00*****	4,00*****
Organic tin				

Element	I Baby, mg/kg	II in direct contact with skin, mg/kg	III with no direct contact with skin, mg/kg	IV Decoration material, mg/kg
TBT, TPhT (x)	0,50	1,00	1,00	1,00
DBT, DMT, DOT, DPhT, DPT, MBT, MOT, MMT, MPhT, TeBT, TeET, TCyHT, TMT, TOT, TPT (x)	1,00	2,00	2,00	2,00
(x) Tributyltin TBT, Triphenyltin TPhT, Dibutyltin DBT, Dimethyltin DMT, Dioctyltin DOT, Diphenyltin DPhT, Dipropyltin DPT, Monobutyltin MBT, Monooctyltin MOT, Methyltin MMT, Monophenyltin MPhT, Tetrabutyltin TeBT, Tetraethyltin TeET, Tricyclohexyltin TCyHT, Trimethyltin TMT, Trioctyltin TOT, Tripropyltin TPT * Quantification limits ** No requirement for accessories and yarns made from inorganic materials respecting the requirements regarding biological active products *** No requirement for accessories made from glass **** For metallic accessories and metallized surfaces: 0,5 mg/kg ***** For metallic accessories and metallized surfaces: 1,0 mg/kg				

The limits for extractable heavy-metals in the new Leather Standard introduced by Oeko-Tex® in 2017 are identical to the limits in the Oeko-Tex® 100 Standard except for chromium (2 mg/kg for product class I, 200 mg/kg for all other product classes) and chromium VI (<3 mg/kg for all product classes).

Table 3 — Limits for heavy metals in digested sample in Oeko-Tex® Standard 100

Element	I Baby, mg/kg	II in direct contact with skin, mg/kg	III with no direct contact with skin, mg/kg	IV Decoration material, mg/kg
Cadmium	40,00	40,00***	40,00***	40,00***
Lead	90,00	90,00***	90,00***	90,00***
*** No requirement for accessories made from glass				

The limits for heavy-metals in digested sample in the Leather Standard introduced by Oeko-Tex® in 2017 are identical to the limits in the Oeko-Tex® 100 Standard.

Test methods for extractable heavy-metals and content-based limits for heavy metals in digested samples are given in a supplement of the Oeko-Tex® Standard 100 entitled: “Testing procedures”. The test method for extractable heavy-metals relies on ISO 105-E04 using the artificial acidic sweat solution (pH 5,5) according to this standard (4 h, 37°C). The test method for the content of heavy metals uses samples which are chemically digested using acids.

Limits for elements/extractable (heavy) metals can also be found in national and European Ecolabel provisions as well as in other voluntary specifications. Table 4 includes limits for elements in the European Ecolabel criteria for textile products (Commission Decision 2014/350/EU) and the textile related product groups of bed mattresses (Commission Decision 2014/391/EU) and of textile floor

coverings (Commission Decision 2009/967/EC, discontinued). The standard ISO 105-E04 using the artificial acidic sweat solution serves also as test method (except for textile floor coverings).

Table 4 — Limits for elements/metals in textile-related European Ecolabel criteria

Element	Textile prod. Baby up to 3 years, mg/kg	Textile prod. All other products, mg/kg	Textile prod. Metal accessories	Bed Mattresses	Textile floor coverings (discontinued)
Antimony	30,00	30,00		PUR foam: 0,50 Tex cover: 30,00 Tex other: 30,00	Polyester: 260,00 Latex, PUR: 0,50
Arsenic	0,20	1,00		Latex foam: 0,50 PUR foam: 0,20 Tex cover: 0,20 Tex other: 1,00	Latex, PUR: 0,50
Cadmium	0,10	0,10	Baby: 50,00 Other: 100,00	Latex foam: 0,10 PUR foam: 0,10 Tex cover: 0,10 Tex other: 0,10	Latex, PUR: 0,10 **
Chromium	1,00/0,50*	2,00/1,00*	Cr plating 60,00	Latex foam: 1,00 PUR foam: 1,00 Tex cover: 1,00/0,50* Tex other: 2,00/1,00*	Latex, PUR: 1,00 **
Chromium (VI)	-	-	-	PUR foam: 0,01	-
Cobalt	1,00	4,00/1,00*	-	Latex foam: 0,50 Tex cover: 1,00/1,00* Tex other:	Latex, PUR: 0,50

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Element	Textile prod. Baby up to 3 years, mg/kg	Textile prod. All other products, mg/kg	Textile prod. Metal accessories	Bed Mattresses	Textile floor coverings (discontinued)
				4,00/1,00*	
Copper	25,00	50,00		Latex foam: 2,00 PUR foam: 2,00 Tex cover: 25,00 Tex other: 50,00	Latex, PUR: 2,00
Lead	0,20	1,00	90,00	Latex foam: 0,50 PUR foam: 0,20 Tex cover: 0,20 Tex other: 1,00	Latex, PUR: 0,50 **
Mercury	0,02	0,02	60,00	Latex: 0,02 PUR: 0,02 Tex cover: 0,02 Tex other: 0,02	Latex, PUR: 0,02 **
Nickel	1,00/0.50*	1,00	REACH A XVII	Latex foam: 1,00 PUR foam: 1,00 Tex cover: 1,00/0,50* Tex other: 1,00/1,00*	Latex, PUR: 1,00
Selenium	-	-	-	PUR foam: 0,50	-
Organic tin	-	-	-	Sum: 0,50***	PUR: non-use
Monobutyltin	-	-	-	0,10	-
Dibutyltin	-	-	-	0,10	-
Tributyltin	-	-	-	0,50	-
* Textiles dyed with metal complex dyes/all other textiles					

Element	Textile prod. Baby up to 3 years, mg/kg	Textile prod. All other products, mg/kg	Textile prod. Metal accessories	Bed Mattresses	Textile floor coverings (discontinued)
** The limit value for the total heavy metal content (Pb, Cd, Cr, Hg) of a fitted carpet is 100 mg/kg.					
*** Sum of Tributyltin (TBT), Dibutyltin (DBT), Monobutyltin (MBT), Tetrabutyltin (TeBT), Monoctyltin (MOT), Dioctyltin (DOT), Tricyclohexyltin (TcyT), Triphenyltin (TPhT)					

The European Ecolabel criteria for hard coverings (Commission Decision 2009/607/EC) include limits for lead (0,5 %), cadmium (0,1 %) and antimony (0,25 %) when these substances (or any of their compounds) are used in glazes. Limits to the release of dangerous substances from glazed tiles in the use stage are also set (Pb: 80 mg/m², Cd: 7 mg/cm²).

The criteria for wood-, cork- and bamboo-based floor coverings (Commission Decision (EU) 2017/176) and for furniture (Commission Decision (EU) 2016/1349) include some limits for elements in recycled wood (arsenic 25 mg/kg, cadmium 50 mg/kg, chromium 25 mg/kg, copper 40 mg/kg, lead 90 mg/kg, mercury 25 mg/kg).

The criteria for footwear (Commission Decision (EU) 2016/1349) provide restrictions for extractable metals which are identical with the ones for textile products as indicated in the second (up to 3 years) and third (all other products) column of Table 4 (only the higher values apply where two limits are indicated followed by an asterisk). Additional requirements cover chromium-tanned leather: chromium VI (3 ppm, in line with the Annex XVII requirement of REACH), as well as total extractable chromium (200 mg/kg).

The criteria for furniture (Commission Decision (EU) 2016/1332) restrict extractable heavy metals in leather, textiles and coated fabric covering materials as well as in upholstery padding materials using limits similar to the ones included in ecolabel criteria for textile products. In addition, there are electroplating restrictions for metal components (chromium VI, nickel) and heavy metal limits in glass (no lead glass, 100 mg/kg limit per metal for lead, mercury or cadmium impurities).

The above European Ecolabel criteria also include limitations for the use of metal containing additives and pigments. Similarly, the criteria for various paper products including converted paper (Commission Decision 2014/256/EU), newsprint paper (Commission Decision 2012/448/EU), copying and graphic paper (Commission Decision 2011/332/EU) and printed paper (Commission Decision 2012/481/EU) exclude dyes or pigments based on certain metals and stipulate metal purity criteria for dyestuffs.

5.7.4 Remarks

The limit values given in the TSD and the Oeko-Tex® Standard 100 or the Leather Standard introduced by Oeko-Tex® are based on different test methods and are therefore not comparable. Also, the list of substances and materials covered differs. Whilst the TSD requirements apply to all toy materials, Oeko-Tex® Standard 100 focuses on textiles including their accessories.

The TSD requirements do not apply to toys or components of toys where any hazard of exposure is excluded. It should be noted that EN 71-3 gives further guidance on the likelihood of sucking, licking or swallowing of toys. According to the standard significant exposure is expected from toys intended to be put in the mouth or to the mouth, cosmetics toys and writing instruments categorized as toys. In addition, all the accessible parts and components of toys intended for children up to 6 years of age can be considered to come into contact with the mouth.

By contrast, the Oeko-Tex® Standard 100 limits applies to kinds of products falling in certain categories of utilization addressing products for babies, products with and without skin contact (i.e. which are worn with only a little part of their surface in direct contact with the skin) and decorative articles.

The TSD requirements for elements relating to scraped-off toy materials have been already recommended for use in the field of child use and care articles by CEN (CEN/TR 13387-2). It would

seem reasonable also to apply the requirements to other articles and components thereof to which (small) children are likely to be significantly exposed. Conversely, the requirements of the Oeko-Tex® Standard 100 go beyond a likelihood of mouthing perspective and, though limited to textile and their accessories, have a broader protection perspective.

European Ecolabel criteria for textile-related products are very similar to the ones included in Oeko-Tex® Standard 100 and based on similar test procedures.

In conclusion, both sets of requirements for elements deserve to be considered when establishing normative rules for consumer relevant articles. The TSD requirements may be first option for children-relevant articles made of all kinds of materials (particularly, when oral exposure can be expected), whilst standards for other consumer-relevant articles made of textile may make use of Oeko-Tex® Standard 100 or the European Ecolabel criteria for textile or leather related products requirements within their scope of application. In addition, limits in other voluntary specifications (e.g. EU or national ecolabel criteria) should be considered.

Recommendation:

When establishing requirements for elements/metals in consumer-relevant articles and their components, the respective provisions of the Toy Safety Directive, the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex® or the European Ecolabel criteria for textile or leather-related articles should be considered. The sets of rules differ in terms of articles and materials as well as elements/metals covered and their approach towards exposure. The choice of requirement will vary depending on the article covered. Limit values in other voluntary specifications (e.g. ecolabel criteria) could be considered, too.

It should be noted that the limits for elements included in the Toy Safety Directive have already been recommended by CEN to be applied to child use and care articles (CEN/TR 13387-2). Hence, these requirements may be the first option for articles relevant for children other than toys or child use and care articles, whilst standards for other consumer-relevant articles could make use of the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex® or European Ecolabel requirements within their scope of application or limits in other voluntary specifications.

Elements in consumer-relevant articles which are comprehensively covered by REACH Annex XVII normally do not need to be addressed. For example, limits for the listed organostannic compounds (entry 20) and lead (entry 63) covered by REACH restrictions do not need to be included in standards for consumer-relevant articles. However, current REACH limits for organostannic compounds could be complemented by limits for notlisted compounds. REACH limits for cadmium could be complemented by (migration) limits for materials other than the covered plastics materials, REACH limits for nickel and chromium VI could be complemented by (migration) limits addressing hazards other than sensitization.

5.8 Flame retardants

Flame retardancy is a property of an article that inhibits or delays the spread of fire in the article in question. The property can be introduced into an article through non-chemical means (design, material) or using flame retardant chemicals.

5.8.1 REACH restrictions for consumer-relevant articles

The following restrictions for flame retardants in Annex XVII of REACH seem to be of particular relevance when determining the need for addressing chemicals in consumer-relevant articles:

The flame retardants listed below are banned in textile articles with skin contact:

- Tris (2,3 dibromopropyl)phosphate, TRIS (entry 4, CAS No 126-72-7);
- Tris(aziridinyl)phosphin oxide, TEPA (entry 7, CAS No 545-55-1);

- Polybromobiphenyls, PBB (entry 8, CAS No 59536-65-1).

In addition, the flame retardants listed below are not allowed in articles, or parts thereof, in concentrations greater than 0,1 % by weight (subject to derogations):

- Diphenylether, pentabromo derivative (entry 44, CAS No 32534-81-9);
- Diphenylether, octabromo derivative (entry 45, CAS No 32536-52-0);
- Bis(pentabromophenyl)ether, decaBDE (entry 67, CAS No 1163-19-5)

5.8.2 Other regulatory provisions for articles and related standards

The Regulation on Persistent Organic Pollutants (POPs), Regulation (EC) No 850/2004, bans the following flame retardants (subject to derogations) at the indicated limits:

- Tetrabromodiphenyl ether (CAS No 40088-47-9, limit 0,001 %);
- Pentabromodiphenyl ether (CAS No 32534-81-9, limit 0,001 %);
- Hexabromodiphenyl ether (CAS No 36483-60-0, limit 0,001 %);
- Heptabromodiphenyl ether (CAS No 68928-80-3, limit 0,001 %);
- Hexabromocyclododecane (HBCDD, CAS No 25637-99-4, limit 0,01 %);
- Short-chain chlorinated paraffins (SCCPs, CAS No 85535-84-8, limit 0,15 %).

NOTE 1 For HBCDD different implementation dates apply beginning with March 2019.

NOTE 2 HBCDD is also included in the REACH list of substances subject to authorization (Annex XIV).

According to the Toy Safety Directive the following substances are restricted at 5 mg/kg (content limit) in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth:

- Tris (2-chloroethyl) phosphate, TCEP (CAS No 115-96-8);
- Tris(1,3-dichloropropyl-2)phosphate, Tris[2-chloro-1-(chloromethyl)ethyl] phosphate, TDCP, TDCPP (CAS No 13674-87-8);
- Tris-monochloro-propyl phosphate, Tris(2-chloro-1-methylethyl) phosphate, TCPP (CAS No 13674-84-5).

NOTE TCEP is also included in the REACH list of substances subject to authorization (Annex XIV).

The harmonized standard EN 71-9 (reference not published in the Official Journal), Table 2A includes action limits (defined as routinely-achievable limit of quantification for a particular substance using the specified method of analysis) for flame retardants as shown in Table 5.

Table 5 — Flame retardants with action limits from EN 71-9

Compound	CAS Number	Limit
Tri-o-cresyl phosphate	78-30-8	Action limit
Tris(2-chloroethyl) phosphate	115-96-8	Action limit

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The action limits (50 mg/kg) apply to textile toys and accessible components of toys intended for children under 3 years of age.

NOTE The action limit for Tris(2-chloroethyl) phosphate (TCEP) was included in EN 71-11 before the regulatory limit (5 mg/kg) was adopted and is not sufficient to verify legal compliance as the legal limit is a factor of 10 lower.

Test methods for flame retardants in Table 5 are provided in EN 71-10 and EN 71-11.

5.8.3 Voluntary specifications for consumer-relevant articles

Oeko-Tex® Standard 100 uses an approval system for flame retardants. Treatments accepted by Oeko-Tex® can be accessed on the website of the organization. The substances shown in Table 6 are forbidden from any approval. The list of forbidden flame retardants in the Leather Standard introduced by Oeko-Tex® in 2017 is identical to the list in the Oeko-Tex® 100 Standard.

Table 6 — Flame retardants forbidden in Oeko-Tex® Standard 100

Compound	CAS Number	Limit
2,2-bis(bromomethyl)-1,3-propanediol	3296-90-0	Not accepted
Bis-(2,3-dibromopropyl)phosphate	5412-25-9	Not accepted
Boric acid	10043-35-3 11113-50-1	Not accepted
Decabromodiphenylether	1163-19-5	Not accepted
Diboron trioxide	1303-86-2	Not accepted
Disodium tetraborate, anhydrous	1303-96-4, 1330-43-4, 12179-04-3	Not accepted
Heptabromodiphenylether, various		Not accepted
Hexabromocyclododecane	25637-99-4	Not accepted
Hexabromodiphenylether	36483-60-0	Not accepted
Octabromodiphenylether	32536-52-0	Not accepted
Pentabromodiphenylether	32534-81-9	Not accepted
Polybrominated biphenyles	59536-65-1	Not accepted
Short chain chlorinated paraffins (C10 - C13)	85535-84-8	Not accepted
Tetraboron disodium heptaoxide, hydrate	12267-73-1	Not accepted
Tetrabromobisphenol A	79-94-7	Not accepted
Tetrabromodiphenylether various		Not accepted
Tri-(2,3-dibromopropyl)-phosphate	126-72-7	Not accepted
Tris-(2-chloroethyl)phosphate	115-96-8	Not accepted
Tris-(1,3-dichloro-2-propyl)phosphate	13674-87-8	Not accepted
Tris-(aziridinyl)-phosphin oxide	545-55-1	Not accepted

Compound	CAS Number	Limit
Trixylylphosphate	25155-23-1	Not accepted

NOTE Hexabromocyclododecane is also included in the REACH list of substances subject to authorization (Annex XIV).

European Ecolabel provisions cover flame retardants in two ways: firstly, by general exclusions based on hazard classes and related hazard statements (with exceptions) as well as by specific substance exclusions.

European Ecolabel criteria for textile products (Commission Decision 2014/350/EU) and for bed mattresses (Commission Decision 2014/391/EU) exclude the substances Hexabromocyclododecane (HBCDD), Pentabromodiphenyl ether (PeBDE), Octabromodiphenyl ether (OcBDE), Decabromodiphenyl ether (DecaBDE), Polybrominated biphenyls (PBBs), Tris(aziridinyl) phosphin oxide (TEPA), Tris (2,3 dibromopropyl) phosphate (TRIS), Tris (2-chloroethyl)phosphate (TCEP) and Paraffin, C10-C13, chlorinated (SCCP).

European Ecolabel criteria for textile floor coverings (Commission Decision 2009/967/EC, discontinued) require that only flame retardants that are chemically bound into the polymer fibre or onto the fibre surface (reactive flame retardants) may be used in the product. Flame retardants which are only physically mixed into the polymer fibre or into a textile coating are excluded (additive flame retardants). If the used flame retardants fall in any of the listed hazard categories, these reactive flame retardants should, on application, change their chemical nature to no longer warrant classification under any of these R-phrases (now H-phrases). Less than 0,1 % of the flame retardant on the treated yarn or fabric may remain in the form as before application. European Ecolabel criteria for furniture (Commission Decision (EU) 2016/1332) exclude mostly already banned flame retardants in polyurethane (PUR) foam. European Ecolabel criteria for footwear (Commission Decision (EU) 2016/1349) allows the use of flame retardants only for certain types of personal protective equipment with an incorporated flame-retardant function to ensure safety at work.

5.8.4 Remarks

The Oeko-Tex® Standard 100 list includes the five substances banned in REACH as well as TCEP and TDCP banned in the Toy Safety Directive for certain toys. In addition, the list includes several substances banned in the ROHS Directive (hexabromodiphenylether, heptabromodiphenylether, decabromodiphenylether) and several substances which have been included in the candidate list and, respectively, Annex XIV of REACH (hexabromocyclododecane, TCEP). Some substances are included which are banned according to the Persistent Organic Pollutants (POP) Directive (Short Chain Chlorinated Paraffins (SCCP), and several brominated biphenylethers – penta, hexa, hepta, octa, deca). Tetrabromobisphenol A is included in the European Chemical Agency's Community Rolling Action Plan (CoRAP), the list of the substances to be evaluated by Member States.

EU-Ecolabel criteria do not include additional substance specific bans that feature in the Oeko-Tex® Standard 100 exclusion list which is the most comprehensive one. However, the provision in European Ecolabel criteria for textile floor coverings (discontinued) to exclude flame retardants which are only physically mixed into the polymer fibre or into a textile coating is another option.

Final remark: it should be noted that flame retardant properties can be achieved not only by using flame retardants but also through selection of materials (non-ignitable or exhibiting reduced flame propagation) and/or design of articles. Thus, legitimate regulatory and normative approaches to enhance fire safety do not justify the use of flame retardants of concern as alternative options are available including chemicals which do not pose risks.

Recommendations:

When establishing requirements for flame retardants in combustible consumer-relevant articles and

their components the list of non-accepted flame retardants in the Oeko-Tex® Standard 100 and the Leather Standard by Oeko-Tex® should be considered. Substances already banned in REACH Annex XVII or in Annex I of the Persistent Organic Pollutants Directive do not need to be included.

It should be considered, where alternatives are available, to exclude flame retardants which are only physically mixed into the matrix/material and to accept only reactive flame retardants (or materials which are inherently non-combustible or show a reduced flame propagation when ignited) or to ensure fire safety through appropriate design.

Other available information sources such as voluntary specifications (e.g. ecolabel criteria) could be considered.

It may also be useful to consider the establishment of a positive list of flame retardants taking into account the functionality of the substances.

5.9 Colourants

Colourants are added to a product to change a colour or to make it a specific colour. Different colourants exist including dyes, (biological) pigments, inks, paint, coloured chemicals and food colourings.

5.9.1 REACH restrictions for consumer-relevant articles

Azocolourants and azodyes (entry 43) are banned in a broad range of textile and leather articles including toys. This refers to azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8 (which currently includes 22 substances, shown in Table 7), in detectable concentrations, i.e. above 30 mg/kg (0,003 % by weight) which may come into direct and prolonged contact with the human skin or oral cavity.

Table 7 — REACH Entry 43 — Azocolourants — List of aromatic amines

No	Compound	CAS Number	Limit
1.	biphenyl-4-ylamine, 4-aminobiphenyl xenylamine	92-67-1	30 mg/kg
2.	benzidine	92-87-5	30 mg/kg
3.	4-chloro-o-toluidine	95-69-2	30 mg/kg
4.	2-naphthylamine	91-59-8	30 mg/kg
5.	o-aminoazotoluene, 4-amino-2',3-dimethylazobenzene, 4-o-tolylazo-o-toluidine	97-56-3	30 mg/kg
6.	5-nitro-o-toluidine	99-55-8	30 mg/kg
7.	4-chloroaniline	106-47-8	30 mg/kg
8.	4-methoxy-m-phenylenediamine	615-05-4	30 mg/kg
9.	4,4'-methylenedianiline, 4,4'-diaminodiphenylmethane	101-77-9	30 mg/kg
10.	3,3'-dichlorobenzidine, 3,3'-dichlorobiphenyl-4,4'-ylenediamine	91-94-1	30 mg/kg
11.	3,3'-dimethoxybenzidine, o-dianisidine	119-90-4	30 mg/kg
12.	3,3'-dimethylbenzidine 4,4'-bi-o-toluidine	119-93-7	30 mg/kg
13.	4,4'-methylenedi-o-toluidine	838-88-0	30 mg/kg

14.	6-methoxy-m-toluidine p-cresidine	120-71-8	30 mg/kg
15.	4,4'-methylene-bis-(2-chloro-aniline), methylene-dianiline	2,2'-dichloro-4,4'- 101-14-4	30 mg/kg
16.	4,4'-oxydianiline	101-80-4	30 mg/kg
17.	4,4'-thiodianiline	139-65-1	30 mg/kg
18.	o-toluidine, 2-aminotoluene	95-53-4	30 mg/kg
19.	4-methyl-m-phenylenediamine	95-80-7	30 mg/kg
20.	2,4,5-trimethylaniline	137-17-7	30 mg/kg
21.	o-anisidine, 2-methoxyaniline	90-04-0	30 mg/kg
22.	4-amino azobenzene	60-09-3	30 mg/kg

NOTE 4,4'-Diaminodiphenylmethane, MDA (CAS No 101-77-9) and 2,2'-dichloro-4,4'-methylene-dianiline, MOCA (CAS No 101-14-4) are also included in the REACH list of substances subject to authorization (Annex XIV).

An indicative list of dyes that may cleave to aromatic amines can be found e.g. in the European Ecolabel criteria for textile products (Appendix 2).

5.9.2 Other regulatory provisions for articles and related standards

The Toy Safety Directive does not stipulate specific requirements for colourants. However, the harmonized standard EN 71-9 (reference not published in the Official Journal) includes such requirements.

EN 71-9, Table 2B includes action limits for colourants as shown in Table 8.

Table 8 — Colourants with action limits from EN 71-9

Colour Index Name	CAS Number	Limit
Acid Red 26	3761-53-3	Action limit
Acid Violet 49	1694-09-3	Action limit
Basic Red 9	569-61-9	Action limit
Basic Violet 1	8004-87-3	Action limit
Basic Violet 3	548-62-9	Action limit
Disperse Blue 1	2475-45-8	Action limit
Disperse Blue 3	2475-46-9	Action limit
Disperse Blue 106	12223-01-7	Action limit
Disperse Blue 124	61951-51-7	Action limit
Disperse Yellow 3	2832-40-8	Action limit
Disperse Orange 3	730-40-5	Action limit

Disperse Orange 37/76	12223-33-5, 13301-61-6	Action limit
Disperse Red 1	2872-52-8	Action limit
Solvent Yellow 1	60-09-3	Action limit
Solvent Yellow 2	60-11-7	Action limit
Solvent Yellow 3	97-56-3	Action limit

NOTE: Basic Violet 3 is included in the REACH “candidate list” for authorization.

The action limits (10 mg/kg) apply to a broad range of toys including those intended for children under 3 years of age made of textile and leather.

Test methods for colourants in Table 8 are provided in EN 71-10 and EN 71-11.

A first-action method for colourants is described in EN 71-10. It constitutes an assessment of whether any colourants can be transferred from textile materials to the mouth, mucous membranes or skin. If textiles are found not to be colourfast when tested in accordance with the test procedure described in Annex A of EN 71-10, they shall be tested by the final-action method for colourants (see also clause on colour fastness below).

5.9.3 Voluntary specifications for consumer-relevant articles

The Oeko-Tex® Standard 100 standard does not allow colorants which may release listed cleavable arylamines (limit 20 mg/kg for arylamines) for all product classes. The list includes two more arylamines compared to the ones contained in the REACH list: 2,4-Xylidine (CAS No 95-68-1) and 2,6-Xylidine (CAS No 87-62-7). The limits are somewhat lower than the corresponding REACH requirements (30 mg/kg). The limits for colourants which may release listed cleavable arylamines in the 2017 Leather Standard by Oeko-Tex® are identical to the limits in the Oeko-Tex® 100 Standard.

In addition, the standard excludes listed colorants including carcinogens, allergens and others (limit 50 mg/kg for dyestuffs) as shown in Tables 9, 10 and 11. Also this applies to all product classes. The limits for the listed colourants in the 2017 Leather Standard by Oeko-Tex® are identical to the limits in the Oeko-Tex® 100 Standard.

Table 9 — Carcinogenic colourants disallowed in Oeko-Tex® Standard 100 standard

Colour Index Name	CAS Number	Limit
Acid Red 26	3761-53-3	50 mg/kg
Basic Blue 26 (with ≥ 0,1 % Michler's ketone or base)	2580-56-5	50 mg/kg
Basic Red 9	569-61-9	50 mg/kg
Basic Violet 3 (with ≥ 0,1 % Michler's ketone or base)	548-62-9	50 mg/kg
Basic Violet 14	632-99-5	50 mg/kg
Direct Black 38	1937-37-7	50 mg/kg
Direct Blue 6	2602-46-2	50 mg/kg
Direct Red 28	573-58-0	50 mg/kg

Disperse Blue 1	2475-45-8	50 mg/kg
Disperse Orange 11	82-28-0	50 mg/kg
Disperse Yellow 3	2832-40-8	50 mg/kg
Pigment Red 104	12656-85-8	50 mg/kg
Pigment Yellow 34	1344-37-2	50 mg/kg

NOTE: Pigment Red 104 and Pigment Yellow 34 are also included in the REACH list of substances subject to authorization (Annex XIV). Basic Blue 26, Basic Violet 3, Direct Black 38, Direct Red 28, Pigment Red 104 and Pigment Yellow 34 are included in the candidate list.

Table 10 — Allergenic colourants disallowed in Oeko-Tex® Standard 100 standard

Colour Index Name	CAS Number	Limit
Disperse Blue 1	2475-45-8	50 mg/kg
Disperse Blue 3	2475-46-9	50 mg/kg
Disperse Blue 7	3179-90-6	50 mg/kg
Disperse Blue 26	3860-63-7	50 mg/kg
Disperse Blue 35	12222-75-2	50 mg/kg
Disperse Blue 102	12222-97-8	50 mg/kg
Disperse Blue 106	12223-01-7	50 mg/kg
Disperse Blue 124	61951-51-7	50 mg/kg
Disperse Brown 1	23355-64-8	50 mg/kg
Disperse Orange 1	2581-69-3	50 mg/kg
Disperse Orange 3	730-40-5	50 mg/kg
Disperse Orange 37	13301-61-6	50 mg/kg
Disperse Orange 76	13301-61-6	50 mg/kg
Disperse Red 1	2872-52-8	50 mg/kg
Disperse Red 11	2872-48-2	50 mg/kg
Disperse Red 17	3179-89-3	50 mg/kg
Disperse Yellow 1	119-15-3	50 mg/kg
Disperse Yellow 3	2832-40-8	50 mg/kg
Disperse Yellow 9	6373-73-5	50 mg/kg
Disperse Yellow 39	12236-29-2	50 mg/kg
Disperse Yellow 49	12239-15-5	50 mg/kg

Table 11 — Other colourants disallowed in Oeko-Tex® Standard 100 standard

Colour Index Name	CAS Number	Limit
Disperse Orange 149	85136-74-9	50 mg/kg
Disperse Yellow 23	6250-23-3	50 mg/kg
Basic Green 4 (oxalate)	2437-29-8, 18015-76-4	50 mg/kg
Basic Green 4 (chloride)	569-64-2	50 mg/kg
Basic Green 4 (free)	10309-95-2	50 mg/kg

In addition, the colourant “Navy Blue” (Index-Nr. 611-070-00-2; EG-Nr. 405-665-4) is banned using the same limit.

NOTE This substance is also banned in Appendix 9 of Annex XVII of REACH (relating to entry 43 – azocolourants).

The European Ecolabel criteria for textile products (Commission Decision 2014/350/EU) also exclude azo dyes that may cleave to aromatic amines known to be carcinogenic (in line with REACH restriction, limit 30 mg/kg). In line with the Oeko-Tex® Standard 100 the list includes additional substances compared to the REACH list: 2,4-Xylidine (CAS No 95-68-1) and 2,6-Xylidine (CAS No 87-62-7). The same holds true for the European Ecolabel criteria for bed mattresses (Commission Decision 2014/391/EU), for textile floor coverings (Commission Decision 2009/967/EC, discontinued), for footwear (Commission Decision (EU) 2016/1349) and for furniture (Commission Decision (EU) 2016/1332).

In addition, the European Ecolabel criteria for textile products require not to use dyes that are carcinogenic, mutagenic or toxic to reproduction (CMR) as well as dyes that are potentially sensitizing. Appendix 2 contains a listing of CMR dyes and of sensitizing dyes that must not be used. Table 12 shows the list of excluded CMR dyes. The list of sensitizing dyes is identical to the Oeko-Tex® Standard 100 list. The European Ecolabel criteria for bed mattresses (Commission Decision 2014/391/EU), for textile floor coverings (Commission Decision 2009/967/EC, discontinued) and for footwear (Commission Decision (EU) 2016/1349) follow the same approach (the list of sensitizing substances in the textile floor coverings document already published in 2009 is slightly shorter).

Table 12 — CMR colourants disallowed in European Ecolabel criteria for textile products

Colour Index Name	CAS Number	Limit
Acid Red 26	3761-53-3	No use
Basic Red 9	569-61-9	No use
Basic Violet 14	632-99-5	No use
Direct Black 38	1937-37-7	No use
Direct Blue 6	2602-46-2	No use
Direct Red 28	573-58-0	No use
Disperse Blue 1	2475-45-8	No use
Disperse Orange 11	82-28-0	No use

Disperse Yellow 3	2832-40-8	No use
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NOTE Direct Black 38 and Direct Red 28 are included in the REACH "candidate list" for authorization.

Additional provisions in the European Ecolabel criteria mentioned above apply to metal containing dyes:

- textile products: chrome mordant dyes must not be used, metal complex dyes based on copper, chrome and nickel are only permitted for dyeing wool fibres, polyamide fibres and blends of wool and/or polyamide with man-made cellulose fibres,
- bed mattresses: as above except that chrome mordant dyes are only not allowed in polyamide and wool fibres and fabrics made of these fibres,
- textile floor coverings: dyes and pigments containing lead (Pb), cadmium (Cd), mercury (Hg) or chromium (chromium total) or Cr(VI) as ingredients of the dyeing component must not be used to dye the materials, and the limit value for the total heavy metal content of a fitted carpet is 100 mg/kg,
- footwear: as for textiles (metal complex dyes also allowed for leather), pigments based on cadmium, lead, chromium (VI), mercury and/or antimony shall not be used,
- furniture: chrome mordant dyes and pigments based on cadmium, lead, chromium (VI), mercury and/or antimony must not be used in leather, textile and coated fabric production stages.

The European Ecolabel criteria for various paper products including converted paper (Commission Decision 2014/256/EU), newsprint paper (Commission Decision 2012/448/EU), and copying and graphic paper (Commission Decision 2011/332/EU) also exclude azo dyes that may cleave to aromatic amines known to be carcinogenic (in line with REACH restriction, limit 30 mg/kg). They also exclude dyes or pigments based on certain metals (dyes or pigments based on lead, copper with the exception of copper phthalocyanine, chromium, nickel or aluminium shall not be used) and stipulate metal purity criteria for dyestuffs.

The European Ecolabel criteria for printed paper (Commission Decision 2012/481/EU) does not allow the use of the following heavy metals or their compounds in printing inks, toners, inks, varnishes, foils and laminates (whether as a substance or as part of any preparation used): cadmium, copper (excluding copper-phthalocyanine), lead, nickel, chromium VI, mercury, arsenic, soluble barium, selenium, and antimony. Cobalt can only be used up to 0,1 % (w/w). Ingredients may contain traces of those metals up to 0,01 % (w/w) deriving from impurities in the raw materials.

5.9.4 Remarks

Azo dyes which, by reductive cleavage of one or more azo groups, may release one or more of the listed 22 aromatic amines covered by the REACH restriction do not have to be addressed in standards for consumer-relevant textile articles or components thereof which may come into direct and prolonged contact with the skin. However, there are other problematic aromatic amines that can be released from azo dyes. Two examples are given above: 2,4-Xylidine and 2,6-Xylidine included in Oeko-Tex® Standard 100 and the Leather Standard by Oeko-Tex® and some European Ecolabel criteria.

But according to a study published in 2014¹ many more aromatic amines can result from reductive cleavage of azo dyes. 470 azo dyes could be identified which can be cleaved into exclusively non-regulated aromatic amines for many of which the toxicity database was found to be insufficient or non-

¹ Brüscheweiler et al., Identification of non-regulated aromatic amines of toxicological concern which can be cleaved from azo dyes used in clothing textiles, Regulatory Toxicology and Pharmacology 69 (2014) 263-272

existent. However, 15 (potentially) carcinogenic and/or genotoxic substances and 11 substances which may (potentially) cause sensitization by skin contact were identified. This issue needs further research. However, substances like 2,4-Xylidine and 2,6-Xylidine and possibly other azo dyes releasing aromatic amines could be addressed.

CMR or sensitizing colourants covered by EN 71-9, the Oeko-Tex® Standard 100 or the European Ecolabel criteria above should be considered for incorporation into consumer-relevant standards for articles or their components made of the materials indicated (textiles, leather, (printed) paper) which, due to their accessibility, function, volume or mass, can reasonably lead to exposure due to sucking, licking, swallowing, or prolonged contact with skin.

However, there are additional substances which have been identified as skin sensitizers. For example, a European Commission funded study on “the link between allergic reactions and chemicals in textile products² identified the following sensitising substances notified in C&L Inventory (see 3.2.2) and reported to be used and to remain on finished textile products not included in the above lists: Disperse Blue 183:1 (CAS 2537-62-4), Disperse Blue 291 (56548-64-2/51868-46-3), Disperse Green 9 (CAS 58979-46-7), Disperse Orange 30 (CAS 5261-31-4), Disperse Orange 44 (CAS 4058-30-4), Disperse Red 82 (CAS 30124-94-8), Disperse Violet 57 (1594-08-7), Disperse Violet 93 (66557-45-7/52697-38-8), Disperse Yellow 42 (CAS 5124-25-4), Disperse Brown 1 (CAS 23355-64-8), Solvent Yellow 1 (CAS 60-09-3), Solvent Yellow 2 (CAS 60-11-7), Solvent Yellow 3 (CAS 97-56-3), Solvent Yellow 163 (CAS 13676-91-0). Hence, these and possible other skin sensitisers should also be considered for exclusion/limitation.

It is recommended to complement colourant specific provisions with colour fastness tests (with respect to washing, to saliva, to perspiration, to dry and wet rubbing) as done in the toys standards or in the Oeko-Tex® Standard 100 or, respectively, in European Ecolabel criteria (see also the section on colour fastness below).

Colourants of possible concern included in other materials should be assessed based on other available sources.

Recommendations:

When establishing requirements for colourants in standards for consumer-relevant products and their components provisions for CMR, sensitizing or other colourants of concern covered by EN 71–9, the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex® or the relevant European Ecolabel criteria should be considered for the materials indicated in these specifications for articles which, due to their accessibility, function, volume or mass, can reasonably lead to an exposure due to sucking, licking, swallowing, or prolonged contact with skin. However, consideration should be given to the inclusion of additional compounds identified in scientific literature.

Azo dyes which, by reductive cleavage of one or more azo groups, may release one or more of the listed 22 aromatic amines covered by the REACH restriction do not need to be addressed. However, additional substances could be covered.

Colour fastness tests are a useful complement to specific substance limits and their inclusion in standards for consumer-relevant articles and their components should be considered. Various tests are available addressing colour fastness to washing, to saliva, to perspiration, to dry and wet rubbing. Such tests could be either used a first-action method for colourants as in case of toys (EN 71–10 and EN 71–1), or could be used as stand-alone tests. This is further discussed in the clause on colour fastness below.

Other available information sources should be considered for materials not covered by the above lists.

² <http://ec.europa.eu/DocsRoom/documents/10481/attachments/1/translations/en/renditions/native>

5.10 Primary aromatic amines

Primary aromatic amines (PAA) are a group of chemical compounds that are used as intermediates in the production of many chemical compounds including azo dyes. Some of these PAA have been shown to have carcinogenic properties.

5.10.1 REACH restrictions for consumer-relevant articles

REACH Annex XVII does not address primary aromatic amines in consumer-relevant articles beyond the case of colourants described in 5.9.1.

5.10.2 Other regulatory provisions for articles and related standards

The Toy Safety Directive does not stipulate specific requirements for aromatic amines. However, the harmonized standard EN 71-9 (reference not published in the Official Journal) includes such requirements. EN 71-9, Table 2C includes action limits for primary aromatic amines as shown in Table 13.

Table 13 — Primary aromatic amines with action limits from EN 71-9

Compound	CAS number	Limit
Benzidine	92-87-5	Action limit
2-Naphthylamine	91-59-8	Action limit
4-Chloroaniline	106-47-8	Action limit
3,3'-Dichlorobenzidine	91-94-1	Action limit
3,3'-Dimethoxybenzidine	119-90-4	Action limit
3,3'-Dimethylbenzidine	119-93-7	Action limit
o-Toluidine	95-53-4	Action limit
2-Methoxyaniline (o-Anisidine)	90-04-0	Action limit
Aniline	62-53-3	Action limit

With the exception of aniline, all other substances are taken from the list of aromatic amines related to REACH Annex XVII restriction of azocolourants (entry 43). The action limits (5 mg/kg) apply to a broad range of toys including those intended for children under 3 years of age made of textile and leather.

Test methods for primary aromatic amines Table 13 are provided in EN 71-10 and EN 71-11.

A first-action method for primary aromatic amines is described in EN 71-10. It constitutes an assessment of whether any colourants can be transferred from textile materials to the mouth, mucous membranes or skin. If textiles are found not to be colourfast when tested in accordance with the test procedure described in Annex A of EN 71-10, they shall be tested by the final-action method for primary aromatic amines.

NOTE The first-action method for primary aromatic amines may not be adequate as these substances are not coloured.

5.10.3 Voluntary specifications for consumer-relevant articles

The Oeko-Tex® Standard 100 standard disallows listed arylamines (limit 20 mg/kg for arylamines) for all materials containing polyurethane or other materials which may contain free carcinogenic arylamines. It is the same list as the one for cleavable aromatic amines given in 5.9.1.3 i.e. the REACH

list of aromatic amines listed in Appendix 8 of Annex XVII complemented by two more substances: 2,4-Xylidine (CAS No 95-68-1) and 2,6-Xylidine (CAS No 87-62-7). The limits are somewhat lower than the corresponding REACH requirements (30 mg/kg). The limits for the listed arylamines in the 2017 Leather Standard by Oeko-Tex® are identical to the limits in the Oeko-Tex® 100 Standard.

5.10.4 Remarks

A comprehensive approach would include requirements concerning primary aromatic amines in addition to provisions relating to azo dyes which may release arylamines.

The requirements concerning primary aromatic amines included in EN 71-9 and EN 71-10 and the Oeko-Tex® Standard 100 standard should be considered as regards components of consumer-relevant articles made of textiles and leather which, due to their accessibility, function, volume or mass, can reasonably lead to an exposure due to sucking, licking, swallowing, or prolonged contact with skin.

Recommendation:

When establishing requirements for chemicals in consumer-relevant articles and their components, provisions for carcinogenic aromatic amines should be considered. This includes the 22 substances listed in Appendix 8 of Annex XVII of REACH and other aromatic amines of concern such as aniline, 2,4-xylidine and 2,6-xylidine. Such provisions should be considered for the materials indicated for articles which, due to their accessibility, function, volume or mass, can reasonably lead to an exposure due to sucking, licking, swallowing, or prolonged contact with skin.

5.11 Monomers

Monomers are individual molecules that bind to other molecules to form polymers (a substance made of multiple monomers), and can be chemical-based (such as ethylene used to make polyethylene plastic) or biological (such as fatty acid monomers used to make lipids). Chemical monomers can be released from the polymer matrix due to the presence of residual amounts of the non-reacted monomer or resulting from decomposition of the matrix, arising in human and environmental exposure to the chemical monomer.

5.11.1 REACH restrictions for consumer-relevant articles

REACH Annex XVII provides that Bisphenol A (entry 66) shall not be placed on the market in thermal paper in a concentration equal to or greater than 0,02 % by weight after 2 January 2020.

5.11.2 Other regulatory provisions for articles and related standards

According to the Toy Safety Directive, Bisphenol A (BPA) is restricted at 0,1 mg/l (migration limit) in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth.

NOTE 1 In November 2016 Member States adopted a Commission proposed limit of 0,04 mg/l (migration limit) for Bisphenol A in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005 to be included in Appendix C of the TSD (see also NOTE 4).

NOTE 2 In November 2016 Member States adopted a Commission proposed limit of 5 mg/l (migration limit) for phenol in polymeric materials in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005. There is also a limit of 10 mg/kg (content limit) for phenol used as a preservative.

NOTE 3 According to Article 46 of the TSD, the Commission may adopt specific limit values for chemical substances used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth, taking into account food contact material legislation (Regulation (EC) No 1935/2004). These specific limit values are listed in Appendix C of Annex II. Of particular relevance concerning monomers is the Regulation on plastic materials and articles intended to come into contact with food (Commission Regulation (EU) No 10/2011).

The harmonized standard EN 71-9 (reference not published in the Official Journal), Table 2D includes limits for monomers as shown in Table 14.

Table 14 — Monomers with limits from EN 71-9

Compound	CAS Number	Limit ^a
Acrylamide	79-06-1	Action limit
Bisphenol A	80-05-7	0,1 mg/l
Formaldehyde	50-00-0	2,5 mg/l
Phenol	108-95-2	15 mg/l
Styrene	100-42-5	0,75 mg/l
^a Limits are expressed as amount of substance per litre of simulant (see EN 71-11).		

The action limit in the aqueous migrate for acrylamide is 0,02 mg/l. Test methods for these monomers in Table 14 are provided in EN 71-10 and EN 71-11.

NOTE 4 The migration limits for bisphenol A and phenol do not correspond to the ones envisaged to be included in Appendix C of the TSD (see also NOTE 1 and NOTE 2).

The limits apply to certain kinds of toys made of polymeric materials, particularly those with intended or likely mouth contact for prolonged periods.

Annex 1 of the Regulation on plastic materials and articles intended to come into contact with food (Commission Regulation (EU) No 10/2011) contains a positive list (a so-called 'Union list' or list of authorized substances) of monomers, additives and other starting substances that may be used for manufacturing of plastics materials in contact with food (around 1 000 substances included). Further details on food contact materials legislation are included in the background information to this Guide (see background information, subclause 1.7).

5.11.3 Voluntary specifications for consumer-relevant articles

No voluntary specifications addressing monomers could be identified.

5.11.4 Remarks

The requirements concerning monomers included in EN 71-9 should be considered as regards standards for consumer-relevant articles which can be placed in the mouth, particularly those with intended mouth contact or likely mouth contact for prolonged periods and taking into account the "Guideline on the interpretation of the concept 'which can be placed in the mouth' as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006" (a similar approach is used in the lead restriction for articles supplied to the general public). However, the limits should be reviewed and adapted, where appropriate (as in the case of phenol).

Annex 1 of the Regulation on plastic materials and articles intended to come into contact with food could be used to identify further monomers (and additives and other starting substances) to be incorporated into standards for consumer-relevant articles made of polymeric materials where prolonged mouth contact can be anticipated (e.g. musical instruments such as fipple flutes).

However, it must be borne in mind that the specific migration limits (SML or SML(T)) contained in the regulation on food contact materials (FCMs) made of plastics cannot be directly applied. The basic FCM model assumes migration from 600 cm² (a cube with a side length of 10 cm) food packaging into 1 kg food consumed by an adult of 60 kg per day. The limit (SML) corresponds to the TDI value (expressed as mg/kg and day) multiplied by the mass of the adult (i.e. 60 kg). Testing is performed using static migration. By contrast, the limits for monomers in the toy standards EN 71-9, EN 71-10 and EN 71-11 are based on the assumption that a child of 10 kg puts in the mouth 10 cm² of a surface for 3 h per day. The maximum permitted amount of the substance released corresponds to (just) 10 % of TDI (or

comparable) value multiplied by the body weight of the child (i.e. 10 kg). Testing is done by using dynamic migration conditions (head-over-heels extraction). This should be taken into account when including additional monomers (or other additives) to the list in EN 71-9 referred to above, i.e. the acceptable amount in 100 ml aqueous extract prepared in accordance with EN 71-10 would be $(SML \times 10/60) \times 0,1$, or $(SML \times 10/60)$ expressed as amount per litre of simulant.

NOTE No adaptation may be required where Annex 1 of the Regulation on plastic materials and articles intended to come into contact with food specifies a specific migration limit “non-detectable (ND)” or content based limits relating to the final product (e.g. food packaging).

Recommendation:

Provisions for monomers included in EN 71-9 should be considered as a starting point for articles and their components made of polymers which, due to their accessibility, function, volume or mass, can reasonably lead to an exposure due to sucking, licking, swallowing, or prolonged contact with skin.

The “Guideline on the interpretation of the concept ‘which can be placed in the mouth’ as laid down in entry 52 of REACH Annex XVII should be taken into consideration.

Annex 1 of the Regulation on plastic materials and articles intended to come into contact with food could be used to identify further monomers (and additives and other starting substances). However, the migration limits (SML or SML(T)) would have to be adapted.

5.12 Plasticizers

Plasticisers are additives that make a brittle material more fluid or more plastic, and are mostly used for plastics, especially polyvinyl chloride (PVC), but can also be used in concrete and clays. As they can leak out of products, they can end up in the environment or in humans, and some can end up being absorbed through the skin.

5.12.1 REACH restrictions for consumer-relevant articles

Toys and childcare articles containing the following phthalates (entry 51) in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market:

- Bis (2-ethylhexyl) phthalate, DEHP (CAS No 117-81-7);
- Dibutyl phthalate, DBP (CAS No 84-74-2);
- Benzyl butyl phthalate, BBP (CAS No 85-68-7).

Toys and childcare articles which can be placed in the mouth by children and containing the following phthalates (entry 52) in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market:

- Di-“isononyl” phthalate, DINP (CAS No 28553-12-0 and 68515-48-0);
- Di-“isodecyl” phthalate, DIDP (CAS No 26761-40-0 and 68515-49-1);
- Di-n-octyl phthalate, DNOP (CAS No 117-84-0).

A “Guideline on the interpretation of the concept ‘which can be placed in the mouth’ as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006” is available here:

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

NOTE The limits apply to the sum of the listed phthalates, see Q&As section on REACH restrictions on the ECHA website: <https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/reach/restrictions>

5.12.2 Other regulatory provisions for articles and related standards

The Toy Safety Directive does not stipulate specific requirements for plasticizers. However, the harmonized standard EN 71-9 (reference not published in the Official Journal) includes such requirements. EN 71-9, Table 2I includes action limits for plasticisers as shown in Table 15.

Table 15 — Plasticisers with limits from EN 71-9

Compound	CAS Number	Limit ^a
Triphenyl phosphate	115-86-6	Action limit
Tri-o-cresyl phosphate	78-30-8	Action limit
Tri-m-cresyl phosphate	563-04-2	Action limit
Tri-p-cresyl phosphate	78-32-0	Action limit
^a Limits are expressed as amount of substance per litre of simulant (see EN 71-11).		

The action limits (0,03 mg/l) apply to certain kinds of toys, particularly with intended mouth contact or likely mouth contact for prolonged periods made of polymeric materials.

Test methods for plasticisers in Table 15 are provided in EN 71-10 and EN 71-11.

5.12.3 Voluntary specifications for consumer-relevant articles

The Oeko-Tex® Standard 100 specifies a limit for phthalates for coated articles, plastisol prints, flexible foams, and accessories made from plastics. The limit for the sum of the indicated phthalates is 0,1 % for all product classes. However, for decoration materials the sum does not include Di-iso-nonylphthalate (DINP). The limits for the listed phthalates in the 2017 Leather Standard by Oeko-Tex® are identical to the limits in the Oeko-Tex® 100 Standard.

The following phthalates are listed:

- Butylbenzylphthalate, BBP (CAS No 85-68-7);
- Dibutylphthalate, DBP (CAS No 84-74-2);
- Di-ethylphthalate, DEP (CAS No 84-66-2);
- Di-(2-ethylhexyl)-phthalate, DEHP (CAS No 117-81-7);
- Di-(2-methoxyethyl)-phthalate, DMEP (CAS No 117-82-8);
- Di-C6-8-branched alkylphthalates, C7 rich, DIHP (CAS No 71888-89-6);
- Di-C7-11-branched and linear alkylphthalates, DHNUP (CAS No 68515-42-4);
- Di-cyclohexylphthalate, DCHP (CAS No 84-61-7);
- Di-hexylphthalate, branched and linear, DHxP (CAS No 68515-50-4);
- Di-iso-butylphthalate, DIBP (CAS No 84-69-5);
- Di-iso-decylphthalate, DIDP (CAS No 26761-40-0, 68515-49-1);
- Di-iso-hexylphthalate, DIHxP (CAS No 71850-09-4);

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- Di-iso-nonylphthalate, DINP (CAS No 28553-12-0, 68515-48-0);
- Di-n-propylphthalate, DPrP (CAS No 131-16-8);
- Di-n-hexylphthalate, DHP (CAS No 84-75-3);
- Di-n-octylphthalate, DNOP (CAS No 117-84-0);
- Di-iso-octylphthalate, DIOP (27554-26-3);
- Di-n-nonylphthalate, DNP (CAS No 84-76-4);
- Di-pentylphthalate (n-, iso-, or mixed), DPP (CAS No 131-18-0, 605-50-5, 776297-69-9, 84777-06-0);
- 1,2-Benzenedicarboxylic acid, di-C6-10 alkyl esters (CAS No 68515-51-5);
- 1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters (68648-93-1).

The European Ecolabel criteria for textile products (Commission Decision 2014/350/EU) provide that polymers shall not contain the phthalates DEHP (Bis-(2-ethylhexyl)-phthalate), BBP (Butylbenzylphthalate), DBP (Dibutylphthalate), DMEP (Bis(2-methoxyethyl) phthalate, DIBP (Diisobutylphthalat), DIHP (Di-C6-8-branched alkylphthalates), DHNUP (Di-C7-11-branched alkylphthalates), DHP (Di-n-hexylphthalate) exceeding in total 0,1 %.

The European Ecolabel criteria for bed mattresses (Commission Decision 2014/391/EU) also provides a list of excluded phthalates (DINP, DNOP, DEHP, DIDP, BBP, DBP) at a lower level (sum 0,01 %). The list is identical to the one included in Annex XVII of REACH. In addition, the intended addition of phthalates in general is not allowed.

The European Ecolabel criteria for textile floor coverings (Commission Decision 2009/967/EC, discontinued) exclude DNOP, DINP and DIDP.

The European Ecolabel criteria for footwear (Commission Decision (EU) 2016/1349) restrict DIHP, DHNUP, DMEP, DIPB, DEHP, DBP, BBP, DPP (n-, iso-, or mixed), DIPP, DnHP) in plastics, rubber, synthetic materials, coatings and printings of materials (sum 0,1 %). In addition, DINP, DNOP and DIDP shall not be used in footwear for children under three years of age (sum 0,05 %).

The European Ecolabel criteria for furniture (Commission Decision (EU) 2016/1332) restrict DBP, DNOP, DEHP, BBP, DIDP, DINP in polyurethane (PUR) foam in furniture for children less than 3 years old (sum 0,01 %).

5.12.4 Remarks

Phthalates have been at the centre of attention for some years. REACH Annex XVII features 6 phthalates in toys and child care articles. The REACH authorization list additionally features diisobutyl phthalate, DIBP (CAS No 84-69-5). This substance is also banned under the ROHS Directive. In addition to DIBP, the REACH “candidate list” also includes the following phthalates: dihexyl phthalate, DHP (CAS No 84-75-3), dipentyl phthalate, DPP (CAS No 131-18-0), diisopentyl phthalate, DIPP (CAS No 605-50-5), N-pentyl-isopentylphthalate (CAS No 776297-69-9), bis(2-methoxyethyl) phthalate, DMEP (CAS No 117-82-8) and 3 phthalates banned in REACH Annex XVII in toys and childcare articles (DEHP, BBP, DBP). The “candidate list” includes also 1,2-Benzenedicarboxylic acid, di-C6-10 alkyl esters (CAS No 68515-51-5) and 1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters (CAS No 68648-93-1).

DIBP and other phthalates which could eventually be incorporated into Annex XIV of REACH are covered by the provisions of 5.2 of the present Guide (exclusion of non-authorized Annex XIV substances). Other phthalates listed above should be considered for incorporation in standards for

consumer-relevant articles made of polymeric materials, particularly those which can be placed in the mouth by small children.

As a result of public debate and legal bans, manufacturers are using increasingly non-phthalate plasticizers such as:

- 2,2,4-trimethyl-1,3 pentanediol diisobutyrate, TPIB, TXIB (CAS No 6846-50-0);
- Di(2-ethylhexyl) adipate, DEHA (CAS No 103-23-1);
- Di(2-ethylhexyl) terephthalate, DEHT (CAS No 6422-86-2);
- Acetyl tributyl citrate, ATBC (CAS No 77-90-7);
- Diisononyl hexahydrophthalate, DINX (CAS No 166412-78-8);
- Tris(2-ethylhexyl) trimellitate (TOTM) CAS 3319-31-1.

In its report on Phthalates and Phthalate Alternatives to the US. Consumer Product Safety Commission (CPSC) dated July 2014 the Chronic Hazard Advisory Panel (CHAP) reviewed the existing toxicological data of the substances listed above and did not find any evidence that any of them presents a hazard to infants or toddlers from mouthing toys or child care articles. However, CHAP also stressed that data on most phthalate alternatives were limited and recommended that the appropriate US agencies obtain the necessary exposure and hazard data to estimate total exposure to the phthalate alternatives and assess the potential health risks. Where in-depth investigations for phthalate alternatives are available indicating a concern, related requirements in standards for consumer-relevant articles made of polymeric materials should be considered, particularly those which can be placed in the mouth by small children.

The requirements concerning plasticizers included in EN 71-9 shown in Table 15 should be also considered as regards to consumer-relevant articles made of polymeric materials which can be placed in the mouth by small children. Whether articles can be placed in the mouth the “Guideline on the interpretation of the concept ‘which can be placed in the mouth’ as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006” should be used.

Recommendation:

Plasticisers including phthalates identified as SVHC which are eventually included in REACH Annex XIV and which are not authorized for use in consumer-relevant articles are covered by the provisions of subclause 5.2 of the present Guide and normative requirements do not need to be included in standards for consumer-relevant articles.

Other plasticisers such as those listed in the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex® or in EN 71-9 should be considered for incorporation of related requirements in standards for consumer-relevant articles made of polymeric materials unless restricted in the particular article in REACH Annex XVII, particularly those which can be placed in the mouth by small children.

Additional plasticisers including the non-phthalate substances could be included when supported by a risk assessment.

The “Guideline on the interpretation of the concept ‘which can be placed in the mouth’ as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006” should be considered where relevant.

5.13 Solvents (content or migration)

Solvents are usually liquid substances that dissolve other substances (whether in liquid, solid or gas form) to form a solution. In the context of articles the release (migration) of residual amounts of solvents may be of concern.

5.13.1 REACH restrictions for consumer-relevant articles

REACH Annex XVII does not address solvents in consumer-relevant articles.

5.13.2 Other regulatory provisions for articles and related standards

The Toy Safety Directive addresses formamide in two ways. First, the substance is covered by the general CMR ban of the Directive. As formamide is toxic to reproduction category 1B a content-based limit of 0,3 % (3 000 mg/kg) applies. Second, for toys intended for use by children under 36 months or in other toys intended to be placed in the mouth, an emission limit of 20 µg/m³ for formamide after a maximum of 28 days from commencement of the emission testing of foam toy materials is stipulated in Appendix C to Annex II (the 0,3 % limit does not apply). Emission testing is not necessary when the formamide content is 200 mg/kg or less (the cut-off value derived in a worst-case exposure scenario).

The harmonized standard EN 71-9 (reference not published in the Official Journal), Table 2E, includes limits for solvents (migration) as shown in Table 16.

Table 16 — Solvents (migration) with limits from EN 71-9

Compound	CAS Number	Limit ^a
Trichloroethylene	79-01-6	Action limit
Dichloromethane	75-09-2	0,06 mg/l
2-Methoxyethyl acetate	110-49-6	0,5 mg/l (total)
2-Ethoxyethanol	110-80-5	
2-Ethoxyethyl acetate	111-15-9	
Bis(2-methoxyethyl) ether	111-96-6	
2-Methoxypropyl acetate	70657-70-4	
Methanol	67-56-1	5 mg/l
Nitrobenzene	98-95-3	Action limit
Cyclohexanone	108-94-1	46 mg/l
3,5,5-Trimethyl-2-cyclohexene-1-one	78-59-1	3 mg/l
Toluene	108-88-3	2 mg/l
Ethylbenzene	100-41-4	1 mg/l
Xylene (all isomers)	various	2 mg/l (total)
^a Limits are expressed as amount of substance per litre of simulant (see EN 71-11).		

NOTE Trichloroethylene, dichloromethane and bis(2-methoxyethyl) ether are also included in the REACH list of substances subject to authorization (Annex XIV).

The action limit for trichloroethylene and nitrobenzene is 0,02 mg/l simulant. The limits apply to certain kinds of toys made of polymeric materials, particularly with intended mouth contact or likely mouth contact for prolonged periods.

Test methods for solvents (migration) in Table 16 are provided in EN 71-10 and EN 71-11.

5.13.3 Voluntary specifications for consumer-relevant articles

Some solvent residues are covered by the Oeko-Tex® Standard 100 for fibre, yarns and coated articles, where solvents are used during production as shown in Table 17. The limits are applicable to all product classes. The limits for solvent residues in the 2017 Leather Standard by Oeko-Tex® are identical to the limits in the Oeko-Tex® 100 Standard.

Table 17 — Solvent residues in the Oeko-Tex® Standard 100

Compound	CAS Number	Limit
N-Methyl-2-pyrrolidone (NMP)	872-50-4	0,10 %
Dimethylacetamide (DMAc)	127-19-5	0,10 %
Dimethylformamide (DMF)	68-12-2	0,10 %
Formamide	75-12-7	0,02 %

NOTE All substances listed in Table 17 are also included in the REACH “candidate list” (as at January 2016).

An exception applies, with a limit of 3,0 %, for products which must be treated hot (in wet or dry stage) during further processing.

The Oeko-Tex® Standard 100 and the Leather Standard by Oeko-Tex® also cover chlorinated benzenes and toluenes which are partly solvents. These are covered separately in subclause 5.16.5 of this document.

The European Ecolabel criteria for footwear (Commission Decision (EU) 2016/1349) and for furniture (Commission Decision (EU) 2016/1332) include a list of solvents which shall not be used in any mixtures or formulations for the processing of materials such as leather, textile or coated materials. It includes all solvents listed in Table 17 except DMAc. However, no limits have been established.

5.13.4 Remarks

The requirements concerning solvents (migration) included in EN 71-9 are relevant for articles with anticipated (prolonged) mouth contact only.

In addition, the content limits for solvent residues the Oeko-Tex® Standard 100 should be considered for the materials specified.

Recommendation:

When establishing requirements relating to the migration or content of solvent residues in consumer-relevant articles or their components the requirements concerning solvents (migration) included in EN 71-9 should be considered as regards consumer-relevant articles made of polymeric materials which can be placed in the mouth, particularly those with intended mouth contact or likely mouth contact for prolonged periods and taking into account the “Guideline on the interpretation of the concept ‘which can be placed in the mouth’ as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006”.

In addition, the content limits for solvent residues in the Oeko-Tex® Standard 100 and in the Leather Standard by Oeko-Tex® should be considered for the materials specified.

5.14 Volatile organic compounds (VOC)

VOCs are organic chemicals that vaporize easily at ordinary room temperature, thereby entering into the air very quickly. They can be human-made or naturally occurring, and most scents or odours are made of VOCs. Evaporation, particularly from larger sized objects, may result in significant concentrations of VOCs in the (indoor) air and may be of concern.

5.14.1 REACH restrictions for consumer-relevant articles

REACH Annex XVII does not address VOCs evaporating from consumer-relevant articles.

5.14.2 Other regulatory provisions for articles and related standards

The Toy Safety Directive addresses formamide emissions for toys intended for use by children under 36 months or in other toys intended to be placed in the mouth as described in 3.3.3. The limit is 20 µg/m³ (emission limit) after a maximum of 28 days from commencement of the emission testing of foam toy materials containing more than 200 mg/kg (cut-off limit based on content).

The harmonized standard EN 71-9 (reference not published in the Official Journal), Table 2F includes provisions for emissions of volatile organic compounds, the limits for solvents (inhalation) are shown in Table 18.

Table 18 — Solvents (inhalation) with limits from EN 71-9

Compound	CAS Number	Limit ^a
Toluene	108-88-3	260 µg/m ³
Ethylbenzene	100-41-4	5 000 µg/m ³
Xylene (all isomers)	Various	870 µg/m ³ (total)
1,3,5-Trimethylbenzene (mesitylene)	108-67-8	2 500 µg/m ³
Trichloroethylene	79-01-6	Action limit
Dichloromethane	75-09-2	3 000 µg/m ³
n-Hexane	110-54-3	1 800 µg/m ³
Nitrobenzene	98-95-3	Action limit
Cyclohexanone	108-94-1	136 µg/m ³
3,5,5-Trimethyl-2-cyclohexene-1-one	78-59-1	200 µg/m ³
^a Conformity with these limits cannot easily be assessed analytically pending further validation of the methods for volatile solvents described in EN 71-11.		

NOTE Trichloroethylene and dichloromethane are also included in the REACH list of substances subject to authorization (Annex XIV). Nitrobenzene is included in the candidate list.

The action limits for trichloroethylene and nitrobenzene are 33 µg/m³. The limits apply to certain toys made of polymeric or textile materials, e.g. inflatable toys with a surface greater than 0,5 m² when fully inflated, toys worn over the mouth or nose or toys which the child can enter.

Test methods for solvents (inhalation) in Table 18 are provided in EN 71-10 and EN 71-11 based on a headspace analysis. However, the methods have not been validated.

EN 71-9 also includes the requirement that 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 “Wood-based panels – Determination of formaldehyde release – Part 3: Formaldehyde release by the flask method”.

NOTE The suitability of the requirement and related method has been questioned and is subject to review.

The Construction Products Regulation (CPR, Regulation (EU) No 305/2011) does not establish performance requirements for construction products as these are the remit of Member States. The

“Declaration of Performance” is a key part of the Construction Products Regulation. It provides information on the performance of a product and relies on measurement methods defined in either European harmonized standards or European Technical Assessments.

Dangerous substances in construction products are the subject of work mandated by the European Commission. Emissions to indoor air were initially addressed by CEN/TS 16516: 2013 “Construction products - Assessment of release of dangerous substances - Determination of emissions into indoor air”. The specification was the subject of further evaluation of repeatability and reproducibility. The draft standard prEN 16516 was launched in May 2015 and received broad support from the CEN membership. The publication of the standard can be expected in 2017.

The draft standard specifies a horizontal reference method for the determination of emissions of regulated dangerous substances from construction products to indoor air. This method is applicable to volatile organic compounds, semi-volatile organic compounds, and volatile aldehydes. It is based on the use of a test chamber and subsequent analysis of the organic compounds by GC-MS or HPLC. A note to the scope of the draft standard describes the overall procedure and makes use of existing standards mainly by normative reference, complemented when necessary with additional or modified normative requirements. It defines a European reference room corresponding to a small normal living room (dimension 3 m x 4 m, height of 2,5 m, the total air volume 30 m³) and emission scenarios taking into account intended conditions of use of the construction products, allowing the establishment of product-specific alteration of certain parameters (e.g. load factors). Measurements are performed after day 3 and day 28. The standard seems equally relevant for non-construction articles emitting (Semi-) Volatile Organic Compounds (S)VOCs to the indoor environment (such as carpets) leaving it to the standardizer of such products to adapt the model for a particular product.

Among other VOCs, the proposed test method in prEN 16516 also covers formaldehyde. The draft standard also mentions several alternative standards for the measurement of formaldehyde in wood-based panels including those which are used for testing of compliance with formaldehyde limits in harmonized product standards (wood-based panels and wood-based flooring as well as other flooring): EN 717-1 “Wood-based panels — Determination of formaldehyde release — Part 1: Formaldehyde emission by the chamber method”, EN 717-2 “Wood based panels — Determination of formaldehyde release — Part 2: Formaldehyde release by the gas analysis method” and EN 120 “Wood based panels — Determination of formaldehyde content — Extraction method called the perforator method”.

The harmonized standard EN 13986:2004+A1:2015 “Wood-based panels for use in construction - Characteristics, evaluation of conformity and marking” defines wood-based panels for use in construction. The standard is the basis for establishing performance declarations and CE marking. It specifies the relevant characteristics and the appropriate test methods to determine these characteristics for wood-based panels, unfaced, overlaid, veneered or coated. It also specifies formaldehyde classes E1 and E2 reflecting national legal requirements in its Annex B.

Requirements for formaldehyde class E1:

- initial type testing for all boards based on EN 717-1 (chamber method, measured at steady-state conditions): release $\leq 0,124$ mg/m³ air (=0,1 ppm);
- factory production control based on EN 120 (perforator, for unfaced particleboard, OSB, MDF) or EN 717-2 (gas analysis, for unfaced plywood, solid wood panels, LVL and coated, overlaid or veneered particleboard, OSB, MDF, plywood, solid wood panels, fibre boards (wet process), cement bonded particleboards, LVL).

In some cases initial type testing for “established products” may also be done on the basis of “existing data” using EN 120 or EN 717-2.

NOTE Formaldehyde emission measurements using EN 717-1 give significantly lower results in comparison with prEN 16516 as a result of the much higher air exchange rate in the former standard.

5.14.3 Voluntary specifications for consumer-relevant articles

The Oeko-Tex® Standard 100 specifies limits for emissions of volatiles as shown in Table 19.

Table 19 — Emissions of volatiles in the Oeko-Tex® Standard 100 (all product classes)

Compound	CAS Number	Limit
Formaldehyde	50-00-0	0,100 mg/m ³
Toluene	108-88-3	0,100 mg/m ³
Styrene	100-42-5	0,005 mg/m ³
Vinylcyclohexene	100-40-3	0,002 mg/m ³
4-Phenylcyclohexene	4994-16-5	0,030 mg/m ³
Butadiene	106-99-0	0,002 mg m ³
Vinylchloride	75-01-4	0,002 mg/m ³
Aromatic hydrocarbons		0,300 mg/m ³
Organic volatiles		0,500 mg/m ³

The requirements apply to textile carpets, mattresses as well as foams and large coated articles not being used for clothing.

The limits for volatiles in the 2017 Leather Standard by Oeko-Tex® applying to leather used on a large scale (e.g. leather for furniture) are identical to the limits in the Oeko-Tex® 100 Standard. Testing is performed using a test chamber (no details provided).

There is also a requirement regarding the determination of (abnormal) odours (see subclause 5.17.2 below).

The European Ecolabel criteria for textile products (Commission Decision 2014/350/EU) and textile floor coverings (Commission Decision 2009/967/EC, discontinued) include provisions for the release of dangerous substances as shown in Table 20.

Table 20 — Release of dangerous substances in the European Ecolabel criteria for textile products and textile floor coverings

Compound	CAS Number	Limit (after 3 days)
Total organic compounds within the retention range C6 – C16 (TVOC)		0,25 mg/m ³ air
Total organic compounds within the retention range > C16 – C22 (TSVOC)		0,03 mg/m ³ air
Total VOC without LCI (*)		0,05 mg/m ³ air
(*) LCI = Lowest Concentration of Interest.		

A more comprehensive set of requirements is included in the European Ecolabel criteria for bed mattresses (Commission Decision 2014/391/EU) as shown in Table 21.

Table 21 — Release of dangerous substances in the European Ecolabel criteria for bed mattresses

Compound	Limit 7th day	Limit 28th day
Formaldehyde	< 0,060 mg/m ³	< 0,060 mg/m ³
Other aldehydes	< 0,060 mg/m ³	< 0,060 mg/m ³
VOCs (total)	< 0,500 mg/m ³	< 0,200 mg/m ³
SVOCs (total)	< 0,100 mg/m ³	< 0,040 mg/m ³
Each detectable compound classified as categories C1A or C1B according to the CLP Regulation	< 0,001 mg/m ³	< 0,001 mg/m ³

Additionally, requirements are specified for latex and PUR foams for bed mattresses as shown in Table 22.

Table 22 — Release of dangerous substances from latex and PUR foams in the European Ecolabel criteria for bed mattresses

Compound	Limit latex foam 24h	Limit PUR foam 72h
1,1,1 — trichloroethane	0,2000 mg/m ³	
4-Phenylcyclohexene	0,0200 mg/m ³	
Carbon Disulphide	0,0200 mg/m ³	
Formaldehyde	0,0050 mg/m ³	0,0050 mg/m ³
Nitrosamines (*)	0,0005 mg/m ³	
Styrene	0,0100 mg/m ³	0,0050 mg/m ³
Tetrachloroethylene	0,1500 mg/m ³	
Toluene	0,1000 mg/m ³	0,1000 mg/m ³
Trichloroethylene	0,0500 mg/m ³	
Vinyl chloride	0,0001 mg/m ³	
Vinyl cyclohexene	0,0020 mg/m ³	
Aromatic hydrocarbons (total)	0,3000 mg/m ³	
VOCs (total)	0,5000 mg/m ³	0,5000 mg/m ³
Aromatic hydrocarbons		0,5000 mg/m ³
Each detectable compound classified as categories C1A or C1B according to the CLP Regulation		0,0050 mg/m ³
Sum of all detectable compound classified as categories C1A or C1B according to the CLP Regulation		0,0400 mg/m ³

(*) N-nitrosodimethylamine (NDMA), N-nitrosodiethylamine (NDEA), N-nitrosomethylethylamine (NMEA), N-nitrosodi-i-propylamine (NDIPA), N-nitrosodi-n-propylamine (NDPA), N-nitrosodi-n-butylamine (NDBA), N-nitrosopyrrolidinone (NPYR), N-nitrosopiperidine (NPIP), N-nitrosomorpholine (NMOR)

Comprehensive instructions regarding the analytical methods are given based on the German AgBB (“Ausschuss für die gesundheitliche Bewertung von Bauprodukten”) scheme and the ISO 16000 standards series. Testing following CEN/TS 16516 is considered equivalent. Test parameters including test loads are defined.

The European Ecolabel criteria for furniture (Commission Decision (EU) 2016/1332) follow a similar scheme. The limits for latex and PUR foams are identical with the ones for bed mattresses given in Table 22. Maximum VOC emission limit values for specific furniture products (armchairs and sofas, office chairs, other furniture items using upholstery coverings made of leather or coated fabrics) are given in Table 23.

Table 23 — Release of dangerous substances in the European Ecolabel criteria for furniture

Compound	3d	28d
Formaldehyde	-	≤ 60 µg/m ³ (all items)
TVOCs	≤ 3,000 µg/m ³ (armchairs, sofas, coated component parts)	≤ 400 µg/m ³ (armchairs, sofas, coated component parts), ≤ 450 µg/m ³ (all other items)
TSVOCs		≤ 100 µg/m ³ (armchairs, sofas, coated component parts), ≤ 450 µg/m ³ (all other items)
C-substances (carcinogens)	≤ 10 µg/m ³ (total, all items)	≤ 1 µg/m ³ (per substance, all items)
R-value for LCI substances		≤ 1 (all items)

Test parameters (chamber volumes, ventilation rates) and test standards are also given (as for bed mattresses above).

The EU ecolabel criteria for furniture include additional limits for emissions of formaldehyde from wood-based panels and shall either:

- be lower than 50 % of the threshold value allowing them to be classified as E1 (as defined in Annex B of EN 13986);
- be lower than 65 % of the E1 threshold value, in the case of Medium Density Fibreboard (MDF) panels;
- Be lower than the limits set out in the CARB (California Air Resources Board) Phase II or the Japanese F-3 star or F-4 star standards.

The required test reports shall be carried out according to the relevant standards (EN 717-1, EN 717-2, EN 120 or ASTM E1333 or ASTM D6007, or JIS A 1460).

The EU ecolabel criteria for wooden floor coverings (Commission Decision (EU) 2017/176) include VOC emission limits as shown in Table 24.

Table 24 — Emission requirements in the European Ecolabel criteria for wood-, cork- and bamboo-based floor coverings

Compound	Products	28d
TVOCs minus acetic acid	Solid wood floorings Multi-layer wood floorings Wood veneer floor covering	< 0,3 mg/m ³
TVOCs	Cork floor coverings Bamboo floor coverings	< 0,3 mg/m ³
TVOCs	Laminate floorings	< 0,16 mg/m ³
TSVOCs	All floor coverings	< 0,1 mg/m ³
C-substances (carcinogens)	All floor coverings	≤ 0,001 mg/m ³
R-value for LCI substances minus acetic acid	Solid wood floorings Multi-layer wood floorings Wood veneer floor covering	≤ 1
R-value for LCI substances	Cork floor coverings Bamboo floor coverings Laminate floorings	≤ 1

Testing shall follow the procedures described in CEN/TS 16516 or equivalent.

The EU ecolabel criteria for wood-, cork- and bamboo-based floor coverings include additional limits for emissions of formaldehyde similar to the ones for furniture as follows:

- formaldehyde emissions that are lower than 50 % of the threshold value allowing them to be classified as E1 as defined in Annex B to EN 13986+A1 (applying to all floor coverings and non-MDF/non-HDF core boards);
- formaldehyde emissions that are lower than 65 % of the E1 as defined in Annex B to EN 13986+A1 threshold limit applying to untreated MDF/HDF core boards;
- formaldehyde emissions that are lower than the limits set out in the California Air Resources Board (CARB) Phase II or the Japanese F-3 star or F-4 star standards.

Assessment and verification: The required test reports shall be carried out according to the relevant standards (EN 717-1, EN 717-2, EN 120 or ASTM E1333 or ASTM D6007, or JIS A 1460).

In the framework of the “European Collaborative Action - Urban Air, Indoor Environment and Human Exposure”, coordinated by the EC Joint Research Centre in Ispra (Italy), a series of 29 reports on indoor quality issues have been published since 1988. ECA Report No 27 published in 2012 describes the consensus achieved by the parties involved in a harmonized framework for the evaluation of indoor emissions including “common core criteria” (already agreed) and “transitional criteria” (to be agreed later) as follows:

CEN Guide 16:2017 (E)

Core criteria:

- total amount of Volatile Organic Compounds (TVOC);
- elimination of volatile carcinogens (category 1A and 1B);
- individual compounds based on LCI-values (Lowest Concentration of Interest);
- formaldehyde.

Transitional criteria:

- substances not having LCI values (i.e. “not-yet-assessed” substances);
- semi-volatile organic compounds (SVOCs);
- sensory evaluation.

NOTE An indicative list of volatile (boiling point between 68 °C and 250 °C) carcinogenic VOCs cat. 1A and 1B can be found in prEN 16516, Annex G.2.

Measurements should take place on day 3 and day 28 after beginning of the test. Precise thresholds are not indicated.

It is envisaged to use the provisions of the validated harmonized testing standard (i.e. the future EN 16516) for measurement of VOCs and formaldehyde when this becomes available. Until that time the ISO 16000 standard series is recommended to be used.

The suggested scheme in the ECA Report was strongly influenced by the German AgBB scheme. The limits set in the scheme (as at February 2015) are as follows:

- TVOC value after 3 days $\leq 10 \text{ mg/m}^3$, after 28 days $\leq 1,0 \text{ mg/m}^3$;
- Carcinogens of categories 1A and 1B may not exceed a concentration of $0,01 \text{ mg/m}^3$ after 3 days, $0,001 \text{ mg/m}^3$ after 28 days (unless a threshold and a LCI-value can be determined);
- Sum of the SVOC concentrations $\leq 0,1 \text{ mg/m}^3$ after 28 days (unless a LCI-value is determined);
- Limits for individual substances following the LCI approach (new version already incorporating some of the harmonized EU-LCIs (see above));
- Sum of individual VOCs not assessable via LCI $\leq 0,1 \text{ mg/m}^3$.

ECA Report No 29 describes a harmonized procedure for establishing a list of compounds and their associated LCI (Lowest Concentration of Interest) values for the evaluation of emissions from construction products (EU-LCI) taking into account existing procedures used in some Member States (in particular, from ANSES in France and AgBB in Germany). EU-LCI values are health-based reference concentrations for inhalation exposure used to assess emissions after 28 days from a single product during a laboratory test chamber procedure as defined in CEN/TS 16516. It establishes a master list containing a total of 177 compounds subdivided into two groups, the first containing 82 compounds with agreed interim EU-LCI values and the second containing 95 compounds for which EU-LCI values are still to be derived.

After publication of the last report, a group of actors continued the work. A website was created by the “EU-LCI Working Group” made up of representatives from public authorities, university and research institutes and industry, where agreed LCI-values are made available. In 2016 this group was constituted as a Subgroup of the Expert Group on Dangerous Substances within the larger committee structure of

the EC Advisory Group on Construction Products. The website (meanwhile hosted by DG GROW) includes among other a list of:

- EU-LCI ‘derived’ values using the EU-LCI protocol;
- EU-LCI ‘ascribed’ values for compounds with identical or very similar LCI values (differing by 20 % or less) in the French ANSES and German AgBB lists (using the lower value).

In December 2015 an updated list was provided with LCI values for 94 compounds agreed (34 derived, 60 ascribed) and these can be downloaded from:

https://ec.europa.eu/growth/sectors/construction/eu-lci_en

The LCI relies on the evaluation of emissions from single products. However, a chemical substance may be emitted from several sources. Therefore, compliance of a construction product with EU-LCI criteria does not necessarily guarantee good indoor air quality in buildings. To overcome this difficulty, the authors of ECA Report No 29 recommended to adjust the limits by application of a ‘multiple sources factor’, i.e. to use 20 % – 50 % of the LCI depending on the likelihood of the presence of other sources. Where other sources can be excluded no correction is considered to be necessary.

5.14.4 Remarks

For some consumer-relevant articles with large areas (such as carpets, curtains or furniture) or articles which can be close to a person's nose for prolonged periods, inhalation of certain volatile organic compounds including residues of solvents may be relevant. In particular, this is also the case for articles which can surround a person, for example a tent.

European efforts to harmonize existing indoor emission schemes as indicated in the reports developed in the framework of the “European Collaborative Action - Urban Air, Indoor Environment and Human Exposure”, followed by the activities of the “EU-LCI Working Group” constitute a good basis for establishing normative requirements for consumer-relevant articles. It should be noted though that the LCI approach is limited to consideration of emissions from single products, i.e. emissions from various sources are not considered. Where exposure of a single volatile compound from several sources is expected a correction factor may be needed.

As long as a complete set of harmonized EU-LCIs does not exist, limits for substances not yet covered could be taken from the German AgBB scheme. This also holds true for other parameters such as TVOC or ban of volatile carcinogenic substances where a consensus in principle has been achieved but no precise limits have been agreed on.

In the above mentioned schemes and activities, only volatile carcinogenic substances are addressed and not all CMRs. This does not preclude the inclusion of other volatile substances of concern which could similarly be considered.

Also the use of the stricter European Ecolabel criteria addressing the release of dangerous substances from bed mattresses (including those from foams) could be considered. By contrast, the European Ecolabel criteria for textile products appear outdated as they cover just a limited number of compounds and do not reflect state-of-the-art approaches as outlined above.

Suitable test methods are included in prEN 16516 to be published in 2017. However, certain test parameters will have to be defined depending on the product in question (e.g. load factors).

Formaldehyde emissions are covered by the approach outlined above. However, the standards for the determination of formaldehyde emissions from wooden products (or the formaldehyde content correlating with emissions) are referenced in harmonized product standards in the construction sector for various products (wood panels, wood and other flooring). EN 717-1 relies on a chamber test method which can be considered as the reference method. However, it is developed for two-dimensional board-shaped products and may have to be adapted for other shapes (including the definition of a load factor). In addition, the air exchange rate used in EN 717-1 (1/h) is considerably higher than the one defined in

prEN 16516 (0,5/h). Hence, the (higher) concentrations measured using the latter standard seem to better reflect conditions in modern well-insulated buildings.

Oeko-Tex® Standard 100 and the Leather Standard by Oeko-Tex® specify limits for emissions of volatiles but offer limited information on the applied testing method. The method in EN 71-11 has not been validated and seems less suited than the other methods discussed above.

Volatile sensitizing fragrances are addressed in the section that follows.

Recommendations:

When establishing requirements for volatile organic chemicals in consumer-relevant articles or their components with large areas or other articles resulting in high exposure, Reports 27 and 29 of the “European Collaborative Action - Urban Air, Indoor Environment and Human Exposure” should be taken into consideration including provisions for TVOC, volatile carcinogenic substances and individual compounds based on LCI-values.

Where available, EU-LCI values developed by the “EU-LCI Working Group” should be used. In absence of such values the German AgBB scheme should be considered.

It should be noted that the LCI concept evaluates the emissions of substances from single products. Where emissions of a substance from several sources can be expected a correction factor should be used and the LCI limits should be reduced accordingly.

VOC measurements should be based on a chamber test as described in prEN 16516. Product-specific parameters (such as load factors) need to be set when developing normative requirements for consumer-relevant articles.

Inclusion of additional volatile substances of concern should be considered, for example by reviewing the lists of substances in the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex®, ecolabel schemes or EN 71-9.

Limits for formaldehyde emissions from wood-based panels (or resin-bonded products of similar shape) should be measured in accordance with EN 717-1 or prEN 16516 taking into consideration that different test conditions (in particular, the air exchange rates) are different and thus, different test results are obtained. Other resin-bonded wood products should be tested either using adapted versions of EN-717-1 or prEN 16516.

5.15 Allergenic fragrances

Fragrances are used to provide a scent to any given product, and these can be derived from either natural sources or chemical synthesis. Some of the fragrances have been identified as contact allergens.

5.15.1 REACH restrictions for consumer-relevant articles

REACH Annex XVII does not address allergenic fragrances in consumer-relevant articles.

5.15.2 Other regulatory provisions for articles and related standards

According to the Toy Safety Directive, toys shall not contain allergenic fragrances as listed in Table 25. However, the presence of traces of these fragrances is allowed, provided that such presence is technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg.

Table 25 — Allergenic fragrances not allowed in toys according to the Toy Safety Directive

No	Name of the allergenic fragrance	CAS number
(1)	Alanroot oil (Inula helenium)	97676-35-2
(2)	Allylthiocyanate	57-06-7

No	Name of the allergenic fragrance	CAS number
(3)	Benzyl cyanide	140-29-4
(4)	4 tert-Butylphenol	98-54-4
(5)	Chenopodium oil	8006-99-3
(6)	Cyclamen alcohol	4756-19-8
(7)	Diethyl maleate	141-05-9
(8)	Dihydrocoumarin	119-84-6
(9)	2,4-Dihydroxy-3-methylbenzaldehyde	6248-20-0
(10)	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5
(11)	4,6-Dimethyl-8-tert-butylcoumarin	17874-34-9
(12)	Dimethyl citraconate	617-54-9
(13)	7,11-Dimethyl-4.6,10-dodecatrien-3-one	26651-96-7
(14)	6,10-Dimethyl-3.5,9-undecatrien-2-one	141-10-6
(15)	Diphenylamine	122-39-4
(16)	Ethyl acrylate	140-88-5
(17)	Fig leaf, fresh and preparations	68916-52-9
(18)	trans-2-Heptenal	18829-55-5
(19)	trans-2-Hexenal diethyl acetal	67746-30-9
(20)	trans-2-Hexenal dimethyl acetal	18318-83-7
(21)	Hydroabietyl alcohol	13393-93-6
(22)	4-Ethoxy-phenol	622-62-8
(23)	6-Isopropyl-2-decahydronaphthalenol	34131-99-2
(24)	7-Methoxycoumarin	531-59-9
(25)	4-Methoxyphenol	150-76-5
(26)	4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4
(27)	1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8
(28)	Methyl trans-2-butenoate	623-43-8
(29)	6-Methylcoumarin	92-48-8
(30)	7-Methylcoumarin	2445-83-2
(31)	5-Methyl-2,3-hexanedione	13706-86-0
(32)	Costus root oil (Saussurea lappa Clarke)	8023-88-9

No	Name of the allergenic fragrance	CAS number
(33)	7-Ethoxy-4-methylcoumarin	87-05-8
(34)	Hexahydrocoumarin	700-82-3
(35)	Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch)	8007-00-9
(36)	2-Pentylidene-cyclohexanone	25677-40-1
(37)	3,6,10-Trimethyl-3,5,9-undecatrien-2-one	1117-41-5
(38)	Verbena oil (Lippia citriodora Kunth)	8024-12-2
(39)	Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)	83-66-9
(40)	4-Phenyl-3-buten-2-one	122-57-6
(41)	Amyl cinnamal	122-40-7
(42)	Amylcinnamyl alcohol	101-85-9
(43)	Benzyl alcohol	100-51-6
(44)	Benzyl salicylate	118-58-1
(45)	Cinnamyl alcohol	104-54-1
(46)	Cinnamal	104-55-2
(47)	Citral	5392-40-5
(48)	Coumarin	91-64-5
(49)	Eugenol	97-53-0
(50)	Geraniol	106-24-1
(51)	Hydroxy-citronellal	107-75-5
(52)	Hydroxy-methylpentylcyclohexenecarboxaldehyde	31906-04-4
(53)	Isoeugenol	97-54-1
(54)	Oakmoss extracts	90028-68-5
(55)	Treemoss extracts	90028-67-4

In addition, the names of the allergenic fragrances in Table 26 need to be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy at concentrations exceeding 100 mg/kg in the toy or any of its components.

Table 26 — Allergenic fragrances to be labelled if used in toys according to the Toy Safety Directive

No	Name of the allergenic fragrance	CAS number
(1)	Anisyl alcohol	105-13-5

No	Name of the allergenic fragrance	CAS number
(2)	Benzyl benzoate	120-51-4
(3)	Benzyl cinnamate	103-41-3
(4)	Citronellol	106-22-9
(5)	Farnesol	4602-84-0
(6)	Hexyl cinnamaldehyde	101-86-0
(7)	Lilial	80-54-6
(8)	d-Limonene	5989-27-5
(9)	Linalool	78-70-6
(10)	Methyl heptine carbonate	111-12-6
(11)	3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5

The requirements for the listed contact allergens are based on the requirements included in Annexes II and III of the Cosmetics Regulation (Regulation (EC) No 1223/2009) but are not identical. Substances number 1-40 in Table 23 are banned in both pieces of legislation (with exceptions for substance numbers 25 and 29). Substance numbers 41-55 in Table 23 are not banned in the Cosmetics Regulation, they must only be labelled as for substance numbers 1-11 in Table 24 (which means that in total 26 substances must be labelled according to the Cosmetics Regulation, with limits of 0,001 % in leave-on products and 0,01 % in rinse-off products).

5.15.3 Voluntary specifications for consumer-relevant articles

European Ecolabel criteria for absorbent hygiene products (Commission Decision 2014/763/EU) contain several requirements that apply specifically to fragrances: products marketed as designed and intended for children as well tampons and nursing pads must be fragrance-free, and a fragrance must be manufactured and handled following the code of practice of the International Fragrance Association (IFRA). The criteria for tissue paper (Commission Decision 2009/568/EC, prolonged until December 2018) excludes fragrances which must be labelled in accordance with the Cosmetics Directive (now Regulation) on product/packaging (concentration limit 0,01 %).

5.15.4 Remarks

According to an opinion of the Scientific Committee on Consumer Safety (SCCS) on fragrance allergens in cosmetic products dated 2011-12-13/14 many more fragrances are of concern and should be labelled in addition to the ones identified earlier. Instead of the 26 substances to be labelled according to the Cosmetics Regulation, 129 fragrances were identified as established or potential contact allergens in humans (i.e. 103 more substances than originally identified).

NOTE Respiratory sensitizers are neither included in the lists referred to above nor were they subject of review by SCCS.

The lists in Table 24 and Table 25 are a suitable starting point for establishing normative rules for sensitizing fragrances in consumer-relevant articles. An alternative would be a more far-reaching exclusion as indicated in the European Ecolabel criteria mentioned above. For some products, complete exclusion of fragrances could be considered. However, the right of consumers to choose fragranced or fragrance-free articles should be balanced against any benefits resulting from exclusions.

Recommendation:

When establishing requirements for fragrances in scented consumer-relevant articles or their components, the respective provisions of the Cosmetics Regulation and the Toy Safety Directive including information provisions should be taken into consideration as well as the 2011 Opinion of the Scientific Committee on Consumer Safety (SCCS) on fragrance allergens in cosmetic products. For some products more extensive restrictions could be considered in line with some European Ecolabel provisions taking due account of the consumer right to choose fragranced or fragrance-free articles.

5.16 Other substances

A series of other substances are addressed in EU legislation and other tools, as they have problematic properties. Substances which do not belong to any of the families of substances covered above are addressed below.

5.16.1 Formaldehyde (not covered by requirements above)

5.16.1.1 REACH restrictions for consumer-relevant articles

REACH Annex XVII does not address formaldehyde in consumer-relevant articles.

5.16.1.2 Other regulatory provisions for articles and related standards

The Toy Safety Directive does not stipulate specific requirements for formaldehyde. However, the harmonized standard EN 71-9:2005+A1:2007 (reference not published in the Official Journal) contains the following requirements for formaldehyde in Clause 4.3 in addition to the requirements for formaldehyde mentioned already above (or used as a preservative):

- accessible textile components of toys intended for children under 3 years of age shall not contain free and hydrolysed formaldehyde in excess of 30 mg/kg when tested in accordance with EN ISO 14184-1 “Textiles – Determination of formaldehyde – Part 1: Free and hydrolysed formaldehyde (water extraction method)”.
- 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 “Paper and board intended to come into contact with foodstuffs – Preparation of a cold water extract” and EN 1541 “Paper and board intended to come into contact with foodstuffs - Determination of formaldehyde in an aqueous extract”.

Test methods are given in each of these standards.

5.16.1.3 Voluntary specifications for consumer-relevant articles

The Oeko-Tex® Standard 100 specifies limits for formaldehyde as shown in Table 27. The limits for formaldehyde in the 2017 Leather Standard by Oeko-Tex® are identical to the limits in the Oeko-Tex® 100 Standard except that a limit of < 10 mg/kg is indicated for baby products.

Table 27 — Formaldehyde limits in the Oeko-Tex® Standard 100

Substance	I Baby, mg/kg	II in direct contact with skin, mg/kg	III with no direct contact with skin, mg/kg	IV Decoration material, mg/kg
Formaldehyde	n.d. ^(x)	75	300	300

^(x) n.d. corresponds according to “Japanese Law 112” test method with an absorbance unit

Substance	I Baby, mg/kg	II in direct contact with skin, mg/kg	III with no direct contact with skin, mg/kg	IV Decoration material, mg/kg
less than 0,05 resp. <16 mg/kg.				

The European Ecolabel criteria for textile products (Commission Decision 2014/350/EU), textile floor coverings (Commission Decision 2009/967/EC, discontinued), footwear (Commission Decision (EU) 2016/1349) and furniture (Commission Decision (EU) 2016/1332) include provisions for the formaldehyde content as shown in Table 28.

Table 28 — Formaldehyde limits in textile-related European Ecolabel criteria

Substance	Textile products	Textile floor coverings	Footwear	Furniture
Formaldehyde	16 ppm (products for children under 3 years and products in direct contact with the skin); 75 ppm (garments with limited skin contact and interior textiles)	30 ppm (or chamber test)	textile: < 20 mg/kg leather: < 20 mg/kg (children's footwear up to 3 years); 75 mg/kg (linings and socks); 100 mg/kg (other parts of the product)	leather, textile and coated fabrics: ≤ 20 mg/kg (children's furniture up to 3 years); ≤ 75 mg/kg (other furniture)

For textiles, EN ISO 14184-1 "Textiles - Determination of formaldehyde - Part 1: Free and hydrolysed formaldehyde (water extraction method)" is used as a test method with a detection limit of 16 mg/kg (16 ppm). For leather, EN ISO 17226-1 "Leather - Chemical determination of formaldehyde content - Part 1: Method using high performance liquid chromatography" is the relevant test method.

In addition, the European Ecolabel criteria for tissue paper containing recycling fibres or mixes of recycling and virgin fibres include a limit of 1 mg/dm² when tested according to EN 1541 "Paper and board intended to come into contact with foodstuffs - Determination of formaldehyde".

5.16.1.4 Remarks

The identified limits address skin contact and complement other provisions for formaldehyde mentioned on other parts of this document. They are particularly relevant for products worn on the body but may be relevant also for other products made of (certain) textiles, leather and paper. It should be noted that significant exposure may be the result of skin contact to various products.

Recommendation:

Standards writers should consider the requirements concerning formaldehyde included in EN 71-9 as regards articles made of textiles or paper which can reasonably lead to an exposure due to prolonged contact with skin taking into account exposure from multiple sources. Limits in the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex® and the European Ecolabel criteria for formaldehyde

in textile or leather articles should be also considered.

5.16.2 N-Nitrosamines and N-Nitrosatable substances

5.16.2.1 REACH restrictions for consumer-relevant articles

REACH Annex XVII does not address N-Nitrosamines and N-Nitrosatable substances in consumer-relevant articles.

5.16.2.2 Other regulatory provisions for articles and related standards

According to the Toy Safety Directive N-nitrosamines and N-nitrosatable substances are prohibited in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth if the migration of the substances is equal to or higher than 0,05 mg/kg for N-nitrosamines and 1 mg/kg for N-nitrosatable substances.

Test methods for N-Nitrosamines and N-nitrosatable substances in toys and parts of toys made from elastomers are provided in EN 71-12 "Safety of toys – Part 12: N-Nitrosamines and N-nitrosatable substances". It also includes limits which are lower than the ones contained in the TSD for finger paints (0,02 mg/kg and 1 mg/kg) and for toys intended for use by children under 36 months and intended or likely to be placed in the mouth (0,01 mg/kg and 0,1 mg/kg).

Commission Directive 93/11/EEC concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers contains the following migration limits: 0,01 mg in total of N-nitrosamines released/kg, 0,1 mg in total of N-nitrosatable substances/kg. Test methods are provided in EN 12868 "Child use and care articles — Methods for determining the release of N-Nitrosamines and N-Nitrosatable substances from elastomer or rubber teats and soothers".

5.16.2.3 Voluntary specifications for consumer-relevant articles

The European Ecolabel criteria for footwear (Commission Decision (EU) 2016/1349) provide that the following N-Nitrosamines are not detectable in rubber:

- N-nitrosodiethanolamine, NDELA (CAS No 1116-54-7);
- N-nitrosodimethylamine, NDMA (CAS No 62-75-9);
- N-nitrosodiethylamine, NDEA (CAS No 55-18-5);
- N-nitrosodipropylamine, NDPA (CAS No 621-64-7);
- N-nitrosodiisopropylamine, NdiPA (CAS No 601-77-4)
- N-nitrosodibutylamine, NDBA (CAS No 924-16-3);
- N-nitrosodiisobutylamine, NdiBA (CAS No 997-95-5);
- N-nitrosodiisononylamine, NdiNA (CAS No 1207995-62-7)
- N-nitrosopiperidine, NPIP (CAS No 100-75-4);
- N-nitrosopyrrolidine, NPYR (CAS No 930-55-2);
- N-nitrosomorpholine, NMOR (CAS No 59-89-2);
- N-nitroso N-methyl N-phenylamine, NMPPhA (CAS No 614-00-6);

— N-nitroso N-ethyl N-phenylamine, NEPhA (CAS No 612-64-6).

The European Ecolabel also uses as a test method the EN 12868 “Child use and care articles — Methods for determining the release of N-Nitrosamines and N-Nitrosatable substances from elastomer or rubber teats and soothers”.

5.16.2.4 Remarks

In March 2012, the European Commission approved the request from the German Federal Government to retain the existing limits provided in German law for N-nitrosamines and N-nitrosatable substances for some toys which are stricter (0,01 mg/kg for N-nitrosamines and 0,1 mg/kg for N-nitrosatable substances) than the limit values specified in Toy Safety Directive. These limits apply to toys made of natural or synthetic rubber designed for children under 36 months and intended or likely to be placed in the mouth. The European Commission concluded that these requirements are justified by the need to protect human health. Against this background the German lower limits were included in the revised standard EN 71-12 published in 2016 for the toy category specified.

The European Ecolabel criteria for footwear include only N-nitrosamines but no N-nitrosatable substances (possibly because prolonged mouthing is not anticipated which may result in the transformation of N-nitrosatable substances to N-nitrosamines in the stomach).

Recommendation:

The requirements for N-nitrosamines included in the European Ecolabel criteria for footwear for rubber products should be considered.

The requirements concerning N-Nitrosamines and N-Nitrosatable substances included in the Toy Safety Directive and EN 71–12 should be considered as regards consumer-relevant articles made of elastomers which can be placed in the mouth, particularly those with intended mouth contact or likely mouth contact for prolonged periods and taking into account the “Guideline on the interpretation of the concept ‘which can be placed in the mouth’ as laid down in entry 52 of REACH Annex XVII.

5.16.3 Per- and polyfluorinated compounds (PFCs)

5.16.3.1 REACH restrictions for consumer-relevant articles

REACH Annex XVII does not address per- and polyfluorinated compounds in consumer-relevant articles.

NOTE A restriction for perfluorooctanoic acid (PFOA), its salts and PFOA-related substances in articles has been proposed by the Commission (25 ppb of PFOA including its salts or 1000 ppb of one or a combination of PFOA-related substances).

5.16.3.2 Other regulatory provisions for articles and related standards

The Regulation on Persistent Organic Pollutants (POP, Regulation (EC) No 850/2004) bans perfluorooctane sulfonic acid and its derivatives (PFOS) in semi-finished products or articles, or parts thereof, if the concentration of PFOS is lower than 0,1 % by weight calculated with reference to the mass of structurally or micro-structurally distinct parts that contain PFOS or, for textiles or other coated materials, if the amount of PFOS is lower than 1 µg/m² of the coated material.

PFOS means a substance with the formula C₈F₁₇SO₂X (X = OH, Metal salt (O-M⁺), halide, amide, and other derivatives including polymers).

5.16.3.3 Voluntary specifications for consumer-relevant articles

The Oeko-Tex® Standard 100 includes provisions for perfluorinated compounds for all product classes for all materials with a water and oil repellent finish or coating as shown in Table 29. The limits for per-

and polyfluorinated compounds in the 2017 Leather Standard by Oeko-Tex® are identical to the limits in the Oeko-Tex® 100 Standard.

Table 29 — Limits for perfluorinated compounds in the Oeko-Tex® Standard 100

Substance ^(X)	I Baby	II in direct contact with skin	III with no direct contact with skin	IV Decoration material
PFOS, PFOSA, PFOSF, N-Me-FOSA, N-Et-FOSA, N-Me-FOSE, N-Et-FOSE; Sum [$\mu\text{g}/\text{m}^2$]	< 1,00	< 1,00	< 1,00	< 1,00
PFOA [$\mu\text{g}/\text{m}^2$]	< 1,00	< 1,00	< 1,00	< 1,00
PFHpA [mg/kg]	0,05	0,10	0,10	0,50
PFNA [mg/kg]	0,05	0,10	0,10	0,50
PFDA [mg/kg]	0,05	0,10	0,10	0,50
PFUdA [mg/kg]	0,05	0,10	0,10	0,50
PFDoA [mg/kg]	0,05	0,10	0,10	0,50
PFTrDA [mg/kg]	0,05	0,10	0,10	0,50
PFTeDA [mg/kg]	0,05	0,10	0,10	0,50
^(X) Perfluorooctane sulfonates, PFOS (CAS No various), Perfluorooctane sulfonamide, PFOSA (CAS No 754-91-6), Perfluorooctane sulfonyl fluoride, PFOSF / POSF (CAS No 307-35-7), N-Methyl perfluorooctane sulfonamide, N-Me-FOSA (CAS No 31506-32-8), N-Ethyl perfluorooctane sulfonamide, N-Et-FOSA (CAS No 4151-50-2), N-Methyl perfluorooctane sulfonamide ethanol, N-Me-FOSE (CAS No 24448-09-7), N-Ethyl perfluorooctane sulfonamide ethanol, N-Et-FOSE (CAS No 1691-99-2), Perfluorooctanoic acids, PFOA (CAS No various), Perfluoroheptanoic acids, PFHpA (CAS No various), Perfluorononanoic acids, PFNA (CAS No various), Perfluorododecanoic acids, PFDA (CAS No various), Heneicosfluoroundecanoic acid, PFUdA (CAS No 2058-94-8), Tricosfluorododecanoic acid, PFDoA (CAS No 307-55-1), Pentacosfluorotridecanoic acid, PFTrDA (CAS No 72629-94-8), Heptacosfluorotetradecanoic acid, PFTeDA (CAS No 376-06-7)				

In addition, the following per- and polyfluorinated substances are limited in baby products with a limit of 0,05 mg/kg each:

Further Perfluorinated carbonic acids:

- Perfluorobutanoic acid, PFBA (CAS No 375-22-4);
- Perfluoropentanoic acid, PFPeA (CAS No 2706-90-3);
- Perfluorohexanoic acid, PFHxA (CAS No 307-24-4);
- Perfluoro(3,7-dimethyloctanoic acid), PF-3,7-DMOA (CAS No 172155-07-6);

Perfluorinated sulfonic acids:

- Perfluorobutane sulfonic acid, PFBS (CAS No 375-73-5, 59933-66-3);
- Perfluorohexane sulfonic acid, PFHxS (CAS No 355-46-4);
- Perfluoroheptane sulfonic acid; PFHpS (CAS No 375-92-8);
- Henicosafuorodecane sulfonic acid, PFDS (CAS No 335-77-3);

Partially fluorinated carbonic / sulfonic acids:

- 7H-Perfluoro heptanoic acid, 7HPFHpA (CAS No 1546-95-8);
- 2H,2H,3H,3H-Perfluoroundecanoic acid, 4HPFUnA (CAS No 34598-33-9);
- 1H,1H,2H,2H-Perfluorooctane sulfonic acid, 1H, 1H, 2H, 2H-PFOS (CAS No 27619-97-2);

Finally, the following per- and polyfluorinated substances are limited in baby products with a limit of 0,50 mg/kg each:

Partially fluorinated linear alcohols:

- 1H,1H,2H,2H-Perfluoro-1-hexanol, 4:2 FTOH (CAS No 2043-47-2);
- 1H,1H,2H,2H-Perfluoro-1-octanol, 6:2 FTOH (CAS No 647-42-7);
- 1H,1H,2H,2H-Perfluoro-1-decanol, 8:2 FTOH (CAS No 678-39-7);
- 1H,1H,2H,2H-Perfluoro-1-dodecanol, 10:2 FTOH (CAS No 865-86-1);

Esters of fluorinated alcohols with acrylic acid:

- 1H,1H,2H,2H-Perfluorooctyl acrylate, 6:2 FTA (CAS No 17527-29-6);
- 1H,1H,2H,2H-Perfluorodecyl acrylate, 8:2 FTA (CAS No 27905-45-9);
- 1H,1H,2H,2H-Perfluorododecyl acrylate, 10:2 FTA (CAS No 17741-60-5).

The European Ecolabel criteria for textile products (Commission Decision 2014/350/EU) exclude fluorinated water, stain and oil repellent treatments including per- and polyfluorinated treatments, but accept the use of fluoropolymer membranes and laminates for outdoor wear and technical outdoor clothing. However, they shall not be manufactured using PFOA or any of its higher homologues as defined by the OECD.

The European Ecolabel criteria for bed mattresses (Commission Decision 2014/391/EU) and for furniture (Commission Decision (EU) 2016/1332) provide that fluorinated water, stain and oil repellent treatments must not be used, including per- and polyfluorinated carbon treatments.

The European Ecolabel criteria for footwear (Commission Decision (EU) 2016/1349) follows a similar approach, but allow the use of fluoropolymer membranes and laminates if the required water penetration of the material is lower than 0,2 g and the water absorption is lower than 30 % according to ISO/Standard 20347. Fluoropolymer membranes shall not be manufactured using PFOA or any of its higher homologues as defined by the OECD.

5.16.3.4 Remarks

Per- and polyfluorinated alkyl substances (PFASs) are a large group of chemicals that have been recognized as highly persistent, potentially bio-accumulative and toxic. In addition, many PFASs have been detected globally in the environment, biota, humans and food items.

Several perfluorinated alkyl substances have been included in the REACH “candidate list” including:

- Ammonium pentadecafluorooctanoate (APFO);
- Perfluorononan-1-oic-acid (PFNA) and its sodium and ammonium salts
- Pentadecafluorooctanoic acid (PFOA);
- Henicosafluoroundecanoic acid (PFUdA);
- Heptacosafuorotetradecanoic acid (PFTeDA),
- Pentacosafuorotridecanoic acid (PFTrDA);
- Tricosafuorododecanoic acid (PFDoA).

There is probably limited scope for addressing PFAS substances in standards for consumer-relevant articles. Assuming that PFOA, its salts and PFOA-related substances will be restricted in REACH, and given that PFOS and its derivatives are already banned in the POP Regulation, these substances do not need to be addressed at all. Further, perfluorinated alkyl substances included in REACH Annex XIV would be covered by the recommendation in subclause 5.2 of this Guide to not allow SVHCs in standards for consumer-relevant articles or their components after the substance’s sunset date, unless an authorization is granted to the holder of an authorization for the use of an SVHC in the production of the article concerned.

However, concern is growing that the substitutes of these long-chain per- and polyfluorinated alkyl substances (PFASs) including shorter-chain fluorinated substances may be as resistant to degradation in the environment as their longer-chain counterparts. This concern expressed by a group of scientists in “Helsingør Statement on poly- and perfluorinated alkyl substances (PFASs)” was published in the journal *Chemosphere* (Volume 114, November 2014, Pages 337–339)³. This merits further attention. Also partially fluorinated compounds, such as those identified in the Oeko-Tex® 100 Standard and the Leather Standard by Oeko-Tex®, may also require attention.

Recommendation:

Perfluorooctane sulfonic acid and its derivatives (PFOS) are banned in the Persistent Organic Pollutants Regulation and do not need to be covered in standards for consumer-relevant articles.

Long-chain perfluorinated alkyl substances included in the Candidate list may in future be included in REACH Annex XIV. In view of the recommendation in 5.2 of this Guide to disallow SVHCs in standards for consumer-relevant articles or their components after the sunset date given for that substance unless an authorization is granted to the holder of an authorization for the use of an SVHC in the production of the article concerned, an inclusion of specific requirements for the PFASs included in Annex XIV of REACH in standards for consumer-relevant articles does not seem warranted.

In addition, perfluorooctanoic acid (PFOA), its salts and PFOA-related substances are likely to be covered by a REACH Annex XVII restriction and therefore do not need to be covered.

Shorter-chain fluorinated substances have also been identified as a matter of concern, and partially

³ <http://www.sciencedirect.com/science/article/pii/S004565351400678X>

fluorinated compounds, such as those identified in the Oeko-Tex® Standard 100 and the Leather Standard by Oeko-Tex®, may require attention. This subject needs further research and discussion.

5.16.4 Alkylphenols and Alkylphenoethoxylates (APEOs)

5.16.4.1 REACH restrictions for consumer-relevant articles

According to REACH Annex XVII (entry 46a) nonylphenol ethoxylates (NPE) shall not be placed on the market after 3 February 2021 in textile articles which can reasonably be expected to be washed in water during their normal lifecycle, in concentrations equal to or greater than 0,01 % by weight of that textile article or of each part of the textile article (second-hand textile articles and textile articles produced exclusively from recycled textiles are exempted).

5.16.4.2 Other regulatory provisions for articles and related standards

No European regulatory provisions for articles and related standards were identified.

5.16.4.3 Voluntary specifications for consumer-relevant articles

The Oeko-Tex® Standard 100 establishes limits in all product classes for alkylphenols and alkylphenoethoxylates as shown in Table 30. The limit for the sum of OP and NP in the 2017 Leather Standard by Oeko-Tex® is < 10,0 mg/kg. The limit for the sum of OP, NP, OP(EO) and NP(EO) is identical to the limit in the Oeko-Tex® 100 Standard.

Table 30 — Limits for alkylphenols and alkylphenoethoxylates in the Oeko-Tex® Standard 100

Compound ^(x)	CAS Number	Limit
OP, NP, Sum	various	< 10,0 mg/kg
OP, NP, OP(EO), NP(EO) Sum	various	< 100,0 mg/kg
^(x) Nonylphenol, NP; Octylphenol, OP; Octylphenoethoxylates, OP(EO); Nonylphenoethoxylates, NP(EO)		

The European Ecolabel criteria for textile products (Commission Decision 2014/350/EU) and bed mattresses (covers and filling materials made of wool) establish a limit value of 25 mg/kg for the sum of the following compounds:

Alkylphenols:

- Nonylphenol, mixed isomers (CAS No 25154-52-3);
- 4-Nonylphenol (CAS No 104-40-5);
- 4-Nonylphenol, branched (CAS No 84852-15-3)
- Octylphenol (CAS No 27193-28-8);
- 4-Octylphenol (CAS No 1806-26-4);
- 4-tert-Octylphenol (CAS No 140-66-9).

Alkylphenoethoxylates (APEOs) and their derivatives:

- Polyoxyethylated octyl phenol (CAS No 9002-93-1);
- Polyoxyethylated nonyl phenol (CAS No 9016-45-9),
- Polyoxyethylated p-nonyl phenol (CAS No 26027-38-3).

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The European Ecolabel criteria for footwear (Commission Decision (EU) 2016/1349) and furniture (Commission Decision (EU) 2016/1332) use the same approach but permit a higher aggregate limit of 100 mg/kg for the listed substances in leather. The standards EN ISO 18218-2 “Leather - Determination of ethoxylated alkylphenols - Part 2: Indirect method” and EN ISO 18254-1 “Textiles - Method for the detection and determination of alkylphenol ethoxylates (APEO) - Part 1: Method using HPLC – MS” are used as test methods.

The European Ecolabel criteria for textile floor coverings (Commission Decision 2010/18/EC, discontinued) and various paper products do not allow the use of alkylphenoethoxylates (or other alkylphenol derivatives).

5.16.4.4 Remarks

The REACH “candidate list” includes 4-Nonylphenol, branched and linear and 4-Nonylphenol, branched and linear, ethoxylated as well as 4-(1,1,3,3-tetramethylbutyl)phenol (Octylphenol) and 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (=Octylphenoethoxylate).

The restriction dossier for nonylphenol ethoxylates also included a proposal to restrict nonylphenol. However, this substance was not included in the restriction in the end, based on the argument that it is not used in the textile manufacturing process and only small amounts of nonylphenol can be found in finished textile articles. These traces were assumed to be negligible compared to NPEO. Nonylphenol ethoxylates do not need to be addressed in standards for consumer-relevant articles.

In addition, alkylphenols and alkylphenoethoxylates which will eventually be incorporated into Annex XIV of REACH are covered by the provisions of 5.2 of the present Guide. However, a lower limit may be useful for some substances and, a limit for the sum of OP and NP could be envisaged following the related provisions in the Oeko-Tex® Standard 100 and the Leather Standard by Oeko-Tex®.

Recommendation:

Alkylphenols and alkylphenoethoxylates identified as SVHC included in REACH Annex XIV and which are not authorized for use in consumer-relevant articles are covered by the provisions of subclause 5.2 of the present Guide. These could be complemented by a limit for the sum of OP and NP in line with the provisions in Oeko-Tex® Standard 100 and the Leather Standard by Oeko-Tex® when setting requirements for chemicals in consumer-relevant articles and their components.

Nonylphenol ethoxylates covered by REACH Annex XVII do not need to be addressed in standards for consumer-relevant articles.

5.16.5 Chlorinated benzenes and toluenes

5.16.5.1 REACH restrictions for consumer-relevant articles

REACH Annex XVII does not address chlorinated benzenes and toluenes in consumer-relevant articles.

5.16.5.2 Other regulatory provisions for articles and related standards

The Persistent Organic Pollutants (POP, Regulation (EC) No 850/2004) does not allow Hexachlorobenzene (CAS No 118-74-1) and Pentachlorobenzene (CAS No 608-93-5) in articles.

5.16.5.3 Voluntary specifications for consumer-relevant articles

The Oeko-Tex® Standard 100 provides a limit of 1 mg/kg for the sum of the listed chlorinated benzenes and toluenes for all product classes. The limits for the listed chlorinated benzenes and toluenes in the 2017 Leather Standard by Oeko-Tex® are identical to the limits in the Oeko-Tex® 100 Standard.

The list includes:

- Chlorobenzene, Dichlorobenzenes, Trichlorobenzenes, Tetrachlorobenzenes, Pentachlorobenzenes and Hexachlorobenzene;

— Dichlorotoluenes, Trichlorotoluenes, Tetrachlorotoluenes and Pentachlorotoluene.

Several European Ecolabel criteria (bed mattresses, textile products, footwear, furniture) include provisions excluding halogenated dyeing accelerants (carriers) such as 1,2-dichlorobenzene, 1,2,4-trichlorobenzene, chlorophenoxyethanol.

5.16.5.4 Remarks

According to Annex XVII of REACH (entry 49) 1,2,4-trichlorobenzene (CAS No 120-82-1) shall not be placed on the market, or used as a substance or in mixtures in a concentration equal to or greater than 0,1 % by weight (exceptions apply). Entry 64, 1,4-dichlorobenzene (CAS No 106-46-7) shall not be placed on the market or used, as a substance or as a constituent of mixtures in a concentration equal to or greater than 1 % by weight, where the substance or the mixture is placed on the market for use or used as an air freshener or deodoriser in toilets, homes, offices or other indoor public areas.

The provisions of the Oeko-Tex® Standard 100 and the Leather Standard by Oeko-Tex® seem a suitable starting point for establishing requirements for chlorinated benzenes and toluenes in standards for consumer-relevant articles.

Recommendation:

The provisions for chlorinated benzenes and toluenes in the Oeko-Tex® Standard 100 and the Leather Standard by Oeko-Tex® should be considered when establishing normative provisions for consumer-relevant articles and their components.

5.16.6 Polycyclic aromatic hydrocarbons (PAHs)

5.16.6.1 REACH restrictions for consumer-relevant articles

Polycyclic Aromatic Hydrocarbons (PAHs) are restricted in toys, including activity toys, and childcare articles (entry 50). Such 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 human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 0,5 mg/kg (0,000 05 % by weight of this component) of any of the listed PAHs:

- Benzo[a]pyrene, BaP (CAS No 50-32-8);
- Benzo[e]pyrene, BeP (CAS No 192-97-2);
- Benzo[a]anthracene, BaA (CAS No 56-55-3);
- Chrysene, CHR (CAS No 218-01-9);
- Benzo[b]fluoranthene, BbFA (CAS No 205-99-2);
- Benzo[j]fluoranthene, BjFA (CAS No 205-82-3);
- Benzo[k]fluoranthene, BkFA (CAS No 207-08-9);
- Dibenzo[a,h]anthracene, DBAhA (CAS No 53-70-3).

In addition, other articles shall not be placed on the market for supply to the general public 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 1 mg/kg (0,000 1 % by weight of this component) of any of the above listed PAHs.

5.16.6.2 Other regulatory provisions for articles and related standards

No European regulatory provisions for articles and related standards were identified.

5.16.6.3 Voluntary specifications for consumer-relevant articles

The Oeko-Tex® Standard 100 sets limits for the same individual PAHs (product class I Baby: 0,5 mg/kg per substance, all other product classes: 1 mg/kg per substance). It also defines a limit for the sum of 24 substances included in a more comprehensive list (product class I baby: 5 mg/kg per substance, all other product classes: 10 mg/kg). This list includes the PAHs shown in Table 31. The PAH limits in the 2017 Leather Standard by Oeko-Tex® are identical to the limits in the Oeko-Tex® 100 Standard.

Table 31 — PAHs with a limit for the sum of all substances in the Oeko-Tex® Standard 100

Compound	CAS Number	Compound	CAS Number
Acenaphtene	83-32-9	Dibenzo[a,h]anthracene	53-70-3
Acenaphthylene	208-96-8	Dibenzo[a,e]pyrene	192-65-4
Anthracene	120-12-7	Dibenzo[a,h]pyrene	189-64-0
Benzo[a]anthracene	56-55-3	Dibenzo[a,i]pyrene	189-55-9
Benzo[a]pyrene	50-32-8	Dibenzo[a,l]pyrene	191-30-0
Benzo[b]fluoranthene	205-99-2	Fluoranthene	206-44-0
Benzo[e]pyrene	192-97-2	Fluorene	86-73-7
Benzo[ghi]perylene	191-24-2	Indeno[1,2,3-cd]pyrene	193-39-5
Benzo[j]fluoranthene	205-82-3	1-Methylpyrene	2381-21-7
Benzo[k]fluoranthene	207-08-9	Naphthalene	91-20-3
Chrysene	218-01-9	Phenanthrene	85-01-8
Cyclopenta[c,d]pyrene	27208-37-3	Pyrene	129-00-0

The European Ecolabel criteria for footwear (Commission Decision (EU) 2016/1349) and furniture (Commission Decision (EU) 2016/1332) set limits for 18 PAHs. In addition to the 8 substances included in the REACH restriction the following PAHs are covered:

- Naphthalene (CAS No 91-20-3)
- Acenaphthylene (CAS No 208-96-8)
- Acenaphthene (CAS No 83-32-9)
- Fluorene (CAS No 86-73-7)
- Phenanthrene (CAS No 85-1-8)
- Anthracene (CAS No 120-12-7)
- Fluoranthene (CAS No 206-44-0)
- Pyrene (CAS No 129-00-0)

- Indeno[1,2,3-c,d]pyrene (CAS No 193-39-5)
- Benzo[g,h,i]perylene (CAS No 191-24-2)

Whilst the REACH restriction (entry 50) covers rubber or plastic components the scope of the two Ecolabel criteria is broader and includes also textiles or leather materials and coatings. The Ecolabel criteria include the following limits:

- for all footwear: the individual concentration limits for PAHs restricted under REACH shall be lower than 1 mg/kg, the sum total concentration limit for the 18 PAHs listed shall be lower than 10 mg/kg;
- for footwear intended for children under three years of age: the individual concentration limits for PAHs restricted under REACH shall be lower than 0,5 mg/kg, the sum total concentration limit for the 18 PAHs listed shall be lower than 1 mg/kg;
- for furniture: the individual concentration limits for PAHs restricted under REACH shall be lower than 1 mg/kg, the sum total concentration limit for the 18 PAHs listed shall be lower than 10 mg/kg.

5.16.6.4 Remarks

In 1977, the US. Environmental Protection Agency (US-EPA) added 16 PAHs to its list of “priority pollutants” of the US. Clean Water Act. The listed substances have been subject to environmental monitoring and market surveillance of products. The former EU Scientific Committee on Food (SCF) identified 15 PAH substances of concern in 2002.

The voluntary German GS-Mark – a product safety mark - specifies individual limits for 11 PAHs: Benzo[a]pyrene; Benzo[e]pyrene; Benzo[a]anthracene; Benzo[b]fluoranthene; Benzo[j]fluoranthene; Benzo[k]fluoranthene; Chrysene; Dibenzo[a,h]anthracene; Benzo[g,h,i]perylene; Indeno[1,2,3-cd]pyrene; Naphthalene. Along with these 11 PAHs, a further 7 PAHs are subject to a sum limit: Acenaphthylene, Acenaphthene, Fluorene, Phenanthrene, Pyrene, Anthracene, Fluoranthene. For a number of these substances, the limits are lower than in corresponding REACH Annex XVII limits.

The German PAH dossier which led to the REACH restriction mentioned above states: “In addition to those addressed in this dossier, clearly many more of the PAHs possibly contained in consumer articles may be genotoxic carcinogens (while others may not) and the reason for them not being listed in Annex VI to the CLP Regulation may simply be that they have up to now not been evaluated for their carcinogenicity by regulatory bodies”.

PAHs are of concern for properties other than being genotoxic carcinogens, so there seems to be scope for considering provisions for PAHs in addition to the ones included in the current REACH restriction which is limited to rubber and plastics materials. However, this needs careful investigation.

Recommendation:

The 8 PAH substances restricted in REACH Annex XVII do not need to be addressed in standards for consumer-relevant articles and their components consisting of plastics and rubber unless lower limits are envisaged.

Provisions going beyond the current REACH restriction in line with existing schemes such as the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex®, the EU Ecolabel criteria for furniture and footwear, or the limits in the German GS-Mark should be considered where the occurrence of PAH substances in consumer-relevant articles is expected.

5.16.7 Pesticide residues

5.16.7.1 REACH restrictions for consumer-relevant articles

REACH Annex XVII does not address pesticide residues in consumer-relevant articles.

5.16.7.2 Other regulatory provisions for articles and related standards

Regulation (EC) No 1107/2009 on the placing of plant protection products on the market lays down rules for the authorization of plant protection products in commercial form and for their placing on the market, use and control within the Community. However, it does not address residues of plant protection products in articles.

5.16.7.3 Voluntary specifications for consumer-relevant articles

The Oeko-Tex® Standard 100 sets a limit for the sum of the listed pesticides shown in Table 32. The limit is 0,5 mg/kg for the product class I Baby and 1 mg/kg for all other product classes and applies to natural fibres. The pesticides limits in the 2017 Leather Standard by Oeko-Tex® are identical to the limits in the Oeko-Tex® 100 Standard and apply only to leather with hairs (e.g. fur).

Table 32 — Pesticides with a limit for the sum of all substances in the Oeko-Tex® Standard 100

Compound	CAS Number	Compound	CAS Number
2,4,5-T	93-76-5	Fenvalerate	51630-58-1
2,4-D	94-75-7	Heptachlor	76-44-8
Acetamiprid	135410-20-7, 160430-64-8	Heptachloroepoxide	1024-57-3
Aldicarb	116-06-3	Hexachlorobenzene	118-74-1
Aldrine	309-00-2	Hexachlorcyclohexane, α-	319-84-6
Azinophosethyl	2642-71-9	Hexachlorcyclohexane, β-	319-85-7
Azinophosmethyl	86-50-0	Hexachlorcyclohexane, δ-	319-86-8
Bromophos-ethyl	4824-78-6	Imidacloprid	105827-78-9, 138261-41-3
Captafol	2425-06-1	Isodrine	465-73-6
Carbaryl	63-25-2	Kelevane	4234-79-1
Chlorbenzilate	510-15-6	Kepone	143-50-0
Chlordane	57-74-9	Lindane	58-89-9
Chlordimeform	6164-98-3	Malathion	121-75-5
Chlorfenvinphos	470-90-6	MCPA	94-74-6
Clothianidin	210880-92-5	MCPB	94-81-5
Coumaphos	56-72-4	Mecoprop	93-65-2

Cyfluthrin	68359-37-5	Metamidophos	10265-92-6
Cyhalothrin	91465-08-6	Methoxychlor	72-43-5
Cypermethrin	52315-07-8	Mirex	2385-85-5
DEF	78-48-8	Monocrotophos	6923-22-4
Deltamethrin	52918-63-5	Nitenpyram	150824-47-8
DDD	53-19-0, 72-54-8	Parathion	56-38-2
DDE	3424-82-6, 72-55-9	Parathion-methyl	298-00-0
DDT	50-29-3, 789-02-6	Perthane	72-56-0
Diazinon	333-41-5	Phosdrin/Mevinphos	7786-34-7
Dichlorprop	120-36-5	Phosphamidone	13171-21-6
Dicrotophos	141-66-2	Propethamphos	31218-83-4
Dieldrine	60-57-1	Profenophos	41198-08-7
Dimethoate	60-51-5	Strobane	8001-50-1
Dinoseb, its salts and acetate	88-85-7 et al.	Quinalphos	13593-03-8
Dinotefuran	165252-70-0	Telodrine	297-78-9
Endosulfan, α -	959-98-8	Thiacloprid	111988-49-9
Endosulfan, β -	33213-65-9	Thiamethoxam	153719-23-4
Endrine	72-20-8	Toxaphene	8001-35-2
Esfenvalerate	66230-04-4	Trifluralin	1582-09-8

The European Ecolabel criteria for textile products (Commission Decision 2014/350/EU) include limits for pesticide residues in cotton and other natural cellulosic seed fibres. In addition, there are limits on ectoparasiticide concentrations on raw wool prior to scouring. These provisions cover many of the substances mentioned above. However, these limits do not apply to the final product.

The European Ecolabel criteria for textile floor coverings (Commission Decision 2009/967/EC, discontinued) exclude different groups of substances for wool treatment by defining a limit for the sum of the substances as follows:

- 0,5 ppm for the sum of γ -hexachlorocyclohexane (lindane), α -hexachlorocyclohexane, β -hexachlorocyclohexane, δ -hexachlorocyclohexane, aldrin, dieldrin, endrin, p,p-DDT, p,p-DDD;
- 2 ppm for the sum of Propetamphos, Diazinon, Dichlofenthion, Fenchlorphos, Chlorpyrifos, Chlorfenvinphos, Ethion, Pirimiphos-Methyl;
- 0,5 ppm for the sum of Cyhalothrin, Cypermethrin, Deltamethrin, Fenvalerate, Flumethrin;
- 2 ppm for the sum of Diflubenzuron, Triflumuron, Dicyclanil.

The European Ecolabel criteria for bed mattresses (Commission Decision 2014/391/EU) and for furniture (Commission Decision (EU) 2016/1332) include limits for residues of individual pesticides

(0,04 ppm each) in latex foams which include at least 20 % natural latex. In case of mattresses the latex foam must contribute to more than 5 % of the total weight of the mattress. The following substances are limited: Aldrin; o,p-DDE; p,p-DDE; o,p-DDD; p,p-DDD; o,p-DDT; p,p-DDT; Diazinone; Dichlorfenthion; Dichlorvos; Dieldrin; Endrin; Heptachlor; Heptachlorepoxyde; Hexachlorobenzene; Hexachlorocyclohexane; α -Hexachlorocyclohexane β -Hexachlorocyclohexane; γ -Hexachlorocyclohexane (Lindane); δ -Hexachlorocyclohexane; Malathion; Methoxichlor; Mirex; Parathion-ethyl; Parathion-methyl.

5.16.7.4 Remarks

The provisions of the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex® and the European Ecolabel criteria seem a suitable basis for establishing requirements for pesticide residues in standards for consumer relevant articles.

Recommendation:

Provisions included in the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex® and the European Ecolabel criteria for textile products and textile floor coverings addressing pesticide residues in natural fibres should be considered when setting requirements for pesticide residues in standards for consumer-relevant articles and their components made of textiles.

For products containing natural rubber the provisions in the European Ecolabel criteria for bed mattresses and furniture may be relevant.

5.16.8 Biocides

A biocide is a substance with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism, and can be classified more specifically according to the type of life it kills, hence fungicides (fungus), herbicides (plants), insecticides (insects), algicides (algae), molluscicides (molluscs), miticides (mites) and rodenticides (rodents). Biocides can also be antimicrobials, including germicides, antibiotics, antibacterials, antivirals, antifungals, antiprotozoals and antiparasites.

5.16.8.1 REACH restrictions for consumer-relevant articles

Organostannic compounds (entry 20) including tri-substituted organostannic compounds such as tributyltin (TBT) compounds and triphenyltin (TPT), dibutyltin (DBT) compounds and dioctyltin (DOT) compounds shall not be used in articles where the concentration in the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin.

Articles or any parts thereof containing dimethylfumarate (DMF, entry 61) in concentrations greater than 0,1 mg/kg shall not be placed on the market.

5.16.8.2 Other regulatory provisions for articles and related standards

The Biocidal Products Regulation (BPR, Regulation (EU) No 528/2012) includes provisions for articles treated with biocides. Only approved substances and authorized biocidal products are allowed to be used in articles in the EU. For imported treated articles the active substance needs to be approved in the EU. Labelling requirements for treated articles apply in case biocidal properties are explicitly claimed or required in the conditions of the approval. The BPR covers articles and materials treated with biocidal products (e.g. furniture treated with wood preservatives), which are imported from third countries. According to the Regulation, articles can only be treated with biocidal products containing active substances approved in the EU (Article 58). However, the BPR excludes certain articles, including those covered by Directive 2009/48/EC on the safety of toys. Hence, in most cases it does not seem necessary to address biocides in normative requirements for articles. On the other hand, long transitional periods up to 2024 apply in the BPR. In addition, it may be possible to avoid biocides even if they are allowed or it may be useful to require a declaration of the biocides used.

The Toy Safety Directive does not stipulate specific requirements for biocides in articles (only for some preservatives in aqueous toy materials). However, the harmonized standard EN 71-9 (reference not published in the Official Journal) includes such requirements. EN 71-9, Table 2 G a) and b) includes action limits for wood preservatives as shown in Table 33.

Table 33 — Wood preservatives with action limits from EN 71-9

Table 2 G a) Outdoor limits		
Compound	CAS Number	Limit
Pentachlorophenol and its salts	various	Action limit
Lindane	58-89-9	Action limit
Table 2 G b) Indoor limits		
Cyfluthrin	68359-37-5	Action limit
Cypermethrin	52315-07-8	Action limit
Deltamethrin	52918-63-5	Action limit
Permethrin	52645-53-1	Action limit

The action limits for pentachlorophenol and lindane are 2 mg/kg, the action limits for the listed pyrethroids (Cyfluthrin, Cypermethrin, Deltamethrin and Permethrin) are 10 mg/kg. Test methods for these monomers in Table 31 are provided in EN 71-10 and EN 71-11.

5.16.8.3 Voluntary specifications for consumer-relevant articles

The Oeko-Tex® Standard 100 requires a certification of biological active products by Oeko-Tex®. For some substances with biocidal properties limits have been set by the organization (e.g. chlorinated phenols, organic tin compounds, DMF). The 2017 Leather Standard by Oeko-Tex® follows the same approach.

The European Ecolabel criteria for textile products (Commission Decision 2014/350/EU) provide that biocides shall not be incorporated into fibres, fabrics or the final product in order to impart biocidal properties. Biocides used to protect textiles during transportation and storage are accepted if the biocides are authorized for use in Europe (BPR and its predecessor legislation – the Biocidal Products Directive). In addition, certain biocides are disallowed for transportation and storage.

Other European Ecolabel criteria (for footwear, bed mattresses) follow similar approaches (only authorized substances and additional restrictions in some cases). The European Ecolabel criteria for wood-, cork- and bamboo-based floor coverings (Commission Decision (EU) 2017/176) disallow the treatment of floor coverings with biocidal products shall not be permitted.

5.16.8.4 Remarks

Biocides are in principle comprehensively covered by the BPR (except for excluded products such as toys). Hence, it does not seem necessary to address biocides in requirements for consumer-relevant articles in standards. However, there are long transitional periods which need to be borne in mind (up to 2024). In addition, the use of biocides could be minimized even if the substances are authorized for a particular purpose. Whilst a substance not authorized in the EU must also not be used in imported articles it remains unclear which thresholds apply to biocides in articles.

Recommendation:

When establishing normative chemical provisions for consumer-relevant articles biocides covered by

Biocidal Products Regulation (BPR) normally do not need to be addressed unless there are specific reasons to do so (e.g. to promote technical solutions for preservation other than by using biocides).

5.17 Other aspects not related to chemical safety assessment

5.17.1 Colour fastness

5.17.1.1 REACH restrictions for consumer-relevant articles

Annex XVII does not address colour fastness.

5.17.1.2 Other regulatory provisions for articles and related standards

No European regulatory provisions for articles and related standards were identified. However, the harmonized standard EN 71-10 (reference not published in the Official Journal) includes a first-action method for colourants in toys. It allows an assessment of whether any colourants can be transferred from textile materials to the mouth, mucous membranes or skin. If textiles are found not to be colourfast when tested in accordance with the test procedure described in Annex A of EN 71-10, they must be tested by the final-action method for colourants.

In the first-action method based on EN ISO 105-E04 “Textiles - Tests for colour fastness - Part E04: Colour fastness to perspiration”, a textile sample is deemed to be colourfast if there is no colour staining or staining equivalent to a change in colour of the multi-fibre adjacent fabric of less than 3 to 4 on the Grey scale as defined in EN 20105-A03 “Tests for colour fastness Part A03: Grey scale for assessing staining”.

EN 1400 “Child use and care articles - Soothers for babies and young children - Safety requirements and test methods” includes requirement for colour fastness based on the German standard DIN 53160-1 “Colourfastness to Saliva; Determination of the colourfastness of articles in common use Part 1: Resistance to artificial saliva”.

5.17.1.3 Voluntary specifications for consumer-relevant articles

The Oeko-Tex® Standard 100 establishes several requirements for colour fastness as shown in Table 34.

Table 34 — Limits for colour fastness in the Oeko-Tex® Standard 100

Colour fastness	I Baby	II in direct contact with skin	III with no direct contact with skin	IV Decoration material
To water	3	3	3	3
To acidic perspiration	3 - 4	3 - 4	3 - 4	3 - 4
To alkaline perspiration	3 - 4	3 - 4	3 - 4	3 - 4
To rubbing, dry ^(x)	4	4	4	4
To saliva and perspiration	Fast			

^(x) No requirements for 'wash-out' – articles, for pigment, vat or sulphurous colorants a

Colour fastness	I Baby	II in direct contact with skin	III with no direct contact with skin	IV Decoration material
minimum grade of colour fastness to rubbing of 3 (dry) is acceptable.				

Testing of the first 4 items is performed in accordance with the ISO 105 standard series (ISO 105-E01 “Textiles - Tests for colour fastness - Part E01: Colour fastness to water”, ISO 105-E04 “Textiles - Tests for colour fastness - Part E04: Colour fastness to perspiration”, ISO 105-X12 “Textiles - Tests for colour fastness - Part X12: Colour fastness to rubbing”). The test for fastness to saliva and perspiration follows provisions of the official collection of analysis methods according to § 64 of the German Food and Feed Code (LFGB) which are identical to the German standards DIN 53160-1 “Colourfastness to Saliva; Determination of the colourfastness of articles in common use Part 1: Resistance to artificial saliva” and DIN 53160-2 “Determination of the colourfastness of articles for common use - Part 2: Test with artificial sweat”.

The 2017 Leather Standard by Oeko-Tex® contains different colour fastness requirements as shown in Table 35.

Table 35 — Limits for colour fastness in the Leather Standard by Oeko-Tex®

Colour fastness	I Baby	II in direct contact with skin	III with no direct contact with skin	IV Decoration material
To water ^(X)	3	3	3	3
To acidic perspiration ^(X)	3	3	3	3
To alkaline perspiration ^(X)	3	3	3	3
To rubbing, dry ^(X)	3	3	3	3
To saliva and perspiration	Fast			
^(X) The colour fastness is tested at the application side of the leather material. If the application side, however, is not known or if both leather sides (finished leather side and flesh side) are relevant for the usage of the article, then both leather sides have to be tested for colour fastness and the results have to be documented in the test report.				

The European Ecolabel criteria for textile products (Commission Decision 2014/350/EU), or furniture (Commission Decision (EU) 2016/1332) and for footwear (Commission Decision (EU) 2016/1349) include also requirements addressing colour fastness to washing, to perspiration (acid, alkaline), to wet rubbing, to dry rubbing and to light. The tests are also based on the ISO 105 standard series.

5.17.1.4 Remarks

Colour fastness tests are a cheap and easy way to ensure that only limited amounts of colourants migrate from materials. One can either use such tests for screening purposes followed by analytical determination of colourants in case a grayscale threshold is not achieved or they can be used as stand-

alone tests. The latter approach ensures that release of colourants and, thereby, exposure to (unknown) colourants is limited in general.

The provisions in the Oeko-Tex® Standard 100 or the European Ecolabel criteria for textile products based on the ISO 105 standard series are applicable to textile products whilst the provisions relating to saliva and perspiration based on the DIN standards mentioned above apply to any coloured material unless the release of colour is intended. The test procedures related to the Leather Standard by Oeko-Tex® were not available at the time this Guide was finalised.

Recommendation:

Provisions included in the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex®, and European Ecolabel criteria for textile products addressing colour fastness should be considered for inclusion in standards for consumer-relevant articles and their components made of textiles, particularly for those in direct contact with skin.

Provisions relating to fastness to saliva and perspiration based on the DIN standards should be considered for articles for small children, particularly those which can be placed in the mouth or those in direct contact with skin.

The “Guideline on the interpretation of the concept ‘which can be placed in the mouth’ as laid down in entry 52 of Annex XVII to REACH Regulation 1907/2006” should be considered where relevant.

The colour fastness test could be foreseen as such or for screening purposes followed by analysis of released colourants which are found not acceptable in the standard.

5.17.2 Sensory evaluation (smell/odour)

5.17.2.1 REACH restrictions for consumer-relevant articles

Annex XVII does not address sensory evaluation.

5.17.2.2 Other regulatory provisions for articles and related standards

No European regulatory provisions for articles and related standards were identified.

5.17.2.3 Voluntary specifications for consumer-relevant articles

In 2012, the “European Collaborative Action - Urban Air, Indoor Environment and Human Exposure”(ECA), coordinated by the EC Joint Research Centre in Ispra (Italy), published ECA Report 27 “Harmonisation framework for indoor products labelling schemes in the EU”. Sensory evaluation is considered to be an important aspect of the assessment of product emissions. However, precise recommendations have not yet been agreed. Some national Ecolabel schemes also include sensory evaluation (Finland, Denmark).

The German AgBB scheme (“Ausschuss für die gesundheitliche Bewertung von Bauprodukten”) supports a compulsory approval scheme for certain construction products emitting substances to the indoor air and launched a pilot phase for sensory testing in 2012. It was based on testing in accordance with ISO 16000-28 “Indoor air - Part 28: Determination of odour emissions from building products using test chambers” where the acceptability of the emissions is assessed using test panels.

The Oeko-Tex® Standard 100 includes provisions for odours. For textile carpets, mattresses and foams, and large coated articles not being used for clothing, an assessment is made using a modified Swiss standard (SNV 195 651) based on panel testing. It also excludes “abnormal odour”, i.e. odour from mould, high boiling fraction of petrol, fish, aromatic hydrocarbons or perfume. Details on the assessment are not given. The Leather Standard by Oeko-Tex® follows the same approach.

5.17.2.4 Remarks

Exposure to odours may result in health effects ranging from mild discomfort to more serious symptoms such as nausea and thus, significantly affect the well-being of humans. Emissions to the indoor air including odours are of increasing concern not least because of enhanced insulation of buildings resulting in reduced air exchange rates and, thus, higher contamination of the indoor air. Of particular interest are articles with larger surface areas (such as floor coverings or carpets). Whilst the importance of sensory evaluation in specifications for certain consumer-relevant articles has been acknowledged a widely accepted scheme for assessment of articles is not yet available and, thus, cannot be recommended. Hence, any normative provisions will have to be based on the choice of the technical committee in charge. ISO 16000-28 allows two alternative assessment methods, the acceptability of the odour emission and the perceived intensity of the odour emission. The standard could be a starting point for developing a scheme.

Recommendation:

In the absence of an agreed framework at European level for testing and assessing odours standardisers establishing normative requirements for consumer-relevant articles and their components wishing to address sensory evaluation would have to create an acceptance scheme themselves. This could require the selection of a test method and specified acceptance criteria based on existing specifications (e.g. Oeko-Tex® Standard 100, Leather Standard by Oeko-Tex®, national Ecolabels) including related test methods. ISO 16000-28 could be a starting point for developing such a scheme.

6 Information provision requirements for chemicals in articles

6.1 REACH information provisions for consumer-relevant articles

REACH Article 33 (1) provides that the supplier of an article containing a concentration above 0,1 % weight by weight of an SVHC included in the candidate list is obliged to “provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance”. According to Article 33(2), the information requirement shall extend to consumers upon request. In this case the information must be provided free of charge within 45 days of receipt of the request.

NOTE Following a ruling by the European Court of Justice in September 2015, the 0,1 % limit applies also to articles in complex products.

6.2 Other regulatory information provisions for consumer-relevant articles

According to the Biocidal Products Regulation (BPR) the supplier of a treated article shall, where a consumer so requests, provide that consumer, within 45 days, free of charge, with information on the biocidal treatment of the treated article (Article 58 (5)). In addition, treated articles must be labelled if:

- a claim that the treated article has biocidal properties is made;
- it is required in the conditions of the approval of the active substance contained in the biocidal product used to treat the article.

The labels need to be easily understandable and visible for consumers.

In June 2016 the European Council and the Parliament reached agreement on the new Medical Devices Regulation (substituting the Medical Devices Directive and the Directive on Active Implantable Medical Devices). It requires that devices, parts thereof or materials used therein that are invasive and come into direct contact with the human body, or that (re)administer medicines, body liquids or other substances, including gases, to/from the body, or that transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body be labelled if they contain substances

which are carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B. This is in accordance with Annex VI Part 3 of the CLP Regulation. They must also be labelled if they contain substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health (either included in the REACH “candidate list” or in accordance with the scientific criteria adopted by the Commission relating to the Biocidal Products Regulation) in a concentration above 0,1 % (w/w).

They shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. Information on residual risks for certain patient groups and on appropriate precautionary measures, if applicable, shall be given in the instructions for use. These information requirements apply if the intended use of such devices includes treatment of children, pregnant or nursing women, or other patient groups considered particularly vulnerable to such substances and/or materials.

6.3 Information provisions in voluntary specifications for consumer-relevant articles

Some industry sectors have established standardized information systems covering chemicals in the supply chain (but not including consumer information). As an example, EN 62474:2012 “Material declaration for products of and for the electrotechnical industry” specifies the procedure, content, and form relating to material declarations for products of companies operating in and supplying the electrotechnical industry. In addition, there is a database (IEC 62474 DB) which specifies the substances, substance groups and material classes that need to be included in material declarations and specifications on the data format for the exchange of material declaration data accessible here:

<http://std.iec.ch/iec62474>

6.4 Remarks

Information requirements according to REACH Article 33(2) have been judged insufficient and impractical by various parties. This is due to a variety of reasons: the information is limited only to substances included in the candidate list and does not need to cover other substances of concern; the information is not required to be readily available (e.g. via the internet); and the supplier is not obliged to respond if the product contains none of the SVHCs in concentrations greater than 0,1 % of the article weight. If the supplier does not respond it remains unclear whether the product does not contain any SVHCs or whether the request was not processed.

A more user friendly approach to REACH Article 33(2) or the Biocidal Products Regulation’s Article 58 (5) would be useful. In addition, one could envisage a more comprehensive approach addressing more substances of concern (e.g. CMR or other CLP-classified substances) and information provisions on concentrations of chemicals included in or released from articles. When establishing quantitative content or release declaration provisions derogations may be granted due to confidentiality of business information where duly justified. The template provided in Annex B to this Guide may be helpful in this regards.

Recommendation:

The provision of information on chemicals contained in or released from articles including articles in complex products or their components should be considered.

A departure point for such information provision could be to include a normative requirement to make available the information required in REACH Article 33(2) or the BPR Article 58 (5) in a systematic and user friendly way on a website. So, providing names of substances included in the candidate list in concentrations greater than 0,1 % in products including articles in complex products or components of articles, complemented by instructions to allow safe use of any article and on the biocidal treatment of any treated article.

Further, it should be considered to extend the information provision to include e.g. further substances (e.g. CMR), lower concentration thresholds than foreseen in REACH (i.e. 0,1 %), information on

concentrations of substances included in articles, release of substances from articles etc. Derogations from declaration requirements due to confidentiality of business data may be granted where duly justified. The template provided in Annex B to this Guide could be useful in this regards.

Annex A (informative)

List of recommendations

A.1 General

The background information to this Guide provides documentation and a more comprehensive description of some of the issues covered in this Guide, including links to important reference documents on the internet and may provide useful additional information. Readers of the Guide are recommended to review and make use of the information included in this complementary document.

A.2 REACH Regulation

The relevant REACH provisions including ongoing developments and how they apply to the concerned product category should be taken into account. This particularly applies to restrictions contained or envisaged to be included in the list of restricted substances (Annex XVII).

When establishing normative chemical provisions for consumer-relevant articles substances covered by Annex XVII relating to the articles and/or materials in question normally do not need to be addressed (since the legal requirements apply anyway) unless there are exceptionally specific reasons to do so, e.g. if only a specific risk or material is addressed in the REACH restriction or lower limits seem preferable in line with sector-specific considerations and established practices and based on a sound scientific assessment in accordance with the state-of-the art of chemical safety assessment. In any case a proper justification should be given where such requirements are established.

A.3 CLP Regulation

Standards writers should include experts that are familiar at least with the basic principles of the CLP Regulation, hazard classification and related standardized hazard statements and pictograms. Of particular importance is Part 3 of Annex VI which includes a list of substances subject to a harmonized classification and labelling of hazardous substances (Table 3.1) and information on classification of substances by industry (self-classification). This and other substance related information is accessible via the ECHA website. Ongoing developments concerning new or amended classifications should be monitored.

A.4 Other relevant chemicals legislation

The substances covered by Annex I of the Regulation on Persistent Organic Pollutants (POP) apply to articles and normally do not need to be addressed (since the legal requirements apply anyway) unless there are exceptionally specific reasons to do so, e.g. if lower limits seem preferable in line with sector-specific considerations and established practices and based on a sound scientific assessment in accordance with the state-of-the art of chemical safety assessment. In any case a proper justification should be given where such requirements are established.

A.5 Relevant EU regulation for articles and associated standards

Standards writers should include experts that are familiar with the chemicals-related regulatory provisions and developments applicable to the articles in question. It is also useful to look at areas where similar materials and/or chemicals are used or exposure situations are comparable. As an example, chemical requirements for toys may be a useful reference in determining requirements applicable to other articles, particularly to articles for children.

A.6 Chemicals relevant EU policy developments, discussions, related scientific opinions and tools

Standards writers should include experts that are familiar with ongoing developments and discussions in the European Union related to implementation, review and revision of current legislative frameworks addressing chemicals in articles to be standardized, as well as relevant strategic policy approaches, risk assessments of specific chemicals in articles or further development of risk assessment methodologies.

A.7 Relevant national product regulation and policy developments

Standards writers should include experts that are familiar with the most relevant legislative instruments, normative provisions and policy developments, initiatives and discussions in pioneering Member States (e.g. Member States with benchmark legislation) related to chemicals in articles to be standardized.

A.8 Voluntary specifications (ecolabel criteria, industry initiatives and standards)

Chemical provisions in existing voluntary initiatives including EU and national ecolabels, product standards and industry or NGO led initiatives establishing criteria for chemicals in articles should be reviewed. It should be kept in mind that the level of ambition varies in different approaches and, therefore, the aspiration level in European standards may be different from other specifications. Similarly, the validity and scientific foundation may vary among initiatives and should be considered. Finally, it should be borne in mind that ecolabel criteria make more extensive use of hazard-based provisions compared to obligatory regulatory approaches.

A.9 Basics of Chemical Safety Assessment (CSA)

Standards writers should include experts that are familiar with the basic principles of chemical risk assessment or chemical safety assessment. Even though, in most cases, standardisers will not conduct a full assessment and will rely on available risk assessments carried out by competent bodies and/or existing limits for other (similar) products or materials and will adapt them to the specific needs of the articles in question.

A.10 Chemical requirements for consumer-relevant articles - General aspects

The substance specific recommendations of this Guide should be considered as a starting point for further in-depth assessment and discussion to adapt the provisions to the specific product needs. Related test methods should be identified or developed to ensure accurate, reproducible and repeatable results. Validated test methods should be given preference. Alternative approaches to testing such as the presentation of safety data sheets and/or a manufacturer's compliance declaration should be also

considered, where appropriate.

A.11 REACH Substances of Very High Concern (SVHC)

A requirement should be considered to ensure that substances included in Annex XIV of REACH generally do not exceed 0,1 % in the article in question or its components by the sunset date given for that substance. An exception should be considered for the holder of an authorization where the authorization is granted for the use of an SVHC in the production of the articles concerned. In addition, checks should be made on the basis of available risk assessments whether lower thresholds are warranted for specific SVHCs. Lower limits defined for specific SVHCs take precedence over the generic threshold.

A.12 Carcinogenic, mutagenic and toxic to reproduction (CMR) substances - generic provisions

A requirement should be considered to ensure that substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under the CLP Regulation (EC) No 1272/2008 are not used in any part of consumer-relevant articles which, due to their accessibility, function, volume or mass, can reasonably lead to an exposure due to sucking, licking, swallowing, prolonged contact with skin or inhalation exceeding the following limits:

- for carcinogenic and mutagenic substances 0,1 % (cat. 1A), 0,1 % (cat. 1B) and 1 % (cat. 2),
- for substances toxic to reproduction 0,3 % (cat. 1A), 0,3 % (cat. 1B) and 3 % (cat. 2).

In addition, a requirement should be considered that these generic concentration limits are superseded by the specific limits included in Annex VI, Table 3.1 of Part 3 of the CLP Regulation, where such limits are available.

Where more specific limits for CMR substances are stipulated in the standard to be prepared such limits should prevail over the generic ones.

In addition, standardisers should seek to identify as a matter of priority specific CMR substances which have been associated with the relevant product category. CMRs without a threshold (i.e. typically cat. 1A and 1B) should not be intentionally used in consumer-relevant articles and their absence should be verified using a sensitive analytical method with a low limit of detection. Limits for other CMR substances should be set using a risk assessment approach. Derogations may be set where any risk for the consumer can be excluded.

The standard could also contain a general recommendation to reduce the levels of CMR substances as far as technically feasible following the ALARA (As Low As Reasonably Achievable) principle.

A.13 Generic provisions for other hazard classes according to the CLP Regulation

Other hazard-based exclusions such as for substances satisfying the criteria for “acute toxicity”, “specific target organ toxicity”, “respiratory and skin sensitisation”, “hazardous to the aquatic environment” and “hazardous to the ozone layer” could be considered as is already the case for European Ecolabel criteria. The exclusion could be limited to certain kinds of articles or families of chemicals (such as dyes) or to accessible parts of articles. The maximum concentrations could be linked to the CLP thresholds for the classification of mixtures (as in case of CMR substances). Alternatively, a risk-based approach for such substances could be used.

A.14 Generic provisions for other hazard properties not covered by the CLP Regulation - Endocrine disrupting chemicals (EDCs)

In the absence of a classification system for Endocrine Disrupting Chemicals (EDCs) such as the one for CMR substances hazard-based exclusions for EDCs are not useful for the time being. It is recommended to screen for the occurrence of substances with EDC properties meeting the WHO definition identified in scientific literature (peer-reviewed journals, recognized scientific bodies, opinions of scientific committees etc.) which are associated with the product category in question and to stipulate, where appropriate, substance specific limits where relevant exposure can be expected.

A.15 Generic provisions for other hazard properties not covered by the CLP Regulation - Persistent, bio-accumulative and toxic (PBT) and very persistent and very bio-accumulative (vPvB) substances

When setting requirements for chemicals in consumer-relevant articles and their components a requirement could be considered to ensure that the article does not contain any persistent, bioaccumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) substances based on the criteria listed in Annex XIII of REACH in amounts exceeding 0,1 % by weight if relevant amounts can be released during the lifecycle of the article. The restriction could be generic or (preferably) include substances identified from existing lists of substances of concern.

A.16 Nanomaterials

The occurrence of nanomaterials associated with the particular article in question should be investigated. Relevant nanomaterials should be assessed case-by-case taking into account risk assessments made by bodies such as EU Scientific Committees. Where toxic effects and/or exposure of nano-forms differ from their bulk counterparts this should be taken into account when establishing limits for such substances.

A.17 Certain elements (metals)

When establishing requirements for elements/metals in consumer-relevant articles and their components, the respective provisions of the Toy Safety Directive, the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex® or the European Ecolabel criteria for textile or leather-related articles should be considered. The sets of rules differ in terms of articles and materials as well as elements/metals covered and their approach towards exposure. The choice of requirement will vary depending on the article covered. Limit values in other voluntary specifications (e.g. ecolabel criteria) could be considered, too.

It should be noted that the limits for elements included in the Toy Safety Directive have already been recommended by CEN to be applied to child use and care articles (CEN/TR 13387-2). Hence, these requirements may be the first option for articles relevant for children other than toys or child use and care articles, whilst standards for other consumer-relevant articles could make use of the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex® or European Ecolabel requirements within their scope of application or limits in other voluntary specifications.

Elements in consumer-relevant articles which are comprehensively covered by REACH Annex XVII normally do not need to be addressed. For example, limits for the listed organostannic compounds (entry 20) and lead (entry 63) covered by REACH restrictions do not need to be included in standards for consumer-relevant articles. However, current REACH limits for organostannic compounds could be complemented by limits for not listed compounds. REACH limits for cadmium could be complemented

by (migration) limits for materials other than the covered plastics materials, REACH limits for nickel and chromium VI could be complemented by (migration) limits addressing hazards other than sensitization.

A.18 Flame retardants

When establishing requirements for flame retardants in combustible consumer-relevant articles and their components the list of non-accepted flame retardants in the Oeko-Tex® Standard 100 and the Leather Standard by Oeko-Tex® should be considered. Substances already banned in REACH Annex XVII or in Annex I of the Persistent Organic Pollutants Directive do not need to be included.

It should be considered, where alternatives are available, to exclude flame retardants which are only physically mixed into the matrix/material and to accept only reactive flame retardants (or materials which are inherently non-combustible or show a reduced flame propagation when ignited) or to ensure fire safety through appropriate design.

Other available information sources such as voluntary specifications (e.g. ecolabel criteria) could be considered.

It may also be useful to consider the establishment of a positive list of flame retardants taking into account the functionality of the substances.

A.19 Colourants

When establishing requirements for colourants in standards for consumer-relevant articles and their components provisions for CMR, sensitizing or other colourants of concern covered by EN 71-9, the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex® or the relevant European Ecolabel criteria should be considered for the materials indicated in these specifications for articles which, due to their accessibility, function, volume or mass, can reasonably lead to an exposure due to sucking, licking, swallowing, or prolonged contact with skin. However, consideration should be given to the inclusion of additional compounds identified in scientific literature.

Azo dyes which, by reductive cleavage of one or more azo groups, may release one or more of the listed 22 aromatic amines covered by the REACH restriction do not need to be addressed. However, additional substances could be covered.

Colour fastness tests are a useful complement to specific substance limits and their inclusion in standards for consumer-relevant articles and their components should be considered. Various tests are available addressing colour fastness to washing, to saliva, to perspiration, to dry and wet rubbing. Such tests could be either used as a first-action method for colourants as in case of toys (EN 71-10 and EN 71-11), or could be used as stand-alone tests. This is further discussed in the clause on colour fastness below.

Other available information sources should be considered for materials not covered by the above lists.

A.20 Primary aromatic amines

When establishing requirements for chemicals in consumer-relevant articles and their components provisions for carcinogenic aromatic amines should be considered. This includes the 22 substances listed in Appendix 8 of Annex XVII of REACH and other aromatic amines of concern such as aniline, 2,4-xylidine and 2,6-xylidine. Such provisions should be considered for the materials indicated for articles which, due to their accessibility, function, volume or mass, can reasonably lead to an exposure due to sucking, licking, swallowing, or prolonged contact with skin.

A.21 Monomers

Provisions for monomers included in EN 71-9 should be considered as a starting point for articles and their components made of polymers which, due to their accessibility, function, volume or mass, can reasonably lead to an exposure due to sucking, licking, swallowing, or prolonged contact with skin.

The “Guideline on the interpretation of the concept ‘which can be placed in the mouth’ as laid down in entry 52 of REACH Annex XVII should be taken into consideration.

Annex 1 of the Regulation on plastic materials and articles intended to come into contact with food could be used to identify further monomers (and additives and other starting substances). However, the migration limits (SML or SML(T)) would have to be adapted.

A.22 Plasticizers

Plasticisers including phthalates identified as SVHC which are eventually included in REACH Annex XIV and which are not authorized for use in consumer-relevant articles are covered by the provisions of subclause 5.2 of the present Guide and normative requirements do not need to be included in standards for consumer-relevant articles.

Other plasticisers such as those listed in the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex® or in EN 71-9 should be considered for incorporation of related requirements in standards for consumer-relevant articles made of polymeric materials unless restricted in the particular article in REACH Annex XVII, particularly those which can be placed in the mouth by small children.

Additional plasticizers including the non-phthalate substances could be included when supported by a risk assessment.

The “Guideline on the interpretation of the concept ‘which can be placed in the mouth’ as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006” should be considered where relevant.

A.23 Solvents (content or migration)

When establishing requirements relating to the migration or content of solvent residues in consumer-relevant articles or their components the requirements concerning solvents (migration) included in EN 71-9 should be considered as regards consumer-relevant articles made of polymeric materials which can be placed in the mouth, particularly those with intended mouth contact or likely mouth contact for prolonged periods and taking into account the “Guideline on the interpretation of the concept ‘which can be placed in the mouth’ as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006”.

In addition, the content limits for solvent residues in the Oeko-Tex® Standard 100 and in the Leather Standard by Oeko-Tex® should be considered for the materials specified.

A.24 Volatile organic compounds (VOC)

When establishing requirements for volatile organic chemicals in consumer-relevant articles or their components with large areas or other articles resulting in high exposure, Reports 27 and 29 of the “European Collaborative Action - Urban Air, Indoor Environment and Human Exposure” should be taken into consideration including provisions for TVOC, volatile carcinogenic substances and individual compounds based on LCI-values.

Where available, EU-LCI values developed by the “EU-LCI Working Group” should be used. In absence of such values the German AgBB scheme should be considered.

It should be noted that the LCI concept evaluates the emissions of substances from single products. Where emissions of a substance from several sources can be expected a correction factor should be used and the LCI limits should be reduced accordingly.

VOC measurements should be based on a chamber test as described in EN 16516. Product-specific parameters (such as load factors) need to be set when developing normative requirements for consumer-relevant articles.

Inclusion of additional volatile substances of concern should be considered, for example by reviewing the lists of substances in the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex®, ecolabel schemes or in EN 71-9.

Limits for formaldehyde emissions from wood-based panels (or resin-bonded products of similar shape) should be measured in accordance with EN 717-1 or EN 16516 taking into consideration that different test conditions (in particular, the air exchange rates) are different and thus, different test results are obtained. Other resin-bonded wood products should be tested either using adapted versions of EN-717-1 or EN 16516.

A.25 Allergenic fragrances

When establishing requirements for fragrances in scented consumer-relevant articles or their components, the respective provisions of the Cosmetics Regulation and the Toy Safety Directive including information provisions should be taken into consideration as well as the 2011 Opinion of the Scientific Committee on Consumer Safety (SCCS) on fragrance allergens in cosmetic products. For some products more extensive restrictions could be considered in line with some European Ecolabel provisions taking due account of the consumer right to choose fragranced or fragrance-free articles.

A.26 Formaldehyde (not covered by requirements above)

Standards writers should consider the requirements concerning formaldehyde included in EN 71-9 as regards articles made of textiles or paper which can reasonably lead to an exposure due to prolonged contact with skin taking into account exposure from multiple sources. Limits in the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex® and in European Ecolabel criteria for formaldehyde in textile or leather articles should be also considered.

A.27 N-Nitrosamines and N-Nitrosatable substances

The requirements for N-nitrosamines included in the European Ecolabel criteria for footwear for rubber products should be considered.

The requirements concerning N-Nitrosamines and N-Nitrosatable substances included in the Toy Safety Directive and EN 71-12 should be considered as regards consumer-relevant articles made of elastomers which can be placed in the mouth, particularly those with intended mouth contact or likely mouth contact for prolonged periods and taking into account the “Guideline on the interpretation of the concept ‘which can be placed in the mouth’ as laid down in entry 52 of REACH Annex XVII.

A.28 Per- and polyfluorinated Compounds (PFCs)

Perfluorooctane sulfonic acid and its derivatives (PFOS) are banned in the Persistent Organic Pollutants Regulation and do not need to be covered in standards for consumer-relevant articles.

Long-chain perfluorinated alkyl substances included in the Candidate list may in future be included in

REACH Annex XIV. In view of the recommendation in 5.2 of this Guide to disallow SVHCs in standards for consumer-relevant articles or their components after the sunset date given for that substance unless an authorization is granted to the holder of an authorization for the use of an SVHC in the production of the article concerned, an inclusion of specific requirements for the PFASs included in Annex XIV of REACH in standards for consumer-relevant articles does not seem warranted.

In addition, perfluorooctanoic acid (PFOA), its salts and PFOA-related substances are likely to be covered by a REACH Annex XVII restriction and therefore do not need to be covered.

Shorter-chain fluorinated substances have also been identified as a matter of concern, and partially fluorinated compounds, such as those identified in the Oeko-Tex® Standard 100 and the Leather Standard by Oeko-Tex®, may require attention. This subject needs further research and discussion.

A.29 Alkylphenols and Alkylphenoethoxylates (APEOs)

Alkylphenols and alkylphenoethoxylates identified as SVHC included in REACH Annex XIV and which are not authorized for use in consumer-relevant articles are covered by the provisions of subclause 5.2 of the present Guide. These could be complemented by a limit for the sum of OP and NP in line with the provisions in Oeko-Tex® Standard 100 and the Leather Standard by Oeko-Tex® when setting requirements for chemicals in consumer-relevant articles and their components.

Nonylphenol ethoxylates covered by REACH Annex XVII do not need to be addressed in standards for consumer-relevant articles.

A.30 Chlorinated benzenes and toluenes

The provisions for chlorinated benzenes and toluenes in the Oeko-Tex® Standard 100 and the Leather Standard by Oeko-Tex® should be considered when establishing normative provisions for consumer-relevant articles and their components.

A.31 Polycyclic aromatic hydrocarbons (PAHs)

The 8 PAH substances restricted in REACH Annex XVII do not need to be addressed in standards for consumer-relevant articles and their components consisting of plastics and rubber unless lower limits are envisaged.

Provisions going beyond the current REACH restriction in line with existing schemes such as the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex®, the EU Ecolabel criteria for furniture and footwear or the limits in the German GS-Mark should be considered where the occurrence of PAH substances in consumer-relevant articles is expected.

A.32 Pesticide residues

Provisions included in the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex® and the European Ecolabel criteria for textile products and textile floor coverings addressing pesticide residues in natural fibres should be considered when setting requirements for pesticide residues in standards for consumer-relevant articles and their components made of textiles.

For products containing natural rubber the provisions in the European Ecolabel criteria for bed mattresses and furniture may be relevant.

A.33 Biocides

When establishing normative chemical provisions for consumer-relevant articles biocides covered by Biocidal Products Regulation (BPR) normally do not need to be addressed unless there are specific reasons to do so (e.g. to promote technical solutions for preservation other than by using biocides).

A.34 Colour fastness

Provisions included in the Oeko-Tex® Standard 100, the Leather Standard by Oeko-Tex®, and European Ecolabel criteria for textile products addressing colour fastness should be considered for inclusion in standards for consumer-relevant articles and their components made of textiles, particularly for those in direct contact with skin.

Provisions relating to fastness to saliva and perspiration based on the DIN standards should be considered for articles for small children, particularly those which can be placed in the mouth or those in direct contact with skin.

The “Guideline on the interpretation of the concept ‘which can be placed in the mouth’ as laid down in entry 52 of Annex XVII to REACH Regulation 1907/2006” should be considered where relevant.

The colour fastness test could be foreseen as such or for screening purposes followed by analysis of released colourants which are found not acceptable in the standard.

A.35 Sensory evaluation (smell/odour)

In the absence of an agreed framework at European level for testing and assessing odours standardisers establishing normative requirements for consumer-relevant articles and their components wishing to address sensory evaluation would have to create an acceptance scheme themselves. This could require the selection of a test method and specified acceptance criteria based on existing specifications (e.g. Oeko-Tex® Standard 100, Leather Standard by Oeko-Tex®, national Ecolabels) including related test methods. ISO 16000-28 could be a starting point for developing a scheme.

A.36 Information provision and labelling requirements for chemicals in articles

The provision of information on chemicals contained in or released from articles including articles in complex products or their components should be considered.

A departure point for such information provision could be to include a normative requirement to make available the information required in Article 33(2) of REACH or Article 58 (5) of the BPR in a systematic and user friendly way on a website, i.e. names of substances included in the candidate list in concentrations greater than 0,1 % in articles including articles in complex products or components of articles complemented by instructions to allow safe use of any article and on the biocidal treatment of any treated article.

Further, it should be considered to extend the information provision to include e.g. further substances (e.g. CMR), lower concentration thresholds than foreseen in REACH (i.e. 0,1 %), information on concentrations of substances included articles, release of substances from articles etc. Derogations from declaration requirements due to confidentiality of business data may be granted where duly justified. The template provided in Annex B to this Guide could be useful in this regards.

Annex B
(informative)

Template for information provision

Information on the supplier of an article	
Producer / importer /distributor	
Contact (website, email, phone number, address)	
Information on the article	
Article name	
Article number of producer / importer /distributor	
Information on part(s) of an article (if applicable)	
Part(s) of article which contain(s) substance(s)	
Substance(s) information	
Substance name(s)	
CAS Number(s)	
Inclusion in REACH Candidate list (date)	
SVHC property in accordance with REACH	
Classification(s) in accordance with CLP	
Concentration(s) of substance(s) in article or part(s) of article	
Release(s) of substance(s) from article or part(s) of article including related test method	
Amount of substance(s) in article	
Function of the substance(s)	
Instructions (if applicable)	
Instructions for use	
Instructions for disposal	



Bibliography

- [1] CEN/TR 13387-2:2015, *Child use and care articles - General safety guidelines - Part 2: Chemical hazards*
- [2] CEN ISO/TR 16178:2012, *Footwear - Critical substances potentially present in footwear and footwear components (ISO/TR 16178:2012)*
- [3] CEN/TR 16417:2016, *Footwear - Footwear industry guideline for substances of very high concern (Annex XIV of REACH)*
- [4] CEN/TR 16741:2015, *Textiles and textile products - Guidance on health and environmental issues related to chemical content of textile products intended for clothing, interior textiles and upholstery*
- [5] EN ISO 20137:2017, *Leather - Chemical tests - Guidelines for testing critical chemicals in leather*