Background information to CEN GUIDE 16

Guide for addressing chemicals in standards for consumer-relevant products

Edition 1, 2017-07-19

Contents

Page

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 a 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 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 by 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 background information to the Guide provides information including regulatory provisions for chemical substances, for specific articles, related standards, as well as internet links where most up-to-date information can be found. Information is also provided for other 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.

The separate Guide includes a framework and recommendations for normative provisions relating to chemicals which should be taken into consideration when developing standards for consumer-relevant articles.

1 EU legal provisions and associated standards

1.1 REACH

REACH is the European Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (Regulation (EC) No 1907/2006), which was adopted in December 2006. It entered into force from 1st June 2007. This Regulation is a centrepiece of chemicals legislation in Europe.

The most recent consolidated version and subsequent amendments of the Regulation are available on the ECHA website: http://echa.europa.eu/regulations/reach/legislation

1.1.1 Key elements REACH relevant for chemicals in articles

In the following sub-sections, some key elements of the Regulation are described with a particular view to provisions relating to articles.

1.1.1.1 Registration

All substances manufactured or imported in quantities greater than 1 tonne per year and manufacturer shall be registered at the European Chemicals Agency (ECHA). However, several categories of substances are exempted from the registration, such as substances used in medical products and foodstuffs, polymers, radioactive substances and many naturally occurring substances.

Before December 2008, companies had to pre-register all substances in order to be able to use the transition registration deadlines of December 2010, June 2013 or June 2018 for so-called phase-in substances (produced or marketed before entry into force of REACH). The due date for final registration depends on the tonnage band (total annual production or import) of a substance or the properties of the chemicals. The most dangerous substances (CMR substances and those toxic to aquatic environment) and the substances produced or imported in the highest amounts (above 1 000 tonnes annually) had to be registered by December 2010.

With the registration, the companies shall deliver information about the physicochemical, toxicological and ecotoxicological properties of the chemicals. The information required increases with the annual production/importation volume. For substances produced or imported in the tonnage band from 1 tonne to 10 tonnes annually, mostly physicochemical properties, few toxicological properties and the biodegradability properties shall be delivered as a part of the registration. For any substances registered in the tonnage band above 10 tonnes annually, a chemical safety report is required as part of the registration dossier. The data requirements depend on the tonnage band. The goal of the chemical safety report is to assess and characterize risks arising from the varied uses of each substance, and to demonstrate that the use of risk management measures can adequately control the potential risks to human health and the environment.

Registration means only that a manufacturer or importer has provided a registration dossier to the Agency based on a self-assessment and not received any indication that it is incomplete. It does not necessarily mean that the substance or preparation is safe.

Publicly available substance information from registration dossiers is available on the ECHA website: http://echa.europa.eu/information-on-chemicals/registered-substances

1.1.1.2 Evaluation

Dossier evaluation is undertaken by ECHA for testing proposals made by industry or to check compliance with the (formal) registration requirements. At least 5 % of the dossiers for each tonnage band shall be selected for compliance checking.

ECHA also coordinates substance evaluation by the MS authorities to investigate chemicals with perceived risks. Priority substances to be evaluated are identified based on risk-based criteria and then listed in the “Community Rolling Action Plan (CoRAP) following the opinion of the Member State

Committee. An evaluating Member State will be designated for each substance on the final CoRAP. The goal is to determine whether a substance suspected to be of concern poses an actual risk to human health and/or the environment.

Information on the CoRAP can be found on the ECHA website:
http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

Substances included in the CoRAP can be found on the ECHA website:
http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

This assessment may be used later to prepare proposals for restrictions or authorization.

1.1.1.3 Authorization

Substances with certain hazardous properties may be identified as substances of very high concern (SVHC) and may be made subject to authorization. These include CMRs, PBTs (Persistent, Bio-accumulative and Toxic substances), vPvBs (very Persistent and very Bioaccumulative substances) and substances identified as causing serious and irreversible effects to humans or the environment equivalent to the effects mentioned on a case-by-case basis. All these substances will be identified in co-operation with the Member States. As a first step such substances are incorporated in a so-called "candidate list" which is published and periodically updated by ECHA. In other words: once a substance is included in the "candidate list", it is considered as a SVHC.

The current candidate list of substances of very high concern is available on the ECHA website: http://echa.europa.eu/web/guest/candidate-list-table

Finally, substances identified as requiring authorization will be taken up in Annex XIV.

A list of substances included in Annex XIV of REACH ("Authorisation List") is available on the ECHA website: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list

Manufacturers may be granted authorization following an application based on opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of ECHA.

A list of granted authorisations is published by the Commission here:
http://ec.europa.eu/DocsRoom/documents/8962

It may take many years before all substances of that category – potentially 1 500-2 000 substances – will have been worked through.

1.1.1.4 Restrictions

Chemical substances can be banned or restricted where there is an unacceptable risk to health or the environment. Before a restriction is adopted for inclusion in Annex XVII a so-called Annex XV dossier is required, i.e. a risk assessment accompanied with a demonstration that current risk management measures are insufficient to control the risk. This can be done by Member States or the ECHA on behalf of the Commission. In addition, article 68(2) allows the European Commission to adopt restrictions for CMRs of categories 1A and 1B on its own, in a mixture or in an article which could be used by consumers using a simplified procedure (see also 4.2 below). Further, article 69(2) allows to restrict substances subject to authorization in (imported) articles if the risk is not adequately controlled. By April 2017, Annex XVII of REACH contained restrictions on 62 chemical substances (or group of substances) covered by 67 entry numbers (5 entries have been deleted: 33, 39, 42, 44, 53), like e.g. use of certain phthalates in toys and child care articles, asbestos, metals, and so forth.

The current restriction list is available on the ECHA website: http://echa.europa.eu/en/addressing-chemicals-of-concern/restrictions/substances-restricted-under-reach

In March 2016, a compendium of analytical methods to check compliance with restriction requirements was published by ECHA. The report was prepared to provide a ready reference of some available analytical methods that authorities or industry may use in order to assess the compliance of chemicals manufactured, used or placed on the European market with the restrictions set forth in Annex XVII to REACH. The document is available here:
http://www.echa.europa.eu/documents/10162/13577/compendium_of_analytical_methods_en.pdf

In a few cases harmonized standards, applying at EU-level, including test methods are available (see entry 27 on nickel below), and in other cases the standardized test methods are referenced directly in the REACH Regulation (see entry 43 on azocolourants and azodyes below).

For consumer articles the following restrictions in Annex XVII seem to be of particular relevance:

Cadmium (entry 23) shall not be used in articles manufactured from certain plastic materials including e.g. polyvinyl chloride (PVC), polyurethane (PUR), low density polyethylene (LDPE), and polypropylene (PP). A limit of 0,01 % applies (with derogations). 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 products intended to come into direct and prolonged contact with the skin (examples include 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 µg/cm^2/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 µg/cm^2/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 the following harmonized standards:

— EN 1811:2011+A1:2015 "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 12472:2005+A1:2009 "Method for the simulation of wear and corrosion for the detection of nickel release from coated items";

— EN 16128:2015 "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 These are the only "harmonised" standards related to REACH at present (April 2017). An updated list can be found here: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/chemical-substances-reach/index_en.htm

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 µg/cm² per hour (equivalent to 0,05 µg/g/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.

An ECHA Guideline is available on lead and its compounds in articles supplied to the general public that can be mouthed by children. The Guideline serves to clarify the meaning of certain terms that define the scope of the restriction (e.g. "accessible part of articles", "normal/reasonably foreseeable conditions of use") and to provide a non-exhaustive list of article types (and examples of sub-types) which fall in or out of the scope of the restriction:
https://echa.europa.eu/documents/10162/13563/lead_guideline_information_en.pdf/43269f58-7035-42ea-a396-268a17abb5ab

Organostannic compounds listed (entry 20) are not allowed in articles where the concentration in the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin. This includes tri-substituted organostannic compounds such as tributyltin (TBT) compounds and triphenyltin (TPT), dibutyltin (DBT) compounds and dioctyltin (DOT) compounds (the latter only in specified articles).

The following **flame retardants** shall not be used in textile articles with skin contact:

— Tris (2,3 dibromopropyl)phosphate (entry 4, CAS No 126-72-7);

— Tris(aziridinyl)phosphinoxide (entry 7, CAS No 545-55-1);

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

In addition, the following flame retardants 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).

Azocolourants and Azodyes (entry 43) shall not be used 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 of Annex XVII (it includes currently 22 substances as shown in Table 1), 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. This includes:

— clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags;

— footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck;

— textile or leather toys and toys which include textile or leather garments;

— yarn and fabrics intended for use by the final consumer.

Table 1 — List of aromatic amines related to entry 43 of Annex XVII of REACH

No	CAS number	Substances
(1)	92–67–1	biphenyl-4-ylamine 4-aminobiphenyl xenylamine
(2)	92–87–5	benzidine
(3)	95–69–2	4-chloro-o-toluidine
(4)	91–59–8	2-naphthylamine
(5)	97–56–3	o-aminoazotoluene 4-amino-2',3-dimethylazobenzene 4-o-tolylazo-o-toluidine
(6)	99–55–8	5-nitro-o-toluidine 4-chloroaniline
(7)	106–47–8	4-chloroaniline
(8)	615–05–4	4-methoxy-m-phenylenediamine
(9)	101–77–9	4,4'-methylenedianiline 4,4'-diaminodiphenylmethane
(10)	91–94–1	3,3'-dichlorobenzidine 3,3'-dichlorobiphenyl-4,4'-ylenediamine
(11)	119–90–4	3,3'-dimethoxybenzidine o-dianisidine
(12)	119–93–7	3,3'-dimethylbenzidine 4,4'-bi-o-toluidine
(13)	838–88–0	4,4'-methylenedi-o-toluidine
(14)	120–71–8	6-methoxy-m-toluidine p-cresidine
(15)	101–14–4	4,4'-methylene-bis-(2-chloro-aniline) 2,2'-dichloro-4,4'-methylene-dianiline
(16)	101–80–4	4,4'-oxydianiline
(17)	139–65–1	4,4'-thiodianiline
(18)	95–53–4	o-toluidine 2-aminotoluene
(19)	95–80–7	4-methyl-m-phenylenediamine
(20)	137–17–7	2,4,5-trimethylaniline

No	CAS number	Substances
(21)	90–04–0	o-anisidine 2-methoxyaniline
(22)	60–09–3	4-amino azobenzene

Appendix 10 of Annex XVII includes test methods for the aromatic amines for different materials:

— EN ISO 17234-1:2010 "Leather — Chemical tests for the determination of certain colorants in dyed leathers — Part 1: Determination of certain aromatic amines derived from azo colorants";

— EN ISO 17234-2:2011 "Leather — Chemical tests for the determination of certain colorants in dyed leathers — Part 2: Determination of aminoazobenzene";

— EN 14362-1:2012 "Textiles — Methods for determination of certain aromatic amines derived from azo colorants — Part 1: Detection of the use certain azo colorants accessible with and without extracting fibres";

— EN 14362-3:2012 "Textiles — Methods for determination of certain aromatic amines derived from azo colorants — Part 3: Detection of the use certain azo colorants, which may release 4-aminoazobenzene".

Articles or any parts thereof containing **dimethylfumarate (DMF)** (entry 61, CAS No 624-49-7) in concentrations greater than 0,1 mg/kg shall not be placed on the market.

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 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 A restriction dossier on Bis(2-ethylhexyl) phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) in a broad range of articles was prepared by ECHA in co-operation with the Danish EPA on the basis of Article 69(2) of REACH for substances included in Annex XIV for which the risk is not adequately controlled.

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 the 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, Benzo[e]pyrene, Benzo[a]anthracene, Chrysene, Benzo[b]fluoranthene, Benzo[j]fluoranthene, Benzo[k]fluoranthene and Dibenzo[a,h]anthracene).

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.

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 mg/kg (0,000 3 % by weight) of the total dry weight of the leather.

The manufacture, placing on the market and use of articles containing listed **asbestos fibres** (entry 6) added intentionally is prohibited subject to derogations.

Wood treated with **creosote** products (entry 31) shall not be used inside buildings, in toys, in playgrounds, in parks, gardens, and outdoor recreational and leisure facilities where there is a risk of frequent skin contact, in the manufacture of garden furniture such as picnic tables and others.

Nonylphenolethoxylates (NPE, entry 46a) 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).

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.

NOTE The Commission has proposed a restriction on **Perfluorooctanoic acid** (**PFOA)** including its salts in a concentration equal to or above 25 ppb and (a combination of) PFOA-related substances in a concentration equal to or above 1 000 ppb which was backed by the Member States.

1.1.1.5 Articles

Articles are within REACH defined as an object, which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition (Article 3(3)). This means that most commercial items (consumer products) are defined as articles, but there are special cases such as ball point pens or printer cartridges that are defined as a combination of an article (functioning as container) and a substance/mixture not considered as an integral part of the article. Chemical products such as cosmetics or paints are not considered as articles.

ECHA has published the following guidance documents concerning chemicals in articles:

— Guidance in a Nutshell - Requirements for Substances in Articles:
https://echa.europa.eu/documents/10162/23036412/nutshell_guidance_articles2_en.pdf

— Guidance - Requirements for Substances in Articles:
https://echa.europa.eu/documents/10162/23036412/articles_en.pdf

According to REACH, substances in articles ought to be registered if they are intentionally released and if they are present in quantities greater than 1 tonne per manufacturer annually (Article 7). This is for example a product with a perfume scent. Chemicals that are unintentionally released during use are not covered, like plasticizers migrating out of a product over time.

If articles contain substances on the candidate list in a concentration above 0,1 % (w/w), the supplier shall provide sufficient information, including as a minimum the name of the substance, to the recipient of the article to allow for its safe use. Information about SVHC substances in an article shall be given to

consumers upon request and within 45 days following the request (Article 33 of REACH). This requirement is independent of the total tonnage of the substance. The supplier may not respond, if the product contains none of the SVHC in concentrations greater than 0,1 % of the article weight.

EU producers and importers of articles shall notify ECHA if their article contains a SVHC substance, in case where the SVHC substance is present in a concentration of above 0,1 % and its quantities in the articles are above 1 tonne in total per year per company (Article 7). This obligation does not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal.

There have been discussions regarding the interpretation of the 0,1 % limit referred to in Articles 7 and 33, as to whether the limit applies to the entire article or also to its components. Several EU/EFTA Member States (Austria, Belgium, Denmark, France, Germany, Sweden and Norway) interpreted that the limit applies to components of articles, while others, ECHA and the Commission had another interpretation. In February 2015, the Advocate General to the European Court of Justice supported the interpretation of the Member States mentioned above, which the Court of Justice took into consideration. The Advocate-General's ruling was confirmed by the European Court of Justice in September 2015 (case C-106/14). Both documents are accessible under the following address:
http://curia.europa.eu/juris/liste.jsf?&num=C-106/14

1.1.1.6 Basics of REACH Chemical Safety Assessment (CSA)

A Chemical Safety Assessment (CSA) is required for all substances subject to registration under REACH in quantities of ten tonnes or more per year per registrant (Article 14). However, all substances subject to authorization under REACH require a CSA, regardless of the tonnage involved. 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. Hence, REACH guidance documents for chemical safety assessment are a useful reference for establishing limit values for articles. In most cases, however, identification of relevant substances including restrictions will rely on available risk assessments carried out by competent bodies and/or existing limits for other (similar) products and will have to be adapted 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 manufacturing and use of a substance is considered to be safe. There are three major steps in the CSA process. These are:

— Hazard assessment;

— Exposure assessment;

— Risk characterization.

The **hazard assessment** requires the collection and evaluation of all available and relevant information on the substance. This includes information on the intrinsic properties of the substance, on the manufacturing and uses, and on the related emissions and exposures. Where existing information is insufficient to satisfy the REACH requirements, additional information has to be generated.

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 that is considered to be safe (also known as no-effect levels).

If as a result of the hazard assessment it can be concluded that the substance does not meet the criteria for classification as dangerous or to be considered a PBT/vPvB, the CSA ends here. If the substance meets any of these criteria, two additional steps are required to complete the process.

The **exposure assessment** is the process of measuring or estimating the dose or concentration of the substance to which humans and the environment are or may be exposed, depending on the uses of the substance.

Within the exposure assessment, the definition of the conditions under which the substance is manufactured and used is critical in order to determine the levels of exposure. The information on the conditions under which a substance is manufactured and used is called the **exposure scenario** under REACH. For each exposure scenario, the exposure levels of humans and the environment need to be determined. The exposure scenarios will cover all identified uses and life stages of the substance.

The third step in the CSA process is the **risk characterization**. For the risk characterization, the levels of exposure are compared with the threshold levels for each effect. Where it is not possible to determine a threshold level for one effect, a qualitative or semiquantitative approach is used.

Risks are regarded as controlled under REACH when the exposure levels to the substance are below the threshold levels considered as safe, both for humans and for the environment. For effects with no threshold levels, emissions and exposures have to be minimized or avoided for risks to be considered to be controlled.

An introduction to CSA can be found in the ECHA publication: "Guidance in a Nutshell - Chemical Safety Assessment": https://echa.europa.eu/documents/10162/23036412/nutshell_guidance_csa_en.pdf

A more in-depth guidance on CSA including all available guidance documents can also be found on the ECHA website: http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

In the following the main steps of a CSA in accordance with the REACH registration procedure for chemicals are briefly explained and complemented by specific considerations for chemicals used in consumer articles.

1.1.1.6.1 Hazard assessment

The hazard assessment usually comprises the following steps:

Step 1. Information gathering and evaluation

The purpose is to collect all relevant and available toxicological and ecotoxicological information on the intrinsic properties of a substance and to identify quality and completeness of the information.

Step 2. Hazard identification

Based on the first step the capacity of the substance to cause adverse effects to human health (and the environment) needs to be determined. In particular, so-called "dose descriptors" need to be identified. The dose descriptor is the term used to identify the relationship between a specific effect of a substance and the dose at which it takes place, e.g. the dose leading to 50 % lethality (e.g. LD_{50} – Lethal Dose) or the highest dose not causing adverse effects (e.g. NOAEL - No Observed Adverse Effect Level) in animal experiments. The dose descriptors will be used later for deriving the no-effect threshold levels for human health and the environment (see below). When a quantitative dose-response relationship cannot be defined, a semiquantitative or qualitative analysis will have to be done.

Step 3. Classification and labelling

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) provides criteria to classify substances and preparations as dangerous (e.g. very toxic, toxic, harmful) based on their intrinsic properties. The classification of a substance as dangerous is a critical input in the CSA process. See more on CLP in 3.2.

Step 4. Derivation of threshold levels

The Derived No-Effect Level or DNEL is the level of exposure to the substance above which humans should not be exposed. The DNELs for each health effect and each relevant exposure pattern are calculated by dividing the value of the health effect dose descriptor by an assessment factor. Typically, NOAELs from animal toxicity studies are extrapolated to humans by applying safety factors between 10 and 1 000. The lowest value (for the most sensitive end point) is used for risk characterization. However, in some cases (e.g. for mutagenic carcinogens) no safe threshold level can be obtained. In such

cases, a semiquantitative value, known as the DMEL or Derived Minimal Effect level may be developed. DMELs can be used later on in the risk characterization process in the same way as DNELs. It should be noted that (contrary to the DNEL concept) the DMEL concept is not incorporated in the REACH Regulation. It is only mentioned in the ECHA Guidelines. DMELs are based on an accepted risk level, e.g. an additional lifetime cancer risk (normally 10^{-5} or 10^{-6} for the general population, i.e. a cancer risk of one per 100 000 or 1 000 000 exposed during a lifetime) for a non-threshold carcinogen.

The environmental counterpart of the DNEL is the Predicted No Effect Concentration or PNEC – it is the concentration of a substance in any environment below which adverse effects will most likely not occur during long term or short-term exposure. The PNEC needs to be determined for each environmental sphere (aquatic, terrestrial, atmospheric, sewage treatment, food chain).

In the field of consumer products limits are often based on the Tolerable Daily Intake (TDI) values which indicate the amount of a substance that can be taken in daily over a lifetime without appreciable health risk. They are conceptually similar to a DNEL.

The DMEL concept has not been frequently used for consumer products. An alternative approach is to minimize exposure to hazardous substances without threshold value, and as far as possible, using the ALARA principle (As Low As Reasonably Achievable), i.e. to eliminate such substances using a low level of detection. An example is the opinion of the Scientific Committee on Health and Environmental Risks (SCHER) entitled "Risk from organic CMR substances in toys" (2010) which recommended: "non-thresholded carcinogens should not be present in toys as intentionally added components. Indeed, the acceptance for those chemicals of a non-threshold mechanism makes the definition of a safe level virtually impossible". Hence, it was concluded that "they should be determined directly *in the toy using appropriate extraction procedures and sensitive chemical-analytical procedures*". This opinion can be found here:
http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_121.pdf

However, in some cases limits have been proposed for non-threshold substances based on additional cancer risk. A recent example is the opinion by SCHER concerning chromium VI (a genotoxic carcinogen) in toys approved in January 2015. A virtually safe dose was calculated for an additional cancer case of 1 in 10^{-6} (i.e. 1 in a million). It should be noted, however, that SCHER was also of the opinion that exposure to chromium VI from toys should be minimized to the lowest levels achievable given the relatively high background exposure. This SCHER opinion can be obtained here:
http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scher_consultation_09_en.htm

Also the Benchmark Dose (BMD) approach was used for this purpose (it can be used also for substances with thresholds). An introduction and assessment of this approach can be found in the "Guidance of the Scientific Committee on a request from EFSA on the use of the benchmark dose approach in risk assessment" which is available for download here:
http://www.efsa.europa.eu/en/efsajournal/doc/1150.pdf

As an example, the EFSA Panel on Contaminants in the Food Chain (CONTAM) used this approach to derive a limit for lead (Scientific Opinion on Lead in Food, EFSA Journal 2010; 8(4):1570):
http://www.efsa.europa.eu/de/efsajournal/pub/1570.htm

In this case developmental neurotoxicity in young children was considered as non-threshold critical end point. The proposed limit corresponds to a decline of the IQ (Intelligence Quotient) by 1 point (95th percentile lower confidence limit).

Step 5. PBT and vPvB assessment

PBT substances are substances that are persistent, bioaccumulative and toxic while vPvB substances are characterized by a high persistency and a high tendency to bioaccumulate, but not necessarily by proven toxicity. These substances may accumulate in parts of the environment, enter the food chain and may exhibit unpredictable (not yet known) effects in the long term. The objective of the PBT/vPvB assessment is to determine if the substance fulfils the criteria set up in Annex XIII of REACH.

1.1.1.6.2 Exposure assessment

Where the hazard assessment shows that the substance meets the classification criteria as dangerous according to the CLP Regulation or the PBT or vPvB criteria, an exposure assessment is required by REACH to define the levels of exposure.

An exposure assessment entails the following two steps:

Step 1. Development of exposure scenarios

Exposure scenarios describe how a substance is used during its life cycle and recommend how to control exposure of humans and the environment.

The qualitative characteristics of the article should be identified. Factors that should be considered include the:

— intended and foreseen age range and ability of the user;

— conditions under which the article is to be used (taking into account the normal behaviour of users such as children);

— environment in which the article is to be used, e.g. indoors taking into account factors such as ventilation;

— length of time of exposure to the article;

— likely route(s) of exposure to the article, e.g. ingestion, skin contact or inhalation.

Step 2. Exposure estimation

When estimating exposure, in principle all human populations liable to exposure and all environmental spheres for which exposure to the substance is known, need to be addressed according to REACH. All the possible exposure patterns need to be taken into account. There are three major routes by which chemicals can enter the body: oral, dermal and inhalation.

Consumer exposure is often difficult to estimate due to limited data availability. It should address not only the direct consumer uses of substances, mixtures or articles that contain the substances but also other exposures (e.g. uses by professionals, indoor air emissions, environmental contaminants). The consumer exposure estimation should not only address the intended uses of the products that contain the substances under investigation but also reasonably foreseeable uses such as mouthing by small children (but not deliberate abuse), i.e. reasonable worst-case situations should be considered. Different pathways of exposure (exposure routes) shall be taken into account as well as combined exposures of a substance from the use of different products (see 4.6).

ECHA Guidance documents recommend a tiered approach for consumer exposure assessment to substances in articles which starts with a conservative screening estimation (Tier 1) which is followed by more refined and more sophisticated approaches.

For articles for children the oral contact route (biting off particles, licking and sucking) seems most relevant. However, for certain substances or articles other exposure routes may be also important. As

an example, typical exposure model assumptions used in the risk assessment of toys applicable for the oral contact route include:

— age < 3 years;

— body weight 7,5 kg;

— material 8 mg (scraped off);

— mouthing area 10 cm^2;

— mouthing time 3 h.

There are several ECHA guidance documents which are of particular importance in this context:

The "Guidance on information requirements and chemical safety assessment Chapter R.15: Consumer exposure estimation" can be found on the ECHA website:
http://echa.europa.eu/documents/10162/13632/information_requirements_r15_en.pdf

The "Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental exposure assessment" can be found on the ECHA website:
https://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf

In addition, the document "Exposure scenario for chemical safety report and communication, Example: consumer use of a substance in cleaning products can be found on the ECHA website:
http://echa.europa.eu/documents/10162/13564/es_for_consumer_20110829_en.pdf

1.1.1.6.3 Risk characterization

The quantitative risk characterization for human health is carried out by comparing the estimated exposure level for a given exposure pattern with the lowest DNEL/DMEL value, i.e. the critical DNEL/DMEL, for that exposure pattern. The comparison needs to be done for each exposure pattern resulting from a given exposure scenario.

The quantitative risk characterization for the environment is carried out by comparing the Predicted Exposure Concentration (PEC) with the PNEC. This is done separately for each environmental sphere, both at a local and regional scale.

A person may be exposed to a substance via different routes of entry into the body or from different products containing the same substances. Then the risk characterization needs to consider risks from combined exposures to a single chemical via different routes or via different sources. However, this is currently only marginally covered in REACH and only to some extent by existing product legislation (see below).

Similarly, multiple exposures to different chemicals with a similar mode of action ("Combination effects") would need to be taken into account. This is currently not covered by REACH or any other EU legislation addressing chemicals in products (see below).

According to REACH the risk will be considered to be adequately controlled if the estimated exposure levels do not exceed the appropriate DNEL/DMEL or PNEC, and for substances for which a DNEL/DMEL or PNEC cannot be determined, the emissions and exposures are minimized by the implementation of the exposure scenario to the level that they do not pose risk.

1.1.2 Associated standards

The latest list of harmonized standards is available here: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/chemical-substances-reach/index_en.htm

The referenced standards address test methods for the release of nickel as stated above (1.1.1.4).

1.1.3 Remarks on REACH

REACH is often considered a "landmark legislation", which made the EU a world leader in chemicals management, and will further strengthen health and environmental protection.

In its 2013 review, the Commission reviewed those key drivers, which are already operational and of particular relevance to the generation of the benefits, namely: registration, information in the supply chain, authorization and restrictions. The Commission also examined dossier evaluation, provision of guidance, inspections and enforcement activities. In general, the Commission concluded that REACH functions effectively and delivers on all objectives that at the time could be assessed. In particular, the Commission stated: "In short, the health and environment objective of REACH is expected to be achieved through (1) better knowledge on the properties and uses of substances resulting in better safety and control measures, reducing exposure and hence, the negative impacts on human health and the environment; and (2) the use of less dangerous alternative substances or technologies to SVHC". Consequently, the Commission concluded that no major overhaul of the legislation is required before the last registration deadline of 2018:
http://ec.europa.eu/DocsRoom/documents/11981/attachments/1/translations/en/renditions/native

Nevertheless, some actors have been calling for the strengthening of chemical requirements in Europe, in REACH as well as in product legislation. In its 2012 strategy for a non-toxic environment "Reducing the risks of hazardous substances", the Swedish Government said: "*REACH is an important but insufficient tool to generate knowledge on hazardous substances and to deal with the risks associated with them. Despite the increasing knowledge about the combination effects of exposure to hazardous substances, REACH does not take a holistic approach to the total use of chemicals by society and the environmental and health risks it poses. This is why there is still a need for additional efforts to reduce the risks in the chemicals area. Above all, the pace at which particularly hazardous substances are being phased out is too slow*". The Swedish Government further concludes that "*significant changes need to be made to REACH and to other relevant legislation after 2020*" and "*product-specific directives are needed to supplement the overarching REACH regulation"*: http://www.sou.gov.se/wp-content/uploads/2014/11/b4bcb300.pdf

The European Union's Environment Action Programme to 2020 "Living well, within the limits of our planet" adopted in November 2013 considers that "*the minimisation of exposure to chemicals in products, including, inter alia, imported products, with a view to promoting non-toxic material cycles and reducing indoor exposure to harmful substances*" as an element of a "*Union strategy for a non-toxic environment*" to be developed by 2018 (see also 4.1 below).

1.2 CLP

Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (CLP), amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH), is based on the United Nations Globally Harmonized System of classification and labelling of chemicals (GHS).The most recent consolidated version of the Regulation and subsequent amendments can be found on the ECHA website:
http://echa.europa.eu/web/guest/regulations/clp/legislation

An "Introductory Guidance on the CLP Regulation" is available on the ECHA website:
https://echa.europa.eu/documents/10162/23036412/clp_introductory_en.pdf

1.2.1 Key elements of the CLP relevant for chemicals in articles

The following section provides a description of key elements of the CLP Regulation with a particular focus on provisions that are relevant for establishing requirements for substances in articles.

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.

Annex 1 of the Regulation includes classification and labelling requirements for hazardous substances and mixtures. Part 3 thereof addresses health hazards and defines in addition to classifications also toxicity categories and subcategories, where appropriate.

EXAMPLE 1 The classification "carcinogenicity" comprises the categories 1 and 2, category 1 contains subcategories 1A and 1B.

CATEGORY 1:	*Known or presumed human carcinogens*
Category 1A:	Known to have carcinogenic potential for humans, classification is largely based on human evidence
Category 1B:	Presumed to have carcinogenic potential for humans, classification is largely based on animal evidence
CATEGORY 2:	Suspected human carcinogens

Moreover, generic classification criteria for mixtures are given in Annex 1 depending on the concentrations of the individual substances in the mixture.

EXAMPLE 2 Concentration thresholds of carcinogens leading to a classification of the mixture.

Category 1A:	*≥ 0,1 %*
Category 1B:	≥ 0,1 %
CATEGORY 2:	≥ 1,0 %

NOTE In addition, concentration thresholds for specific substances are defined in Table 3.1 of Part 3 of Annex VI.

Finally, pictograms and hazard phrases are defined.

EXAMPLE 3 Carcinogenic substances.

Classification	Category 1 (Category 1A, 1B)	Category 2
GHS Pictograms		
Signal Word	Danger	Warning
Hazard Statement	H350: May cause cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	H351: Suspected of causing cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)

Along the same lines environmental hazards are defined in Part 4 of Annex I (classification "Hazardous to the aquatic environment"). Part 5 of Annex 1 addresses "Additional hazards" (classification "Hazardous to the ozone layer").

A list of hazard statements is provided in Part 1 of Annex III. The other parts of Annex III give supplemental hazard information and supplemental label elements. A list of precautionary statements (e.g. "Keep out of reach of children") is provided in Annex IV. Hazard pictograms for hazard classes and hazard categories are given in Annex V.

Manufacturers, importers and downstream users of substances or mixtures are responsible for the classification ("self-classification"). Different suppliers may classify a substance or a mixture differently.

In some cases, the classification of a chemical is harmonized and obligatory at Community level ("harmonised classification"). In particular, this applies to the most hazardous substances such carcinogenic, mutagenic, toxic for reproduction or respiratory sensitizers. Annex VI covers the harmonized classification and labelling for certain hazardous substances. Of particular importance is Part 3 of Annex VI, which includes Table 3.1: List of harmonized classification and labelling of hazardous substances.

NOTE Table 3.2 includes a list of harmonized classification and labelling of hazardous substances from the previous legislation, which could be used for a transitional period. This has become obsolete in June 2015.

The Classification and Labelling Inventory is a database, which contains classification and labelling information on notified and registered substances received from manufacturers and importers. It also includes the list of harmonized classifications (Tables 3.1 and 3.2 of Annex VI to the CLP Regulation) and the names of harmonized substances translated in all EU languages.

The C&L Inventory is accessible here: http://echa.europa.eu/regulations/clp/cl-inventory

1.2.2 Associated standards

None.

1.2.3 Remarks on CLP

Basic knowledge of CLP is required in the context of chemical safety assessment and to establish requirements for articles relying on the hazard classification.

1.3 Biocidal Products Regulation (BPR)

The Biocidal Products Regulation (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.

The most recent consolidated version of the Regulation is available on the ECHA website:
http://echa.europa.eu/regulations/biocidal-products-regulation/legislation

1.3.1 Key elements of the BPR relevant for chemicals in articles

The Regulation is based on an evaluation of active substances at the Union level, and product authorization at Member State level. Some biocidal products are authorized at the Union level. The approval of an active substance does not include the nanomaterial form unless explicitly mentioned.

Active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as carcinogen category 1A or 1B, or mutagen category 1A or 1B, or toxic for reproduction category 1A or 1B shall not be approved.

Active substances which are considered as having endocrine-disrupting properties that may cause adverse effects in humans or which are identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties shall not be approved. The Commission is required to provide scientific criteria by no later than 13 December 2013 (these criteria are yet to be developed). Pending the adoption of these criteria, substances may be considered as having endocrine-disrupting properties if:

— they are classified in accordance with Regulation (EC) No 1272/2008 as, or meet the criteria to be classified as, carcinogen category 2 and toxic for reproduction category 2;

— they are classified in accordance with Regulation (EC) No 1272/2008 as, or meet the criteria to be classified as, toxic for reproduction category 2 and that have toxic effects on the endocrine organs.

Active substances which meet the criteria for being PBT or vPvB according to Annex XIII to Regulation (EC) No 1907/2006 shall not be approved. However, approval may be granted under certain conditions (negligible risk, the active substance is essential to prevent or control a serious danger, disproportionate negative impact on society of non-approval).

Unlike its predecessor legislation (Directive 98/8/EC), 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). The Regulation excludes articles covered by Directive 2009/48/EC on the safety of toys.

Biocidal products are classified into 22 biocidal product-types (Annex V), grouped in four main areas:

— Main group 1: Disinfectants;

— Main group 2: Preservatives;

— Main group 3: Pest control;

— Main group 4: Other biocidal products.

A complete list of the 22 biocidal product types can be found on the ECHA website:
http://echa.europa.eu/regulations/biocidal-products-regulation/product-types

A list of approved substances (about 200 in February 2017) can be found on the ECHA website:
http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances

Upon request, suppliers of treated articles shall provide consumers with free-of-charge information on the biocidal treatment of the treated article within 45 days.

The BPR also requires manufacturers and importers of treated articles to label treated articles 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.

It should be noted that the BPR includes a series of transitional measures including the systematic examination of all existing active substances commenced under its predecessor legislation (Directive 98/8/EC) until 2024.

1.3.2 Associated standards

None.

1.3.3 Remarks on BPR

Biocides are in principle comprehensively covered by the Regulation, except for toys. Hence, it may not be necessary to address biocides in requirements for articles – be it through regulations or standards. However, there are long transitional periods which need to be borne in mind.

The BPR is an interesting model to follow from in other areas. In particular, the exclusion criteria could be interesting for other articles, specifically the wording for the CMR exclusion, which does not only cover CMRs with harmonized classification, but also others "which meet the criteria to be classified". The envisaged scientific criteria for EDCs to be established by the Commission are clearly relevant for all categories of products.

1.4 Persistent Organic Pollutants (POPs)

The objective of Regulation (EC) No 850/2004 on Persistent Organic Pollutants (POPs) is to protect human health and the environment from persistent organic pollutants by prohibiting, phasing out as soon as possible, or restricting the production, placing on the market and use of such substances.

The Regulation is based on two Conventions:

— The Protocol to the regional UNECE Convention on Long-Range Transboundary Air Pollution (CLRTAP) on POPs, opened for signatures in June 1998 and entered into force on 23 October 2003;

— The global Stockholm Convention on POPs, opened for signatures in May 2001 and entered into force on 17 May 2004.

Consolidated versions of the Regulation can be found here: http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:32004R0850

1.4.1 Key elements of the POPs Regulation relevant for chemicals in articles

Annex I includes substances subject to prohibitions which are also applicable to articles. The following substances are included (limits in articles in brackets):

— Tetrabromodiphenyl ether (≤10 mg/kg, 0,001 %);

— Pentabromodiphenyl ether (≤10 mg/kg, 0,001 %);

— Hexabromodiphenyl ether (≤10 mg/kg, 0,001 %);

— Heptabromodiphenyl ether (≤10 mg/kg, 0,001 %);

— Perfluorooctane sulfonic acid and its derivatives, PFOS (<0,1 % for structurally or micro-structurally distinct parts, 1 µg/m^2 for coated materials);

— DDT (-);

— Chordane(-);

— Hexachlorocyclohexanes including lindane (-);

— Dieldrin (-);

— Endrin (-);

— Heptachlor (-);

— Endosulfan (-);

— Hexachlorobenzene, HCB (-);

— Chlordecone (-);

— Aldrin (-);

— Pentachlorobenzene (-);

— Polychlorinated biphenyls, PCBs (-);

— Mirex (-);

— Toxaphene (-);

— Hexabromobiphenyl (-);

— Hexabromocyclododecane (100 mg/kg, 0,01 %, different implementation dates beginning in March 2019;

— Hexachlorobutadiene (-);

— Polychlorinated naphthalenes (-);

— Short-chain chlorinated paraffins, SCCPs (<0,15 %).

The prohibitions do not apply to substances occurring as an unintentional trace contaminants. In some cases derogations from the limits given above apply, e.g. the limit for the brominated diphenylethers for articles produced partially or fully from recycled materials or materials from waste prepared for re-use is 0,1 %.

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

1.4.2 Associated standards

None.

1.4.3 Remarks on POPs Regulation

The Regulation is mainly important to identify specific substances, which do not need to be addressed in developing standards.

1.5 General Product Safety Directive (GPSD)

The General Product Safety Directive (GPSD), Directive 2001/95/EC, applies in the absence of specific EU regulations on safety of products intended for consumers and complements the provisions of sector legislation, which do not cover certain matters, for instance in relation to producers' obligations and the authorities' powers and tasks. The purpose of this Directive is to ensure that products placed on the market are safe.

Consolidated versions of the GPSD can be found here: http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:32001L0095

1.5.1 Key elements of the GPSD relevant for chemicals in articles

Producers are obliged to place only safe products on the market. The Directive provides a generic definition of a 'safe product' (Article 2(b)).

A product is to be presumed safe if it meets the requirements of voluntary national standards transposing European standards, the references of which were published by the Commission in the Official Journal of the European Union. Article 4 of the GPSD lays down the procedure for drawing up European standards. Under that procedure, the Commission is to set the specific safety requirements,

which European standards should satisfy and subsequently give a mandate to the European standardization bodies to draw up those standards.

In the absence of such standards, other means are available to assess compliance with the general safety requirement.

The GPSD does not contain any chemical requirements nor does it have an instrument to establish regulatory limits on a permanent basis. However, Article 13 of the GPSD 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 child use and care articles and for dimethylfumarate (DMF) and both have been later incorporated into Annex XVII of REACH.

Apart from that, chemical requirements can only be addressed in form of safety requirements which form the basis of mandates to European Standards Bodies (ESOS) unless a specific regulation is adopted.

1.5.2 Chemical requirements in safety requirements and mandates

According to Article 4 of the GPSD, "*requirements intended to ensure that products which conform to these standards satisfy the general safety requirement*" shall be set up as basis of mandates to the ESOs. The safety requirements are published in form of Commission decisions (at present for about 15 product groups). A handful of these decisions include chemical requirements however without giving detailed instructions (e.g. gymnastic equipment, Commission Decision 2011/479/EU). In some cases, legal compliance is called for (e.g. certain products in the sleep environment of children, Commission Decision 2010/376/EU or certain seats for children, Commission Decision 2013/121/EU).

Two draft safety requirements include chemical requirements. The first one relates to alcohol-powered flueless fireplaces (Commission Decision (EU) 2015/547) which requires to address emissions:

"Alcohol-powered flueless fireplaces shall be constructed in such a way as to avoid any risk to human health which may arise from combustion or other emissions through inherently safe design and construction, or where this is not possible by adequate protection measures, including alarms, or information to users.

The standard should address in particular:

— carbon monoxide and carbon dioxide (CO, CO_2);

— nitrogen oxides such as NO, NO_2 and NO_X;

— aldehydes such as formaldehyde;

— volatile organic compounds (VOCs);

— aromatic hydrocarbons such as benzene and polycyclic aromatic hydrocarbons (PAHs);

— soot and other particle emissions;

— emissions from unburnt fuel;

— any other emissions that may be relevant".

It was published in spring 2015.

The second safety requirement decision in preparation addresses candles, candle supports, containers and accessories and is in the adoption process (to be reviewed in final version). It contains provisions on chemical requirements (i.e. lead and nickel) and emissions.

1.5.3 Associated standards

In the above context, a few mandated standards contain chemical requirements. The latest list of harmonized standards (more than 60) is available here: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/general-product-safety/index_en.htm

These include standards for child use and care articles (though not all of these standards are harmonized as indicated below). These standards contain requirements related to elements corresponding to limits applicable to toys and refer to EN 71-3 (see below), sometimes also limits for nickel release are included. A few standards for this product group include further chemical requirements, including:

— EN 1400:2013 +A1:2014 "Child use and care articles - Soothers for babies and young children - Safety requirements and test methods" (harmonized, reference not published in the Official Journal);

— EN 14350-2:2004 "Child use and care articles – Drinking equipment Part 2: Chemical requirements and tests" (not harmonized);

— EN 14372:2004 "Child use and care articles - Cutlery and feeding utensils - Safety requirements and tests" (not harmonized).

addressing issues such as (not all requirements are included in all standards, different limits apply):

— Elements - significantly lower migration limits compared to TSD limits for scraped-off toy materials (though not all elements covered);

— N-nitrosamines and N-nitrosatable substances - reflecting limits in Directive 93/11/EEC;

— 2-Mercaptobenzothiazole (MBT) - migration limit;

— Antioxidants - migration limit for certain antioxidants (BHT, Cyanox 425, Antioxidant 2246, Wingstay L, Irganox 1520);

— Formaldehyde - migration limit;

— Bisphenol A - migration limit;

— Volatile compounds - content limit;

— Colour fastness to saliva;

— Nickel – migration limit;

— Phthalates – limit for the total content of DINP, DEHP, DNOP, DIDP, BBP.

CEN Technical Committee CEN/TC 252 "Child use and care articles" revised its safety guidelines (CEN/TR 13387:2004 "Child use and care articles - Safety guidelines") to be used by its Working Groups when preparing standards. The edition published in July 2015 has been split in different parts. The second part covers chemical hazards (CEN/TR 13387-2:2015 "Child use and care articles - General safety guidelines - Part 2: Chemical hazards"). The chemical provisions are strongly based on regulatory and normative provisions applicable to toys. CEN/TC 252 has also adopted an implementing mechanism to ensure that the guidelines are actually used (annual report on the uptake of the safety guidelines to the TC). In addition, the Task Group on chemicals which elaborated the document can be consulted to assist the WGs in drafting chemical provisions. These documents are not only intended for standardisers, but should also inform other parties interested in child safety. .

The guideline seemed to be a quite suitable template for the development of the present CEN Guide. Its basic structure is as follows:

— Scope;

— Regulatory, normative and policy background;

— Basics of Chemical Safety Assessment (CSA);

— Child use and care articles specific approaches.

The latter comprises general aspects including Substances of Very High Concern (SVHC) or CMRs, and addresses different categories of substances such as certain elements, flame retardants, colourants, primary aromatic amines and monomers. The document identifies limits and the specific materials which the limits are intended for.

Following publication of CEN/TR 13387-2:2015 the draft standard FprEN 1272:2016 “Child care articles - Table mounted chairs – Safety requirements and test methods” was prepared including chemical requirements for formaldehyde, colourants and primary aromatic amines in addition to limits for elements.

Recently also several draft standards for textile child care articles mandated by the Commission and prepared by CEN/TC 248 “Textiles and textile products” were launched which include chemical requirements beyond addressing elements (though the mandate did not ask for such requirements). The drafts dealing with children's cot duvets (prEN 16779-1), children's cot bumpers (prEN 16780) and children's sleeping bags (prEN 16781) included also restrictions for formaldehyde and flame retardants.

1.5.4 Remarks on GPSD

The GPSD seems not to be a suitable framework for establishing legal chemical requirements. Only in exceptional cases, temporary measures (one year) can be adopted, and this happened twice since the adoption of the Directive. In addition, the option to set chemical requirements via safety requirements, mandates and standards seems limited by the lack of resources and expertise on the side of Member States and the European Commission.

1.6 Toy Safety Directive (TSD)

The Toy Safety Directive (TSD), Directive 2009/48/EC, was published in June 2009. Part III of Annex II contains the chemical requirements, which are summarized below. Consolidated versions of the TSD can be found here: http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:32009L0048

1.6.1 Key elements of the TSD relevant for chemicals in articles

CMRs of category 1A, 1B or 2 according to the Classification, Labelling and Packaging (CLP) Regulation (Regulation (EC) No 1272/2008) shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys except if one of the following conditions is met:

— If the use and presence of the chemical substance is allowed according to Appendix A of Annex II;

— these chemical substances are inaccessible to children in any form, including inhalation;

— the concentration of the chemical substances does not exceed the concentration limits as set for the classification of mixtures containing these chemical substances in the CLP regulation.

The generic limits for CMR substances in the TSD are the CLP Regulation's generic concentration limits for the classification of mixtures containing these chemical substances as follows:

— for carcinogenic and mutagenic substances 0,1 %, 0,1 % and 1 % (for cat. 1A, 1B and 2);

— for substances toxic to reproduction 0,3 %, 0,3 % and 3 % (for cat. 1A, 1B and 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.

Allergenic fragrances listed in the Table 2 shall not be used in toys. 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 2 - Allergenic fragrances not allowed to be used in toys

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

No	Name of the allergenic fragrance	CAS number
(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
(33)	7-Ethoxy-4-methylcoumarin	87–05–8
(34)	Hexahydrocoumarin	700–82–3
(35)	Peru balsam, crude (Exudation of Myroxylon pereirae (Royle)	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 3 shall be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy, as such, at concentrations exceeding 100 mg/kg in the toy or components thereof.

Table 3 - Allergenic fragrances to be labelled if used in toys

No	Name of the allergenic fragrance	CAS number

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

It should be noted that these requirements are adapted from the requirements included in Annex III of the Cosmetics Regulation (Regulation (EC) No 1223/2009).

Furthermore, requirements on migration of 19 **elements** are set for three different types of materials as shown in Table 4. The limits are based on assumption of a daily intake of 100 mg dry, brittle, powder-like or pliable toy material, 400 mg of liquid or sticky toy material and 8 mg of scraped-off toy material using and the tolerable daily intake doses such as TDIs.

For the elements arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, the limits have been set at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee, in order to ensure that only traces that are compatible with good manufacturing practice will be present (preamble of the TSD, recital 22).

Table 4 - Migration limits, from toys or components of toys, scraped-off toy materials

Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material	mg/kg in scraped-off toy material
Aluminium	5 625	1 406	70 000
Antimony	45	11,3	560
Arsenic	3,8	0,9	47
Barium	1 500	375	18 750
Boron	1 200	300	15 000
Cadmium	1,3	0,3	17
Chromium (III)	37,5	9,4	460
Chromium (VI)	0,02	0,005	0,2
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700
Lead	13,5	3,4	160

Element	**mg/kg in dry, brittle, powder-like or pliable toy material**	**mg/kg in liquid or sticky toy material**	**mg/kg in scraped-off toy material**
Manganese	1 200	300	15 000
Mercury	7,5	1,9	94
Nickel	75	18,8	930
Selenium	37,5	9,4	460
Strontium	4 500	1 125	56 000
Tin	15 000	3 750	180 000
Organic tin	0,9	0,2	12
Zinc	3 750	938	46 000

These limit values shall not apply to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin.

NOTE The Commission proposed a reduction of the limit values for lead which was supported by the Council. The limits are: 2,0 mg/kg, 0,5 mg/kg and 23 mg/kg for the toy categories indicated in the table.

N-nitrosamines and N-nitrosatable substances are prohibited in toys intended to be used 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.

According to Article 46, 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. By April 2017, the following substances were listed with a specific limit value:

— Tris (2-chloroethyl) phosphate (TCEP, CAS No 115-96-8), 5 mg/kg (content limit),

— Tris-monochloro-propyl phosphate (TCPP, CAS No 13674-84-5), 5 mg/kg (content limit),

— Tris(1,3-dichloropropyl-2)phosphate (TDCP, CAS No 13674-87-8), 5 mg/kg (content limit),

— Bisphenol A (CAS No 80-05-7), 0,1 mg/l (migration limit) when tested in accordance with EN 71-10 and EN 71-11,

— Formamide (CAS No 75-12-7), 20 µg/m^3 after a maximum of 28 days (emission limit), emission testing is not necessary when the formamide content is 200 mg/kg or less,

— 1,2-Benzisothiazol-3(2H)-one (1,2-benzisothiazolin-3-one, BIT, CAS no 2634-33-5), 5 mg/kg (content limit) when tested in accordance with EN 71-10 and EN 71-11,

— 5-Chloro-2-methyl-isothiazolin-3(2H)-one (CMI, CAS No 26172-55-4), 0,75 mg/kg (content limit),

— 2-methylisothiazolin-3(2H)-one (MI, CAS No 2682-20-4), 0,25 mg/kg (content limit),

— CMI and MI in a ratio of 3:1 (CAS No 55965-84-9), 1 mg/kg (content limit).

NOTE A strengthening of the limit value for Bisphenol A in Appendix C of the TSD is under preparation to reflect a new temporary TDI suggested by EFSA. The Commission proposed a limit of 0,04 mg/l (migration limit) in accordance with the methods laid down in EN 71–10:2005 and EN 71–11:2005. In addition, the Commission proposed a limit of 5 mg/l (migration limit) for phenol in polymeric materials and a limit of 10 mg/kg (content limit) for phenol as a preservative.

According to Article 18, manufactures shall, before placing a toy on the market, carry out analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards. This is also called a safety assessment. Manufacturers shall also demonstrate that the toy complies with the requirements set in Annex II. The assessment shall be kept in the technical documentation.

1.6.2 Associated standards

1.6.2.1 Harmonized standards - references published in the Official Journal

The latest list of harmonized standards is available here: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/toys/index_en.htm

Chemical requirements and test methods are included in the following standards:

— EN 71-3:2013+A1:2014, “Safety of toys - Part 3: Migration of certain elements”; this standard contains requirements and test methods for the 19 elements regulated in the TSD;

— EN 71-4:2013, “Safety of toys - Part 4: Experimental sets for chemistry and related activities”;

— EN 71-5:2015, “Safety of toys - Part 5: Chemical toys (sets) other than experimental sets”;

— EN 71-7:2014, “Safety of toys - Part 7: Finger paints - Requirements and test methods”;

— EN 71-12:2016, “Safety of toys - Part 12: N-Nitrosamines and N-nitrosatable substances”;

— EN 71-13:2014, “Safety of toys - Part 13: Olfactory board games, cosmetic kits and gustative games”.

The last five standards include chemical requirements, which complement the TSD requirements.

Most of the standards are of limited relevance for consumer articles in general, as they apply to very specific toys that contain chemical substances or mixtures. EN 71-3 just reproduces the limits included in the TSD. EN 71-12 contains requirements in addition to the TSD with lower limits for N-nitrosamines and N-nitrosatable substances in finger paints (0,02 mg/kg and 1 mg/kg) and in 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).

1.6.2.2 Harmonized standards - references not published in the Official Journal

These are:

— 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”.

European standards EN 71-9, EN 71-10 and EN 71-11, which do not provide a presumption of conformity to TSD requirements, include limit values and test methods for certain organic chemical compounds. The most relevant ones are indicated below.

These three standards were not harmonized because of a critical opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) entitled "*Assessment of the European Committee for Standardisation (CEN) Report on the Risk Assessment of Organic Chemicals in Toys*", November 2003.

EN 71-9, EN 71-10 and EN 71-11 cover only a limited number of organic chemical substances. Consequently, the introduction of EN 71-9 states: "*This document, therefore, supports but does not reduce the responsibility of toy manufacturers, importers and suppliers for ensuring that the use of other substances will not endanger the health whilst playing with toys as intended or in a reasonably foreseeable way*".

NOTE European standards EN 71–9, EN 71–10 and EN 71–11 were published 10 years ago, and contain partly outdated requirements. A decision on the need for a revision will be taken in 2017.

Flame retardants:

EN 71-9, 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

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.

Colourants

EN 71-9, Table 2B includes action limits for colourants as shown in Table 6.

Table 6 - Colourants with action limits from EN 71–9

Colour Index Name	CAS Number	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
Basic Red 9	569–61–9	Action limit
Basic Violet 1	8004–87–3	Action limit

Basic Violet 3	548–62–9	Action limit
Acid Red 26	3761–53–3	Action limit
Acid Violet 49	1694–09–3	Action limit

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 the Table are provided in EN 71-10 and EN 71-11.

A first-action method for colourants is described in EN 71-10. 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.

Primary aromatic amines

EN 71-9, Table 2C includes action limits for primary aromatic amines as shown in Table 7.

Table 7 - 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

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 in the Table are provided in EN 71-10 and EN 71-11.

A first-action method for primary aromatic amines is described in EN 71-10. 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.

Monomers (migration)

EN 71-9, Table 2D includes limits for monomers as shown in Table 8.

Table 8 - 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. The limits apply to certain kinds of toys, particularly those with intended mouth contact or likely mouth contact for prolonged periods. It should be noted that the limit for phenol is based on an outdated TDI value. The envisaged regulatory limit is supposed to be a third of the value included in the Table.

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

NOTE 1 The limit value for Bisphenol A corresponding to the latest temporary TDI suggested by EFSA would be 0,04 mg/l (migration limit).

NOTE 2 The migration limit for phenol is based on an outdated tolerable daily intake (TDI). EFSA reduced the TDI of phenol from 1,5 mg/kg body weight per day to 0,5 mg/kg body weight per day. The limit corresponding to this TDI would be 5 mg/l.

Solvents (migration)

EN 71-9, Table 2E includes limits for solvents (migration) as shown in Table 9.

Table 9 - 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).

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

Test methods for solvents (migration) in Table 9 are provided in EN 71-10 and EN 71-11.

Solvents (inhalation)

EN 71-9, Table 2F includes limits for solvents (inhalation) as shown in the Table 10.

Table 10 - 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/m³ (total)
1,3,5-Trimethylbenzene (mesitylene)	108–67–8	2 500 µg/m³
Trichloroethylene	79–01–6	Action limit
Dichloromethane	75–09–2	3 000 µg/m³
n-Hexane	110–54–3	1 800 µg/m³
Nitrobenzene	98–95–3	Action limit
Cyclohexanone	108–94–1	136 µg/m³
3,5,5-Trimethyl-2-cyclohexene-1-one	78–59–1	200 µg/m³
[a] Conformity with these limits cannot easily be assessed analytically pending further validation of the methods for volatile solvents described in EN 71–11.		

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. for 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 10 are provided in EN 71-10 and EN 71-11. However, the methods have not been validated.

Plasticizers (migration)

EN 71-9, Table 2I includes action limits for plasticizers as shown in Table 11.

Table 11 - Plasticizers 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 for all plasticizers are 0,03 mg/l. The limits 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 plasticizers in Table 11 are provided in EN 71-10 and EN 71-11.

Formaldehyde

EN 71-9:2005+A1:2007 contains the following requirements for formaldehyde in Clause 4.3 in addition to the requirements for formaldehyde used as monomer or 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.

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.

Test methods are given in the standards referenced above.

NOTE The suitability of EN 717–3 as a test method for toys has been questioned and is subject to review.

1.6.3 Remarks on TSD

The revised TSD published in 2009 has been considered as a significant step forward compared to its predecessor legislation as regards chemicals. Additional chemical requirements on CMRs, allergenic fragrances, elements and N-nitrosamines and N-nitrosatable substances had been introduced together

with an option to 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 in Appendix C of Annex II.

The migration limits for 19 elements were based on a report by the Dutch National Institute for Public Health and the Environment (RIVM) entitled "Chemicals in Toys - A general methodology for assessment of chemical safety of toys with a focus on elements" published in 2006 which can be downloaded here: http://www.rivm.nl/bibliotheek/rapporten/320003001.pdf

The report made assumptions regarding the ingested amounts of toy materials. However, there was an inconsistency in the original report. Whilst tables included in chapter 8 assumed that a child would ingest 100 mg/day of dry, brittle, powder-like or pliable toy material, 400 mg/day of liquid or sticky toy material and 8 mg/day of scraped-off toy material, the text in chapter 3 indicated that the ingested amounts for the first two categories were not per day but per week. An erratum was published with corrected tables in January 2015. Consequently, the Commission asked the scientific committee SCHER for advice on whether the limits for elements in the TSD would have to be changed. However, SCHER in its opinion on "Estimates of the amount of toy materials ingested by children" published in April 2016 did not follow the RIVM arguments and stated that the current estimated ingestion amounts are still appropriate. The opinion can be found here:
http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_170.pdf

The chemical requirements of the revised legislation have been subject of debate since the adoption of the revised directive. The Scientific Committee on Health and Environmental Risks (SCHER) particularly questioned the limits for CMR substances and called for eliminations of non-threshold CMRs from toys. This opinion (July 2010) can be found here:
http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_121.pdf

Some limits seem to be outdated by now. As regards lead, the Commission suggested a reduction of the limits by a factor of about 7 based on an opinion of the European Food Safety Agency (EFSA) issued in 2015, and proposed a draft measure that did not get enough support from the Member States. However, the Council endorsed the proposal in 2016.

In another opinion (January 2015), SCHER also called for significantly reduced limits for Chromium VI:
http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_167.pdf

Further opinions of SCHER concerning chemicals in toys can be found on the SCHER website:
http://ec.europa.eu/health/scientific_committees/environmental_risks/opinions/index_en.htm

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 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 the human health and stated "(88) With regard to nitrosamines and nitrosatable substances, the Commission agrees that exposure parameters with regard to children's mouthing behaviour where not appropriately considered when establishing limit values in the Directive. The Commission will require asked CEN to consider these parameters to lower the limit values within the standardisation process".

NOTE This position was taken into account in the revision of EN 71–12 (see 1.6.2.1)

Thus, the Commission considered that the German request was based on a real concern with regard to children's health, and do not constitute a disguised restriction on trade between Member States. The document can be accessed under the following link: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012D0160&rid=1

Hence, the requirements included in the TSD need to be taken with some caution, e.g. when making use of the requirements in similar areas (other articles for children).

1.7 Food Contact Materials Regulation (FCM)

Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food (FCM) is a framework regulation. It sets up general requirements for all food contact materials.

Consolidated versions of the FCM framework regulation can be found here:
http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:32004R1935

For the groups of materials and articles listed in Annex I of the Regulation, "specific measures" may be adopted by the Commission (Article 5). It includes: active and intelligent materials and articles, adhesives, ceramics, cork, rubbers, glass, ion-exchange resins, metals and alloys, paper and board, plastics, printing inks, regenerated cellulose, silicones, textiles, varnishes and coatings, waxes and wood.

For some of these materials "specific measures" have been adopted.

An overview including links to the various legal texts is provided here:
http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation/index_en.htm

1.7.1 Key elements of the FCM legislation relevant for chemicals in articles

The FCM provides that under normal or foreseeable conditions of use, materials and articles shall not transfer their constituents to food in quantities, which could:

— endanger human health; or

— bring about an unacceptable change in the composition of the food; or

— bring about deterioration in the organoleptic characteristics thereof.

NOTE Excluded from the scope is fixed public or private water supply equipment.

The "specific measures" cover the following:

o **Ceramics** (Council Directive 84/500/EEC) containing requirements for the migration of lead and cadmium. The limit depends on the type of food contact material.

NOTE In 2012, the European Commission (EC) initiated a revision of the Directive with a view to significantly reduce the limit values for the migration of lead (by a factor of 400) and cadmium (reduction by factors between 50 and 70). However, the process seems to have come to a halt.

o **Elastomers and rubbers** (Commission Directive 93/11/EEC) containing migration limits for N-nitrosamines and N-nitrosatable substances for parts of teats or soothers made of elastomer or rubber (0,01 mg in total of N-nitrosamines released/kg, 0,1 mg in total of N-nitrosatable substances/kg).

o **Regenerated cellulose film** (Commission Directive 2007/42/EC) containing a list of substances that are authorized in the manufacture of uncoated and coated regenerated cellulose films (positive list).

o **Active and intelligent materials** (Commission Regulation 450/2009/EC) providing that a Community list of authorized substances should be drawn up by the Commission after the completion of the safety assessment of all substances for which a valid application was submitted. Substances can also be used even though they are not on the list of authorized substances subject to conditions, i.e. if they are not in direct contact with food ("functional barrier"), migration in food is equal or less than 0,01 mg/kg and provided they are not classified as "mutagenic", "carcinogenic", or "toxic to the reproduction" in accordance with the criteria set out in sections 3.5, 3.6 and 3.7 of Annex I to Regulation (EC) No 1272/2008 and are not nanoparticles.

- **Plastic materials** (Commission Regulation (EU) No 10/2011) containing in Annex 1 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). Consolidated versions of this Regulation can be found here: http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:32011R0010

Substances not listed in Annex I including polymer production aids, colorants and solvents may additionally be used and may be subject to national law. All salts of the cations in Annex II of authorized acids, phenols or alcohols are permitted although not specifically listed. With the exemption of CMR and non-authorized substances in nano-form, non-listed substances can be used behind a functional barrier, under the condition that the migration is equal to or less than 0,01 mg/kg in food. All used substances which are not included in Annex I shall be assessed in accordance with internationally recognized scientific principles on risk assessment to demonstrate compliance with Article 3 of Regulation (EC) No 1935/2004

Substances permitted in Annex I or II can be subject to a specific migration limit (SML) or maximum permitted quantity of the substance in the finished material (QM). In some cases groups of permitted substances belong to the same SML/QM (SML-T; QM-T).

The inertness of all plastics food contact materials in general is measured by the overall migration limit of 10 mg/dm^2 of the finished packaging surface resp. 60 mg/kg food for materials and articles intended to be brought into contact with food intended for infants and young children.

Annex II contains restrictions for some cations (Aluminium, Barium, Cobalt, Copper, Iron, Lithium, Manganese, Zinc) and primary aromatic amines.

- **Vinyl chloride monomer** (Council Directive 78/142/EEC) containing a limit value for the maximum vinyl chloride monomer level in food contact materials of 1 mg/kg.

- **Plasticizers in gaskets in lids** (Commission Regulation 372/2007/EC) containing specific migration limits for seven different plasticizers from gasket in lids into food.

- **Recycled plastics** (Commission Regulation 282/2008/EC) setting requirements for recycled plastics to be used in food contact materials and introducing an authorization procedure of recycling processes used in the manufacture of recycled plastics for food contact use.

- **Certain epoxy derivatives** (Commission Regulation (EC) No 1895/2005) containing migration limits for BADGE (Bisphenol A diglycidyl ether) and banning the use or presence of BFDGE (Bisphenol F diglycidyl ether) and NOGE (novolac glycidyl ethers).

1.7.2 Associated standards

Around 50 normative documents (non-harmonized standards, technical specifications and technical reports) have been prepared by CEN/TC 194 "Utensils in contact with food" providing test methods. A list is available here: http://standards.cen.eu/dyn/www/f?p=204:105:0 (select CEN/TC 194 from committee list)

1.7.3 Remarks on FCM legislation

Of the 17 materials listed in Annex I of the Regulation, only 4 have had EU measures developed for them. The rest can be addressed through national requirements. While plastic materials are extensively regulated (except colourants and solvents), specific requirements for other materials are missing (e.g. for paper and board, printing inks, metals, coatings). In addition, some rules are outdated (metal migration from ceramics). A "roadmap" published by the Commission in 2012 announced an impact

assessment and corresponding consultations concerning non-plastics materials but this was put on hold and the envisaged revision of the Ceramics Directive is still pending (see also 2.9). The Regulation has recently come under scrutiny again, particularly in the context of the EU's Circular Economy package and efforts to ensure higher levels of quality recycling, and in relation to endocrine-disruptors found in certain FCM materials. The European Commission's Joint Research Centre is expected to produce in a study to provide a comprehensive overview of the current situation concerning FCMs for which no specific measures are in place at EU level (to be reviewed in final version).

In 2014, a study entitled "*Food contact substances and chemicals of concern: a comparison of inventories*" was published identifying 175 chemicals of concern in food packaging:
http://www.tandfonline.com/doi/full/10.1080/19440049.2014.931600#.VPiPuLFSnap

1.8 Packaging and Packaging Waste Directive

Directive 94/62/EC on packaging and packaging waste lays down measures aimed at

— preventing the production of packaging waste;

— reusing packaging, recycling, and other forms of recovering packaging waste and, hence, at reducing the final disposal of such waste.

Consolidated versions of the Packaging Directive can be found here:
http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:31994L0062

1.8.1 Key elements of the Packaging Directive relevant for chemicals in articles

The Packaging Directive sets targets for recovery and recycling of packaging waste provision for return/collection of used packaging/packaging waste, reuse, recovery, or recycling in order to be able to meet the set targets.

According to Article 11, Member States shall ensure 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.

Packaging shall comply with the essential requirements defined by this Directive, including those set out in Annex II. One of these essential requirements relates to chemicals:

"Packaging shall be so manufactured that the presence of noxious and other hazardous substances and materials as constituents of the packaging material or of any of the packaging components is minimized with regard to their presence in emissions, ash or leachate when packaging or residues from management operations or packaging waste are incinerated or landfilled".

1.8.2 Associated standards

The latest list of harmonized standards can be found here: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/packaging/index_en.htm

There are two harmonized standards addressing chemicals:

— EN 13428:2004 "Packaging - Requirements specific to manufacturing and composition - Prevention by source reduction";

— EN 13432:2000 "Packaging - Requirements for packaging recoverable through composting and biodegradation - Test scheme and evaluation criteria for the final acceptance of packaging".

In addition, there are two technical reports:

— CR 13695-1:2000 "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";

— CEN/TR 13695-2:2004 "Packaging – Requirements for measuring and verifying the four heavy metals and other dangerous substances present in packaging and their release into the environment – Part 2: Requirements for measuring and verifying dangerous substances present in packaging and their release into the environment".

EN 13428 (prevention) describes *inter alia* the methodology and procedure for determining the presence of the four heavy metals and for determining the presence and minimization of any dangerous substances or preparations if they are present in packaging and are likely to be released into the environment as a result of waste management operations. The procedures contained in CR 13695-1 and CEN/TR 13695-2 referred to. The key requirements regarding chemicals in this standard are:

— The supplier shall be able to demonstrate that the substances or preparations classified as dangerous to the environment and assigned with the symbol 'N' present in the packaging components have been minimized (if they are likely to be present in emissions, ash or leachate when packaging residues from management operations or packaging waste are incinerated or landfilled). Using the minimum adequate amount of a substance has to be established in relation to the functional performance or purpose of the substance. The process of how minimization is achieved shall be documented.

NOTE The N-classification refers to a category of substances classified as dangerous to the environment and requiring labelling according to the Dangerous Substances Directive that became obsolete in June 2015. It is replaced with the new Classification, Labelling and Packaging (CLP) Regulation EC 1272/2008. The new Regulation does not contain any corresponding N-classification, but it provides corresponding requirements and criteria for labelling with Hazard pictograms. Work is on-going to update the standards accordingly.

— The supplier shall be able to demonstrate that the presence of the four named heavy metals (lead, cadmium, mercury, and hexavalent chromium) in the packaging components does not exceed the specified limits. Shall be measured, calculated, or via upstream information.

EN 13432 (composting and biodegradation) establishes *inter alia* limits for certain elements in packaging as shown in Table 12.

Table 12 - Limits for certain elements from EN 13432

Element	mg/kg on dry substance	Element	mg/kg on dry substance
Zn	150	Cr	50
Cu	50	Mo	1
Ni	25,0	Se	0,75
Cd	0,5	As	5
Pb	50	F	100
Hg	0,5		

The limits are based on limits set in the EU Ecolabel criteria for soil improvers in 1998 and are set at 50 % of the maximum concentration of those requirements assuming that 50 % of the original weight of the packaging or packaging material will remain in compost after biological treatment together with the complete original amount of hazardous substances. These limits are still valid (Commission Decision (EU) 2015/2099 concerning EU Ecolabel criteria for growing media, soil improvers and mulch).

1.8.3 Remarks on the Packaging Directive

Regulatory limits exist for a limited number of metals in packaging (Pb, Cd, Hg, Cr VI). The limits are set as a sum parameter although the various elements are different in terms of toxicity (while 100 ppm seems an adequate limit for lead it would be a rather high concentration for chromium VI). In addition, additional limits for certain elements have been included in the harmonized standard for compostable and biodegradable packaging. The required minimization of hazardous substances relates to "*their presence in emissions, ash or leachate when packaging or residues from management operations or packaging waste are incinerated or landfilled*". Consumers' safety and health are out of the scope of the Directive.

The minimization imperative included in the essential requirements concerning the presence of noxious and other hazardous substances is further detailed in EN 13428, however, this standard does not include any limits for chemical substances.

In 2013, the EU Parliament (Rapporteur: MEP Margrete Auken) called for a revision of the Packaging Directive with respect to lightweight plastic bags asking also for the inclusion of the following requirement: *"Member State shall ensure that packaging is manufactured in such a way that it does not contain substances in concentrations above 0,01 % that are carcinogenic, mutagenic or toxic to reproduction or that are endocrine disrupters"*. It was removed later in the negotiations between the Council and the Parliament.

1.9 Restriction of Hazardous Substances (RoHS) Directive

Directive 2011/65/EU on the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment established limits for chemicals in a broad range of products "*with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE*".

Consolidated versions of the RoHS Directive can be found here:
http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:32011L0065

1.9.1 Key elements of the RoHS Directive relevant for chemicals in articles

According to Annex II in its original form, maximum concentration values tolerated by weight in homogeneous materials were given for the following restricted substances:

— Lead (0,1 %);

— Mercury (0,1 %);

— Cadmium (0,01 %);

— Hexavalent chromium (0,1 %);

— Polybrominated biphenyls (PBB) (0,1 %);

— Polybrominated diphenyl ethers (PBDE) (0,1 %).

Annex II may be amended by the Commission by means of delegated acts, based on a thorough assessment, taking into account e.g. negative impacts of substances during EEE waste management operations or unacceptable exposure of workers involved in the waste EEE collection or treatment processes. The preamble (recital 10) proposes to consider an assessment of the substances Hexabromocyclododecane (HBCDD), Bis (2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutyl phthalate (DBP) as a priority for restrictions. This has been accomplished meanwhile. HBCDD was banned in the POP Regulation with a threshold of 0,01 %, (see 1.4.1) and the listed phthalates were included with a threshold of 0,1 % in Annex II (see 1.9.3).

According to Article 6: *"a review, based on a thorough assessment, and amendment of the list of restricted substances in Annex II shall be considered by the Commission before 22 July 2014, and periodically thereafter on its own initiative or following the submission of a proposal by a Member State (…)"*.

Derogations may be granted subject to several conditions where: compliance is "*scientifically or technically impracticable*"; the reliability of substitutes is not ensured; and negative health, environment and safety impacts outweigh positive ones. Further criteria include the socioeconomic impact of substitution and adverse impacts on innovation. Exemptions are listed in Annexes III and IV.

1.9.2 Associated standards

The latest list of harmonized standards can be found here:
http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/restriction-of-hazardous-substances/index_en.htm

Only one harmonized standard has been published:

— EN 50581:2012 "Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances".

A non-harmonized standard which may be interesting in the context of the current study is:

— EN 62474:2012 "Material declaration for products of and for the electrotechnical industry".

This standard 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: http://std.iec.ch/iec62474

A series of standards has been prepared by IEC/TC 111 "Environmental standardization for electrical and electronic products and systems" and has been adopted as European standards series (EN 62321) which are dealing with the analytical determination of certain substances:
http://www.iec.ch/dyn/www/f?p=103:22:0::::FSP_ORG_ID:1314

1.9.3 Remarks on the RoHS Directive

The number of restricted substances in the RoHS Directive is somewhat limited. Even the preamble of the Directive identifies several substances, which should be assessed as a matter of priority: Hexabromocyclododecane (HBCDD), Bis (2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutyl phthalate (DBP).

Several studies have been conducted to identify further relevant chemicals in EEE, however haven't yet led to a revision of the Directive. Some of the key studies are indicated in the following:

The German Öko-Institut conducted a study entitled "Study on Hazardous Substances in Electrical and Electronic Equipment, Not Regulated by the RoHS Directive" (October 2008). It was published before the recast of the ROHS 1 Directive and recommended - in addition to the substances mentioned above - a ban of TBBP-A (tetrabromo bisphenol A) due to formation of dangerous degradation/reaction products during the collection and treatment of EEE. Further, Öko-Institut recommended to phase out organobromine and organochlorine substances and PVC. The study covers a number of other substances (such as chlorinated paraffins, beryllium, beryllium oxide, antimony trioxide). The study is available here: http://ec.europa.eu/environment/waste/weee/pdf/hazardous_substances_report.pdf

The Environment Agency Austria conducted a study entitled "Study for the review of the list of restricted Substances under RoHS 2" (January 2014). It consists of a methodology to identify and assess substances based on the criteria in Recital 10 and Article 6(1) and 6(2) of RoHS2 and to assess the substances addressed in Recital 10 of RoHS 2 with a view to their future restriction. An overview is

given on the website of the Commission:
http://ec.europa.eu/environment/waste/rohs_eee/review/index_en.htm

The results are available on the website of the Environment Agency Austria:
http://www.umweltbundesamt.at/rohs2

The substances were divided into 4 priority categories.

Eight substances were identified to be of highest priority:

— the 4 phthalates Di-(2-ethylhexyl)phthalate (DEHP), Di-n-butyl phthalate (DBP), Butyl benzyl phthalate (BBP) and Diisobutyl phthalate (DiBP);

— the chlorinated flame retardant tris(2-chloroethyl)phosphate;

— the 2 brominated flame retardants Hexabromocyclododecane (HBCDD) and 2,3-dibromo-1-propanol;

— Dibromoneopentyl-glycol.

Four substances were identified to be of the second highest priority:

— Antimony trioxide;

— Diethyl phthalate (DEP);

— Tetrabromobisphenol A (TBBPA);

— Medium-chain chlorinated paraffins.

The polymer PVC was classified to be of the third highest priority, in particular because of its high waste relevance.

Five substances were identified to be of the fourth highest priority:

— the Be-(compounds): beryllium metal and beryllium oxide (BeO);

— the Ni-compounds: nickel sulphate and nickel sulfamate (=Nickel bis sulfamidate);

— Indium phosphide.

Four substances were identified to be of the fifth highest priority:

— the two As-compounds di-arsenic pentoxide; (i.e. Arsenic pentoxide; Arsenic oxide) and di-arsenic trioxide (i.e. Arsenic trioxide);

— the two Co-compounds cobalt dichloride and cobalt sulfate.

Two substances were identified to be of the sixth highest priority:

— Cobalt metal;

— Nonylphenol.

Detailed assessments of the substances HBCDD, DEHP, BBP and DBP are provided.

An additional study was performed by Öko-Institut and Eunomia, and is entitled “Study for the Review of the List of Restricted Substances under RoHS 2. Analysis of Impacts from a Possible Restriction of Several New Substances under RoHS 2” (May 2014). The aim is to provide input concerning

quantitative usage data for the 21 priority substances in EEE identified by the Austrian EPA, or where this is not possible, a magnitude ranking, with a view to a refined prioritization for future review cycles.

This study is available here:
http://rohs.exemptions.oeko.info/fileadmin/user_upload/reports/20140604_Substance_Review_plus_Dossier_final.pdf

It included also a RoHS Annex II Dossier for DIBP:
http://rohs.exemptions.oeko.info/fileadmin/user_upload/reports/20140520_DIBP_AnnexII_Dossier_final.pdf

In March 2015, Annex II of the Directive was amended and the phthalates DEHP, BBP, DBP and DiBP were banned (threshold 0,1 %). However, the ban is applicable for some devices only from July 2021:
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015L0863

It remains to be seen whether additional substances will be proposed for restriction by the Commission.

The Swedish Chemicals Agency (Kemi) intends to prepare a RoHS Annex II dossier for the restriction of the use of medium-chain chlorinated paraffins (MCCPs) in electrical and electronic equipment, in accordance with Article 6(1) of the Directive and has commissioned a study on the subject:
http://rpaltd.co.uk/projects/mccp

1.10 Ecodesign Requirements for Energy Related Products (ErP) Directive

Directive 2009/125/EC (ErP) provides a framework for the setting of ecodesign requirements for energy-related products covered by implementing measures. Products covered shall fulfil those requirements in order to be placed on the market and/or put into service.

The term "Energy-related product" is defined as "*any good that has an impact on energy consumption during use which is placed on the market and/or put into service, and includes parts intended to be incorporated into energy-related products covered by this Directive which are placed on the market and/or put into service as individual parts for end-users and of which the environmental performance can be assessed independently*".

Consolidated versions of the ErP Directive can be found here: http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:32009L0125

1.10.1 Key elements of the ErP Directive relevant for chemicals in articles

According to Article 15 4. (a), the Commission, in preparing a draft implementing measure, shall "*consider the life cycle of the product and all its significant environmental aspects, inter alia, energy efficiency. The depth of analysis of the environmental aspects and of the feasibility of their improvement shall be proportionate to their significance*". While the ErP states that all significant environmental aspects should be taken account, the focus so far has been put on energy consumption.

A list of adopted implementing measures and voluntary agreements can be found here:
https://ec.europa.eu/energy/sites/ener/files/documents/list_of_ecodesign_measures.pdf

The implementing measures for non-directional household lamps (Commission Regulation (EC) No 244/2009), for fluorescent lamps without integrated ballast, for high intensity discharge lamps, and for ballasts and luminaires able to operate such lamps (Commission Regulation (EC) No 245/2009) and for directional lamps, light emitting diode lamps and related equipment (Commission Regulation (EU) No 1194/2012) identify the mercury content a significant environmental aspect. It is stated that this issue is considered to be regulated under Directive 2002/95/EC. However, the implementing measures include the requirement that the amount of mercury contained in the lamps shall be stated on the packaging in mg Hg. The implementing measure for televisions (Commission Regulation (EC) No 642/2009) extends this labelling requirement to lead.

1.10.2 Associated standards

The latest lists of harmonized standards complementing implementing measures can be found here: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/ecodesign/index_en.htm

The harmonized standards are not related to chemicals.

1.10.3 Remarks on the ErP Directive

Current implementing measures do not address chemical in energy-related products. However, Article 21 of the Directive requires that, by 2012: "*the Commission shall assess, notably, the appropriateness of extending the scope of the Directive to non-energy-related products, in order to significantly reduce environmental impacts throughout such products' whole life-cycle*". A broadening of the scope of the Directive would thus shift the focus from energy consumption to other environmental issues.

1.11 Batteries Directive

Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators prohibits the marketing of batteries containing some hazardous substances, defines measures to establish schemes aiming at a high level of collection and recycling, and fixes targets for collection and recycling activities. The Directive also sets out provisions on labelling of batteries and their removability from equipment.

Consolidated versions of the Directive can be found here:
http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:32006L0066

1.11.1 Key elements of the Batteries Directive relevant for chemicals in articles

The Directive applies to all types of batteries and accumulators (professional and consumer uses), apart from those used e.g. in equipment to protect Member States' security or for military purposes, or in equipment designed to be sent into space. The Directive (Article 4) prohibits:

— batteries and accumulators, whether or not incorporated in appliances, containing more than 0,000 5 % by weight of mercury (except for button cells, which are allowed to have a mercury content of up to 2 % by weight until 1 October 2015);

— portable batteries and accumulators, including those incorporated in appliances, with a cadmium content by weight of more than 0,002 % (except for portable batteries and accumulators for use in emergency and alarm systems, medical equipment or – until 31 December 2016 – in cordless power tools).

Examples of portable batteries and accumulators, which are all-sealed batteries and accumulators that an average person could carry by hand without difficulty and that are neither automotive batteries or accumulators nor industrial batteries or accumulators, include single cell batteries (such as AA and AAA batteries) and batteries and accumulators used by consumers or professionals in mobile telephones, portable computers, cordless power tools, toys and household appliances such as electric toothbrushes, razors and hand-held vacuum cleaners (including similar equipment used in schools, shops, restaurants, airports, offices or hospitals) and any battery or accumulator that consumers may use for normal household applications.

Batteries, accumulators and button cells containing more than 0,000 5 % mercury, more than 0,002 % cadmium or more than 0,004 % lead, shall be marked with the chemical symbol for the metal concerned: Hg, Cd or Pb (subject to further provisions).

1.11.2 Associated standards

None.

1.11.3 Remarks on the Batteries Directive

No remarks.

1.12 Low Voltage Electrical Equipment Directive (LVD)

Directive 2014/35/EU relating to the making available on the market of electrical equipment designed for use within certain voltage limits aims "*to ensure that electrical equipment on the market fulfils the requirements providing for a high level of protection of health and safety of persons, and of domestic animals and property, while guaranteeing the functioning of the internal market*". The applies to electrical equipment designed for use with a voltage rating of between 50 V and 1 000 V for alternating current and between 75 V and 1 500 V for direct current.

Consolidated versions of the Directive are available here:
http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:32014L0035

1.12.1 Key elements of the LVD relevant for chemicals in articles

Annex I of the LVD includes "*principal elements of the safety objectives*". Chemical hazards are not explicitly referred to.

1.12.2 Associated standards

Several hundred harmonized standards are associated with this Directive. The latest list of harmonized standards can be found here: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/low-voltage/index_en.htm

Those standards do not specifically address hazardous chemicals. For example, the standard series EN 60335 addresses household and similar electrical appliances. Its first part, EN 60335-1:2012 "Household and similar electrical appliances – Safety – Part 1: General requirements" includes a clause (32) entitled "Radiation, toxicity and similar hazards" which reads: "*Appliances shall not emit harmful radiation or present a toxic or similar hazard due to their operation in normal use*". In theory, the specific standards (Part 2 standards) could potentially set such limits.

1.12.3 Remarks on the LVD

The LVD and associated standards do not specifically address chemicals. Chemical requirements for the product group in question are set in the RoHS Directive.

1.13 Radio Equipment Directive (RED)

Directive 2014/53/EU on radio equipment establishes requirements to ensure:

— the protection of health and safety of persons and of domestic animals and the protection of property, including the objectives with respect to safety requirements set out in Directive 2014/35/EU, but with no voltage limit applying;

— an adequate level of electromagnetic compatibility as set out in Directive 2014/30/EU.

Typical products which are covered by the Directive include radio-terminals (e.g. GSM handsets); other radio equipment (e.g. GSM base stations, car-door openers and other short range radio devices); fixed network terminal equipment (e.g. normal analogue telephones, ISDN terminals, cable and PC modems).

Consolidated versions of the Directive are available here:
http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1426089737877&uri=CELEX:32014L0053

1.13.1 Key elements of the RED relevant for chemicals in articles

There are only the generic health and safety provisions mentioned in the previous clause. No specific provisions relate to chemicals.

1.13.2 Associated standards

There are more than 60 harmonized standards not related to chemical safety. The latest list of harmonized standards can be found here: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/rtte/index_en.htm

At the time of writing, a draft mandate on RED is under preparation by the Commission and should request the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI), to draft harmonized standards for radio equipment, in support of the implementation of Article 3 of RED.

1.13.3 Remarks on the Radio Equipment Directive

The Radio Equipment Directive and associated standards do not specifically address chemicals. Chemical requirements for the product group in question are set in the ROHS Directive.

1.14 Personal Protective Equipment (PPE) Directive

Directive 89/686/EEC relating to personal protective equipment provides that PPE may be placed on the market and brought into service if it preserves the health and ensures the safety of users. PPE are considered as products that the user can wear or hold, in order to be protected against hazards either at home, at work or whilst engaging in leisure activities.

Consolidated versions of the Directive can be found here:
http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:31989L0686

A revised PPE Regulation was published in March 2016 (Regulation (EU) 2016/425). This Regulation can be found here: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0425

Directive 89/686/EEC is repealed with effect from 21 April 2018.

1.14.1 Key elements of the PPE Directive/Regulation relevant for chemicals in articles

PPE covered by the Directive shall satisfy the basic health and safety requirements laid down in Annex II (Article 3). This includes general requirements applicable to all PPE as well as additional requirements common to several types of PPE or to particular risks.

The relevant requirement as regards chemicals is included in section I (general requirements). Clause 1.2. is entitled “Innocuousness of PPE”. It includes provision 1.2.1. “*Absence of inherent risks and other nuisance factors*”: PPE shall be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use. One sub clause is 1.2.1.1.” Suitable constituent materials”: the materials of which the PPE is made, including any of their possible decomposition products, shall not adversely affect the health or safety of users. The new PPE Regulation includes identical requirements.

The Directive is complemented by the “PPE Guidelines”. The latest version of the document (October 2015) is available here:
http://ec.europa.eu/DocsRoom/documents/9214/attachments/1/translations/en/renditions/native

These guidelines are intended to be a manual for all parties directly or indirectly affected by the Directive and to facilitate the application of the Directive. They are, of course, not legally binding. The have been prepared by the relevant services of the European Commission in collaboration with Member States, European industry, European standardization and Notified Bodies.

Regarding the above mentioned clause of Annex II (1.2.1.1.), the following clarification is provided: "*The constituent materials cannot (in the foreseeable conditions of normal use), release or degrade to release substances generally known to be toxic, carcinogenic, mutagenic, allergenic, teratogenic or otherwise harmful*". Examples are given of possible documents to demonstrate conformity to this requirement (e.g. safety data sheets, test reports, etc.). Further, the following statement is made: "*Particular attention should be paid to the presence of plasticizers, unreacted components, heavy metals, impurities and the chemical identity of pigments and dyes*". Finally, reference is made to legislation concerning the protection of workers and relating to chemicals applicable at the time.

1.14.2 Associated standards

About 300 standards have been adopted. The latest list of harmonized standards can be found here: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/personal-protective-equipment/index_en.htm

Some of these standards include a few chemical requirements, including:

— EN 420:2003+A1:2009 "Protective gloves – General requirements and test methods" establishes a limit for the content of chromium VI in gloves of 3 mg/kg (this limit is meanwhile also a REACH Annex XVII requirement);

— EN 1077:2007 "Helmets for alpine skiers and snowboarders" requires: "*For those parts of the helmet coming into contact with the skin the material used shall not be subject to any known appreciable alteration from contact with sweat or with substances likely to be found in toiletries. Materials shall not be used which are known to cause skin disorders or other adverse effects on health. For a material not in general use advice as to its suitability shall be sought before its introduction*" and reproduces some text of the PPE Guidelines;

— EN 1078: 2012+A1:2012 "Helmets for pedal cyclists and for users of skateboards and roller skates" provides: "*For those parts of the helmet coming into contact with the skin, the material used should be known not to undergo appreciable alteration from contact with sweat or with substances likely to be found in toiletries. Materials shall not be used which are known to cause skin disorders*";

— EN ISO 13688:2013 "Protective clothing - General requirements" reproduces widely the text of the PPE Guidelines on chemicals mentioned above and establishes a limit for the content of chromium VI of 3 mg/kg (this limit is meanwhile also a REACH Annex XVII requirement) as well as nickel release from metals and carcinogenic amines from azo colorants (in line with existing REACH Annex XVII requirements);

— EN ISO 20345:2011 "Personal Protective Equipment - Safety footwear" establishes a limit for the content of chromium VI in various parts of footwear containing leather of 3 mg/kg (this limit is meanwhile also REACH Annex XVII requirement).

1.14.3 Remarks on the PPE Directive

Chemical requirements in the PPE Directive are addressed through a generic sentence, and the supporting PPE Guidelines do not provide clear-cut recommendations. The requirements found in several harmonized standards are either just reflecting legal limits or are generic ("*materials shall not be used which are known to cause skin disorders*").

1.15 Construction Products Regulation (CPR)

Regulation (EU) No 305/2011 laying down harmonized conditions for the marketing of construction products establishes harmonized rules on how to express the performance of construction products in relation to their essential characteristics.

Consolidated versions of the Directive can be found here:
http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:32011R0305

1.15.1 Key elements of the CPR relevant for chemicals in articles

Unlike other Directives or Regulations for products, the CPR does not establish performance requirements for construction products. Member States retain their competence to set technical requirements for the performance of construction products, in particular for specific uses of the products in a building or civil engineering work (e.g. fire safety requirements for escape routes). Such requirements shall be based on performance characteristics measured or calculated in accordance with harmonized European standards or European Assessment Documents ("harmonised technical specifications"), which provide a technical basis to assess the performance of construction products. They enable manufacturers to draw up the Declaration of Performance as defined in the CPR, and affix the CE marking.

The harmonized technical specifications should address the "*basic requirements for construction works*" listed in Annex I. The "essential characteristics" of construction products are supposed to reflect the basic requirements for construction works. The Commission may adopt delegated acts to establish classes of performance in relation to the essential characteristics of construction products. Classes and thresholds may be also set by European Standards Organisations (ESOs) based on mandates.

One of the "Basic requirements for construction works" – "3. Hygiene, health and the environment" - covers chemicals:

"*The construction works shall be designed and built in such a way that they will, throughout their life cycle, not be a threat to the hygiene or health and safety of workers, occupants or neighbours, nor have an exceedingly high impact, over their entire life cycle, on the environmental quality or on the climate during their construction, use and demolition, in particular as a result of any of the following:*

(a) the giving-off of toxic gas;

(b) the emissions of dangerous substances, volatile organic compounds (VOC), greenhouse gases or dangerous particles into indoor or outdoor air;

(c) the emission of dangerous radiation;

(d) the release of dangerous substances into ground water, marine waters, surface waters or soil;

(e) the release of dangerous substances into drinking water or substances which have an otherwise negative impact on drinking water;

(f) faulty discharge of waste water, emission of flue gases or faulty disposal of solid or liquid waste;

(g) dampness in parts of the construction works or on surfaces within the construction works".

In principle, the harmonized European Technical Specifications should take on board current regulations on chemicals, which exist in Member States.

The manufacturers do not need to declare the content or emissions of chemicals if there is no national legislation, which sets requirements for these substances. In such cases, the manufacturer may make use of the so-called "No Performance Determined" (NPD) option, unless the declaration is required based on a decision of the Commission by means of delegated acts in accordance with Article 3(3).

According to Article 6(5), the declaration of performance shall be accompanied by information on the content of hazardous substances in the construction product in order to improve the possibilities for sustainable construction and to facilitate the development of environment-friendly products. Information on the content of hazardous substances should initially be limited to substances referred to in Articles 31 (substances or mixtures) and 33 (articles) of REACH.

In addition, Article 67 states: "*By 25 April 2014, the Commission shall assess the specific need for information on the content of hazardous substances in construction products and consider the possible*

extension of the information obligation provided for in Article 6(5) to other substances, and shall report thereon to the European Parliament and to the Council. In its assessment, the Commission shall take into account, inter alia, the need to ensure a high level of protection of the health and safety of workers using construction products and of users of construction works, including with regard to recycling and/or reuse requirements of parts or materials. If appropriate, the report shall, within 2 years of its submission to the European Parliament and to the Council, be followed up by appropriate legislative proposals".

A study "Study on specific needs for information on the content of dangerous substances in construction products" was published in October 2013:
http://ec.europa.eu/DocsRoom/documents/4456/attachments/1/translations/en/renditions/native

In August 2014, in its report to the European Parliament and the Council, the Commission concluded: "*The European Commission considers therefore that for the purpose of consolidating the Internal Market for construction products within the framework of the implementation of Regulation (EU) 305/2011 the specific needs for information on the content of hazardous substances in construction products, are sufficiently addressed by the current provisions of the CPR, in particular Article 4 in combination with Article 6(5)*". This report is available here: http://www.ipex.eu/IPEXL-WEB/dossier/document/COM20140511.do

The Commission is considering the possibility of a common reporting format for emissions into indoor air. A proposal to this end entitled "Harmonized EU VOC-Classes" was presented in December 2014. It is based on existing VOC classification systems in France and Germany. The recently introduced regulation in Belgium is based on the German AgBB scheme.

1.15.2 Associated standards

The latest list of harmonized standards can be found here: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/construction-products/index_en.htm

The first generation of standards for construction products based on mandates given under the former Construction Products Directive (Council Directive 89/106/EEC), do not address dangerous substances. Warnings are included in the "Annex ZA" that additional requirements regarding dangerous substances may apply and should be complied with.

A "Guidance Paper H" entitled "A harmonised approach relating to dangerous substances under the Construction Products Directive" was first published in December 1999. A revised edition was published in September 2002. The document was aimed at those involved in the writing of technical specifications. They were advised to check existing national regulations and to incorporate provisions in the specifications accordingly. However, this approach proved difficult and, thus, only a limited number of standards included provisions for a few substances. As an example, some standards included requirements for formaldehyde (defining classes E1 and E2) and pentachlorophenol, including:

— EN 13986:2004+A1:2015 "Wood-based panels for use in construction - Characteristics, evaluation of conformity and marking";

— EN 14041:2004+ AC:2005-05+AC:2005-11+AC:2006 "Resilient, textile and laminate floor coverings – Essential characteristics";

— EN 14342:2013 "Wood flooring and parquet - Characteristics, evaluation of conformity and marking";

— EN 14904:2006 "Surfaces for sports areas - Indoor surfaces for multi-sports use – Specification";

— EN 14915:2013: "Solid wood panelling and cladding - Characteristics, evaluation of conformity and marking".

Another example is EN 14411:2012 “Ceramic tiles - Definitions, classification, characteristics, evaluation of conformity and marking” that establishes measurement requirements on the release of cadmium and lead (measured in accordance with EN ISO 10545-15).

A more comprehensive list of metals is required to be tested in addition to formaldehyde in EN 15102:2007+A1:2011 “Decorative wall coverings - Roll and panel form”, including antimony, arsenic, barium, cadmium, chromium, lead, mercury, and selenium.

Based on the advice of the “Experts Group on Dangerous Substances”, the Commission started identifying the relevant substances for the specific product groups and incorporating respective requirements in amended mandates. This is an ongoing process involving the Technical Committees concerned.

In addition, the Commission issued a horizontal mandate for the “Development of horizontal standardised assessment methods for harmonised approaches relating to dangerous substances under the Construction Products Directive (CPD). Emission to indoor air, soil, surface water and ground water” (March 2005). This led to the creation of a Technical Committee in CEN/TC 351 “Construction Products - Assessment of release of dangerous substances” in April 2006. The idea is that the product committees can make use of these horizontal test methods when incorporating requirements relating to dangerous substances in their standards a later stage. CEN/TC 351 has published several Technical Reports and Technical Specifications and a terminology standard. The most relevant documents in the context of the present project are:

— CEN/TR 16045:2010 “Construction Products - Assessment of release of dangerous substances - Content of regulated dangerous substances - Selection of analytical methods”,

— CEN/TR 16496: 2013 “Construction Products - Assessment of release of dangerous substances - Use of harmonised horizontal assessment methods”,

— CEN/TS 16516: 2013 “Construction products - Assessment of release of dangerous substances - Determination of emissions into indoor air”.

NOTE The CEN/TS 16516 is in the process of being transformed into the European standard EN 16516 to be submitted to the Formal Vote in 2017.

Three Technical Specifications were published on leaching tests associated with a number of analytical standards. The methods included in the Technical Specifications were subject to inter-laboratory or round robin testing. Once horizontal test methods are available the product committees will be able to reference them in harmonized product standards incorporating requirements for the declaration of dangerous substances in construction products.

1.15.3 Remarks on the CPR

The CPR does not establish performance requirements for products, including for chemicals. Great efforts are made to establish a harmonized declaration scheme based on Technical Specifications to match existing national regulations with the provisions of the CPR. This means that, in the case of indoor emissions, emissions of volatile substances (VOCs) will need to be declared in future as a basis for facilitating the free circulation of construction products in the EU. At the same time, Member States regulations concerning emissions from construction products will need to be respected (i.e. Germany, France Belgium and in future possibly also Sweden, see 5.6 below) to ensure that only products complying with these regulations will enter the national markets. For all other Member States, no restrictions apply (i.e. construction products can be used irrespective of their emissions). In addition, a manufacturer does not need to declare these emissions based on the NOD option, unless the Commission has established performance classes (in the form of Delegated Acts) that shall be reported in the performance declaration. However, this will be the case once the Delegated Acts on the

classification of performance of construction products in relation to their emissions of dangerous substances into indoor air are adopted.

1.16 Medical Devices Directive

Council Directive 93/42/EEC on medical devices covers products used in the diagnosis, prevention, monitoring, and treatment of diseases and the improvement of the quality of life of people suffering from disabilities. They cover a large spectrum of products, from home-use items like sticking plasters, contact lenses and pregnancy tests to dental filling materials, X-ray machines, pacemakers, breast implants, hip replacements and HIV blood tests. There are around 500 000 or more different types of devices on the market. They are classified in different risk classes (I - low risk, IIa - low to medium risk, IIb - medium to high risk and III – high risk).

Consolidated versions of the Directive can be found here:
http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:31993L0042

1.16.1 Key elements of the Medical Devices Directive relevant for chemicals in articles

Medical devices shall meet the essential requirements contained in Annex 1 of the Directive, i.e. the necessary measures to ensure a high level of safety and performance of these devices. They shall not compromise the clinical condition or the safety of patients, or the health and safety of users, or, where applicable, other persons, when they are used under the conditions and for the purposes intended.

Section II of Annex I includes “Requirements regarding design and construction”. It includes Clause 7 on “Chemical, physical and biological properties”. Some of its key elements regarding chemicals include:

— Particular attention shall be paid to:

  — the choice of materials used, particularly as regards toxicity and, where appropriate, flammability;

  — the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device.

— The devices shall be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention shall be paid to the tissues exposed and to the duration and frequency of exposure.

— The devices shall be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

— If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.

1.16.2 Associated standards

The latest list of harmonized standards can be found here: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices/

Some of the standards seem to be of particular importance in the context of the present study. A key role plays the standard series EN ISO 10993 concerning the biological evaluation of medical devices. It

provides guidance for a risk assessment approach. The most relevant parts in the context of the current study are:

— EN ISO 10993-1:2009+AC:2010 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process";

— EN ISO 10993-7:2008+AC:2009 "Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals";

— EN ISO 10993-17:2009 "Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances".

Other parts address tests for genotoxicity, carcinogenicity and reproductive toxicity (Part 3), tests for local effects after implantation (Part 6), tests for irritation and skin sensitization (Part 10) or chemical characterization of materials (Part 18). Only Part 7 on ethylene oxide establishes limits. In fact, the standard series leaves it largely to industry to assess the chemical safety of medical devices.

The following harmonized standards cover products of particular relevance for consumers including those with disabilities:

— EN ISO 4074:2015 "Natural latex rubber condoms - Requirements and test methods";

— EN ISO 14607:2009 "Non-active surgical implants – Mammary implants";

— EN 12183:2014 "Manual wheelchairs — Requirements and test methods";

— EN 12184:2014 "Electrically powered wheelchairs, scooters and their chargers — Requirements and test methods";

— EN 1985:1998 "Walking aids — General requirements and test methods".

EN ISO 4074:2015 on rubber condoms calls for biocompatibility assessments in accordance with ISO 10993-1 and an evaluation for cytotoxicity according to ISO 10993-5, irritation according to ISO 10993-10, and sensitization (delayed contact hypersensitivity) according to ISO 10993-10 ("*The results shall be interpreted by a qualified toxicologist or any other appropriately qualified expert*").

EN ISO 14607:2009 on mammary implants includes a clause on chemical evaluation (7.2.3) which says that "*shell and filler materials shall be chemically evaluated*". This is further detailed in subclauses with respect to shell materials, silicone elastomers or coated materials that "*an analysis of the extractable or releasable chemicals (especially the characterization and quantification of materials of low molecular mass) is necessary to assess the safety of the device*". With respect to filler materials it is stated that "*a detailed chemical characterization of the filler material shall be established*". Clear-cut requirements are missing.

EN 12183:2014 on manual wheelchairs does not establish chemical requirements either but refers to EN 12182:2012 "Assistive products for persons with disability — General requirements and test methods" (see below) with respect to "biocompatibility and toxicity" as well as "contaminants and residues". The same approach is used in EN 12184:2014 regarding electrically powered wheelchairs. EN 1985 on walking aids also refers to (an older version of) EN 12182.

EN 12182:2012 "Assistive products for persons with disability — General requirements and test methods" is not included in the list of harmonized standards. However, by normative references its requirements become part of harmonized standards and, as a consequence, give a presumption of conformity to the essential requirements of the Directive. The standard includes Clause 5.3 "Biocompatibility and toxicity". It provides that "materials which come into contact with the human body shall be assessed for biocompatibility using the guidance in EN ISO 10993-1". In addition, the following requirement applies: "*The assistive products shall be designed and manufactured in such a way*

as to reduce to a minimum the risks posed by substances leaking from the assistive product. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction and other substances of very high concern (SVHCs). The assessment should follow the guidance given in Annex D".

Annex D "Environmental and consumer related requirements" – although just informative - includes a number of provisions, which are relevant in the context of the present study. Key recommendations include:

— eliminate SVHC wherever possible as soon as practicable;

— avoid CMRs from all three categories – reduce the levels of CMRs as far as technically feasible using a precautionary approach;

— avoid any PBT and vPvB substances exceeding 0,1 % by weight;

— avoid using substances "of equivalent concern" once included in the candidate list in amounts exceeding 0,1 % by weight unless lower levels seem to be warranted;

— textile products or components should comply with the relevant Oeko-Tex® Standard 100 requirements and other ecolabels (e.g. for organic textiles) should be also considered;

— plastic materials should not exceed a limit of 100 ppm for the sum of lead, cadmium, mercury and hexavalent chromium in line with the European Packaging Directive;

— plastic materials should not include polybrominated biphenyls (PBB), polybrominated diphenylether (PBDE) and short-chained chloroparaffins;

— plastic materials should not contain phthalates in quantities higher than 0,1 ppm unless there is evidence that phthalates are necessary on technical grounds and cannot be substituted by other plasticizers;

— metal parts should not be coated with cadmium, chromium, nickel and their compounds (subject to exceptions);

— wood should not release formaldehyde in excess of 0,13 mg formaldehyde/m^3 measured in a test chamber in accordance with EN 717-1 (or comply with equivalent measurements).

1.16.3 Remarks on the Medical Devices Directive

The chemicals related requirements rely on risk assessment procedures without clear-cut restrictions, and limit values for chemicals are exceptional. They are neither included in the Directive, nor available in the associated standard series EN ISO 10993 (with the exception of ethylene oxide sterilization residuals) nor included in the standards investigated.

The approach included in the generic standard EN 12182 for assistive products for persons with disability seems to be a good starting point for more far reaching normative requirements to be included in a future edition of the standard, and may also inspire chemical requirements in other areas.

It should be noted that the Commission adopted a proposal for a Regulation of the European Parliament and of the Council on medical devices in September 2012, which is available here:
http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/revision/index_en.htm

There was no significant change of the provisions as regards chemicals. The scope of the labelling provisions was, however, slightly broadened including also "devices, or parts thereof, that are intended to be invasive devices and to come into contact with the body of the patient for short- or long-term".

In its first reading (2013-10-22), the European Parliament (EP) called for far-reaching amendments as far as chemicals are concerned. These include bans of CMRs and substances having endocrine disrupting properties as follows:

— medical devices or parts thereof that are invasive or come into contact with the body of patients, or (re)administer medicines, body liquids or other substances, including gases, to/from the body, or transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body, shall not contain, in concentrations above 0,1 % by weight in homogeneous materials, substances which are carcinogenic, mutagenic or toxic to reproduction in accordance with Part 3 of Annex VI to the CLP Regulation; or

— substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health or which are identified in accordance with the procedure set out in Article 59 of REACH; or

— are endocrine disrupters pursuant to Commission Recommendation (.../.../EU) on criteria for the identification of endocrine disrupters.

Exemptions may be granted by the Commission subject to conditions for a period not exceeding four years.

In addition, a broadening of the labelling requirements by including e.g. also endocrine disrupters was called for by the EP.

The adopted text of the EP can be found here:
http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2013-428

The Council and the EP reached an agreement and endorsed a compromise text in June 2016. According to this text, the use of CMRs cat. 1A and 1B or EDCs (included in the Candidate list or satisfying the EDC criteria relating to the BPR adopted by the Commission) in the medical devices mentioned above in a concentration exceeding 0,1 %, is only allowed "when justified". Justification criteria are given and guidelines are envisaged to be published by the Commission. If the threshold of 0,1 % is exceeded the devices must be labelled. Publication is expected in May 2017.

1.17 Gas Appliances Directive (GAD)

Directive 2009/142/EC (GAD) relating to appliances burning gaseous fuels aims to ensure that appliances may be placed on the market and put into service only if, when normally used, they do not compromise the safety of persons, domestic animals and property. It covers a broad range of products used e.g. for cooking, heating and hot water production, from simple camping equipment to heating boilers for large buildings blocks.

The text of the Directive can be found here: http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1426679516457&uri=CELEX:32009L0142

A revised Gas Appliances Regulation was published in March 2016 (Regulation (EU) 2016/426). This Regulation can be found here: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0426

Directive 2009/142/EC is repealed with effect from 21 April 2018.

1.17.1 Key elements of the Gas Appliances Directive/Regulation relevant for chemicals in articles

Gas appliances shall meet the essential requirements contained in Annex 1 of the Directive. There are few requirements, which are – or could be – related to chemicals.

One clause of Annex 1 is dealing with materials (Clause 2) saying that:

— materials shall be appropriate for their intended purpose and shall withstand the technical, chemical and thermal conditions to which they will foreseeably be subjected;

— the properties of materials that are important for safety shall be guaranteed by the manufacturer or the supplier of the appliance (indent deleted in the Regulation).

Another part of Annex 1 addresses design and construction (Clause 3) covering unburned gas release (addressing a dangerous accumulation of unburned gas) and combustion (addressing the release of combustion products – such as CO - in a dangerous quantity).

Finally, Clause 3.7 "Foodstuffs and water used for sanitary purposes" of the GAD states:

— Without prejudice to the Community rules in this area, materials and components used in the construction of an appliance, which may come into contact with food or water used for sanitary purposes, shall not impair their quality.

The Regulation uses a slightly different wording including references to the relevant legal acts.

1.17.2 Associated standards

The latest list of more than 90 harmonized standards can be found here: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/appliances-burning-gaseous-fuels/index_en.htm

Assuming that standards addressing the release of gas or combustion products (e.g. CO, NOx) are of limited relevance for the purpose of this study, the most relevant standards seem to be:

— EN 30-1-1:2008+A3 "Domestic cooking appliances burning gas – Part 1-1: Safety – General";

— EN 89:2015 "Gas-fired storage water heaters for the production of domestic hot water".

EN 30-1-1 on domestic cooking appliances just disallows materials containing asbestos and includes a modified version of the text in the Directive on food contact materials: "*The nature and state of the surface of materials intended to come into contact with food shall be such that they cannot contaminate or degrade this food*".

EN 89 on storage water heaters includes some requirements relative to the metallic, plastic and other non-metallic materials that are used in water heaters. These requirements include:

— the use of asbestos-based materials is forbidden;

— the use of cadmium containing solder is forbidden;

— parts in contact with water shall be made of materials of quality so that the water for domestic hot water use cannot be polluted;

— metallic materials shall be corrosion-resistant,

— the release of lead and cadmium ions or compounds from enamelling into the water shall not exceed the following limit values:

Lead:

— cold water test: 0,3 mg/(m^2·d);

— hot water test: 0,3 mg/(m^2·h);

Cadmium:

- cold water test: 0,03 mg/(m^2·d);
- hot water test: 0,03 mg/(m^2·h);

— plastic materials shall be suitable for coming into direct contact with food and not pose any health threat - examples for the selection of the plastic materials are given in Annex J (J.4);

— other non-metallic operating and auxiliary materials including rubber, sealant, adhesives and also lubricants on moving parts that come into contact with the water intended for human consumption shall satisfy the physiological and hygiene requirements in force.

1.17.3 Remarks on the Gas Appliances Directive/Regulation

The Gas Appliances Directive/Regulation and related standards address chemicals in a limited way. As regards materials in contact with drinking water and the formerly envisaged European Acceptance Scheme (EAS), see 4.9 below.

1.18 Pyrotechnic Articles Directive

Directive 2013/29/EU relating to the making available on the market of pyrotechnic articles establishes rules designed to achieve the free movement of pyrotechnic articles in the internal market while ensuring a high level of protection of human health and public security and the protection and safety of consumers and taking into account the relevant aspects related to environmental protection. Article 6 contains categories of pyrotechnic of according to their type of use, or their purpose and level of hazard, including their noise level. There are 3 types of pyrotechnic articles: fireworks, theatrical pyrotechnic articles and other pyrotechnic articles.

The text of the Directive is available here: http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1426691161439&uri=CELEX:32013L0029

1.18.1 Key elements of the Pyrotechnic Articles Directive relevant for chemicals in articles

Pyrotechnic articles shall meet the essential requirements contained in Annex 1 of the Directive. Some of the requirements touch upon chemicals, in particular:

— each pyrotechnic article shall be designed and manufactured in such a way that it can be disposed of safely by a suitable process with minimum effect on the environment

— fireworks may only be constructed of materials which minimize risk to health, property and the environment from debris

— "other" pyrotechnic articles shall be designed in such a way as to minimize risk to health, property and the environment from debris when initiated inadvertently

1.18.2 Associated standards

The latest list of harmonized standards can be found here: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/pyrotechnic-articles/index_en.htm

More than 20 harmonized standards are available. Only one seems relevant in the context of the current study: EN 15947-5:2015 "Pyrotechnic articles — Fireworks, Categories 1, 2, and 3 — Part 5: Requirements for construction and performance". It does not stipulate chemical requirements other than limiting the content of explosives (though it excludes from its scope fireworks including certain substances such as arsenic, lead, mercury and their compounds).

1.18.3 Remarks on the Pyrotechnic Articles Directive

The Pyrotechnic Articles Directive and related standards do not (substantially) address chemicals including those which may contaminate the environment following the explosion of the article.

1.19 Recreational Craft Directive

Directive 94/25/EC relating to recreational craft covers boats of any type intended for sports and leisure purposes of hull length from 2,5 m to 24 m regardless of the means of propulsion. However, there are a number of exclusions such as canoes and kayaks, gondolas, pedalos and (sailing) surfboards.

The items covered by the Directive may be placed on the market and put into service for use in accordance with their intended purpose only if they do not endanger the safety and health of persons, property or the environment when correctly constructed and maintained.

Consolidated versions of the Directive are available here:
http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:31994L0025

1.19.1 Key elements of the Recreational Craft Directive relevant for chemicals in articles

Products covered by the Directive shall meet the essential requirements contained in Annex 1 of the Directive. Apart from essential requirements for exhaust emissions from propulsion engines (which are thought to be of limited relevance in the context of the present study) no chemicals related requirements have been set.

1.19.2 Associated standards

The latest list of harmonized standards can be found here: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/recreational-craft/index_en.htm

Based on the absence of chemical requirements in the directive, an analysis of the titles of the standards and some spot checks it is concluded that it is unlikely that any of the harmonized standards includes chemical requirements.

1.19.3 Remarks on the Recreational Craft Directive

Apart from exhaust emissions, the Recreational Craft Directive and related standards do not substantially address chemicals.

1.20 Machinery Directive

Directive 2006/42/EC on machinery provides that manufacturers or authorized representatives shall ensure that the machinery satisfies the essential health and safety requirements set out in Annex I of the Directive before placed on the market.

Consolidated versions of the Directive can be found here:
http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:32006L0042

1.20.1 Key elements of the Machinery Directive relevant for chemicals in articles

Annex I includes generic principles (1.1.2.) such as:

— Machinery shall be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.

— The aim of measures taken shall be to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping.

On clause addresses materials and products (1.1.3) stating that:

— The materials used to construct machinery or products used or created during its use shall not endanger persons' safety or health. In particular, where fluids are used, machinery shall be designed and constructed to prevent risks due to filling, use, recovery or draining.

One particular clause deals with emissions of hazardous materials and substances (1.5.13) as follows:

— Machinery shall be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided.

— Where a hazard cannot be eliminated, the machinery shall be so equipped that hazardous materials and substances can be contained, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.

— Where the process is not totally enclosed during normal operation of the machinery, the devices for containment and/or evacuation shall be situated in such a way as to have the maximum effect.

Special provisions apply to machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products.

1.20.2 Associated standards

The latest list of harmonized standards can be found here: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/machinery/index_en.htm

A distinction is made between different categories of safety standards:

— A-type standards specify basic concepts, terminology and design principles applicable to all categories of machinery;

— B-type standards deal with specific aspects of machinery safety or specific types of safeguard that can be used across a wide range of categories of machinery;

— C-type standards provide specifications for a given category of machinery.

Most of the C-type standards cover machines which are not relevant for consumers (such as packaging machines, earth-moving machinery, mobile road construction machinery, etc.). Of possible interest may be:

— Series EN ISO 11148 “Hand-held non-electric power tools”;

— EN 12733:2001+A1:2009 “Agricultural and forestry machinery — Pedestrian controlled motor mowers — Safety”;

— EN 13683:2003+A2:2011+AC:2013 “Garden equipment — Integrally powered shredders/ chippers — Safety”;

— EN 13684:2004+A3:2009 “Garden equipment — Pedestrian controlled lawn aerators and scarifiers — Safety”;

— EN 14910:2007+A1:2009 “Garden equipment — Walk-behind combustion engine powered trimmers — Safety”;

— EN 16029:2012 “Ride-on, motorized vehicles intended for the transportation of persons and not intended for use on public roads — Single-track two-wheel motor vehicles — Safety requirements and test methods”;

— EN 16230-1:2013+A1:2014 “Leisure karts — Part 1: Safety requirements and test methods for karts”.

The checked standards do not contain chemical requirements apart from provisions relating to exhaust air or gases, dust and fumes or prevention of spilling of battery fluids. The last standard (EN 16230) also includes under 7.3 “Materials and products” a statement: “No part or system shall contain asbestos or other materials endangering persons’ safety or health”.

1.20.3 Remarks on the Machinery Directive

The Machinery Directive does not substantially address chemicals apart from emissions considered outside the scope of the present study.

1.21 EC-type Approval System for Motor Vehicles

The relevant pieces of legislation include:

— Directive 2007/46/EC establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles.

Directive applies to the type-approval of vehicles designed and constructed in one or more stages for use on the road, and of systems, components and separate technical units designed and constructed for such vehicles. Consolidated versions of the Directive can be found here:
http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:32007L0046

The Directive includes in Annex IV Part I a list of regulatory acts for EC type-approval of vehicles produced in unlimited series.

Of relevance in the context of the current study might be:

— Directive 2005/64/EC on the type-approval of motor vehicles with regard to their reusability, recyclability and recoverability;

— Directive 2006/40/EC relating to emissions from air conditioning systems in motor vehicles;

— Regulation (EC) No 661/2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefore

These pieces of legislation do not include chemical requirements apart from Directive 2006/40/EC which addresses fluorinated greenhouse gases with a global warming potential exceeding a certain threshold (higher than 150). This is considered to be outside the scope of the present study as well as other regulatory provisions relating to vehicle emissions.

1.21.1 Associated standards

None.

1.21.2 EC-type Approval System for Motor Vehicles

The current regulatory framework does not include chemical provisions except for emissions from combustion engines or air conditioning systems.

2 EU policy developments, discussions, related scientific opinions and tools

2.1 7th Environmental Action Programme

By Decision No 1386/2013/EU the European Parliament and the Council adopted the General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' in November 2013.

The text of this 7th environmental action programme can be found here: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013D1386

It will be guiding European environment policy until 2020 in line with some long-term visions for 2050. It identifies three key objectives:

— to protect, conserve and enhance the Union's natural capital;

— to turn the Union into a resource-efficient, green, and competitive low-carbon economy;

— to safeguard the Union's citizens from environment-related pressures and risks to health and wellbeing.

The document acknowledges that water pollution, air pollution and chemicals remain among the general public's top environmental concerns in the Union (point 44). It is stressed that "there is still uncertainty about the full impacts on human health and the environment of the combined effects of different chemicals (mixtures), nanomaterials, chemicals that interfere with the endocrine (hormone) system (endocrine disruptors) and chemicals in products (point 50). Hence, several actions to improve the current situation are proposed. The most important one concerning relates to the development of a "Union strategy for a non-toxic environment" by 2018 (point 54 (iv)) to ensure:

(1) the safety of manufactured nanomaterials and materials with similar properties;

(2) the minimization of exposure to endocrine disruptors;

(3) appropriate regulatory approaches to address combination effects of chemicals; and

(4) the minimization of exposure to chemicals in products, including, *inter alia*, imported products, with a view to promoting non-toxic material cycles and reducing indoor exposure to harmful substances.

2.2 Circular Economy

In December 2015, the European Commission published a Communication "Closing the loop - An EU action plan for the Circular Economy" to support Europe's transition towards a circular economy, thereby facilitating closed loop product lifecycles through greater recycling and reuse, and bringing both environmental and economic benefits. Although there is a strong focus on waste-related policies and activities, chemicals-related elements do feature.

Closing the loop will be partly facilitated through the promotion of non-toxic material cycles and better tracking of chemicals of concern in products, hence the interactions between legislations on waste, products and chemicals will be assessed. This assessment will help to identify the most appropriate EU-level course of action to address the presence of substances of concern, to limit unnecessary burden for recyclers and to facilitate the traceability and risk management of chemicals in recycling processes. This work will also feed into the future EU strategy for a non-toxic environment mentioned in the previous section.

Plastics feature as a priority area, particularly as there is a need to significantly increase recycling levels and to avoid their ending up as marine litter. Specific to chemicals, the Communication states: "The

presence of hazardous chemical additives can pose technical difficulties and the emergence of innovative types of plastics raises new questions, e.g. as regards plastics biodegradability."

A separate Action Plan details a timeline for the various activities described in the package, and includes "analysis and policy options to address the interface between chemicals, products and waste legislation, including how to reduce the presence and improve the tracking of chemicals of concern in products" by 2017. A strategy on plastics and the environment is also to be prepared for 2017.

The Commission Communication text can be found here: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52015DC0614; and the Annex can be found here: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52015DC0614.

2.3 Banning CMR substance in consumer products based on Article 68(2) of REACH

Article 68(2) of REACH allows the Commission to use a simplified procedure without extensive scientific scrutiny and socio-economic impact analysis to restrict CMR substances of categories 1A and 1B on its own, in a mixture or in an article, which could be used by consumers. It is still unclear, which procedure shall be followed in this case. A study ("The potential impact on industrial competitiveness of restrictions on certain CMR 1A and 1B substances in articles" - Scoping study for the application of art. 68.2 of REACH to CMR substances requiring priority action") was commissioned to assist in the development of such procedure. It was published in November 2013 and can be found here: http://ec.europa.eu/growth/sectors/chemicals/reach/studies/index_en.htm

In October 2015, the Commission initiated a consultation concerning the application of the article to ban CMR substances in textiles including a table, which lists 291 substances for which an indication of (possible) presence in textile or clothing articles was publicly available. More details can be found here: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8299

A restriction proposal by the Commission is expected in 2017.

2.4 REACH SVHC roadmap

In February 2013, the "Roadmap for SVHCs identification and implementation of REACH Risk Management measures from now to 2020" ("SVHC Roadmap") was adopted. Its major goal is to identify all "relevant" SVHCs and to include them in the candidate list by 2020. In addition to CMR substances (categories 1A/1B), PBTs and vPvBs, as well as petroleum/coal stream substances with CMR or PBT properties, the document also identifies sensitizers and endocrine disrupters as relevant substance categories ("equivalent concern"). Substances with other human health related hazard profiles, which may give rise to equivalent levels of concern, may be identified.

It does not include quantitative goals, such as the number of substances to be included in the candidate list, but presents a process and a methodology. Nevertheless, the Commission made a preliminary, worst case estimation of 440 substances to be investigated. The Roadmap is based on the "Risk Management Options" (RMO) approach, which identifies, where appropriate, the best regulatory option to manage the risk, either in REACH or outside of REACH (with another legislation).

The document was complemented by a "SVHC Roadmap to 2020 Implementation Plan" published by ECHA in November 2013. It is also envisaged to publish an annual progress report. The first one was published in March 2015.

Further information on the SVHC roadmap and related activities can be obtained from the ECHA website: http://echa.europa.eu/en/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

2.5 Endocrine Disrupting Chemicals

In the past 15 years, a large number of chemicals have been identified as causing endocrine disruptive effects in humans and wildlife, and these include chemicals that have very different properties, sources and fates in the environment. According to WHO/IPCS (2002) an Endocrine Disrupting Chemical (EDC) is defined as "*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*".

EDCs may be man-made or natural, and are subject to both biological and environmental transformations and in turn, may form other different types of EDCs. They are used and found in a large variety of materials, products and articles: pesticides, flame-retardants in consumer products, additives for plastics, active ingredients of pharmaceuticals, additives in food or personal care products.

Although some pieces of EU sectoral legislation include provisions on EDCs (notably the BPR and the PPPR, as well as REACH), no formal criteria have yet been adopted at the EU level in order to identify EDCs.

A Community Strategy[1] on endocrine disruptors was adopted by the Commission in 1999. A review and the development of a potential new strategy, taking into account the newest scientific knowledge, was planned as part of the Commission Working Programme 2012 with the main aim to define horizontal criteria for the identification of endocrine disruptors. The review is still ongoing with a Commission Staff Working Paper on the evaluation of the old strategy and a Communication to the European Parliament, the Council and the European Economic and Social Committee on a new Strategy under development.

In this context, the Commission mandated the European Food Safety Authority to deliver a "Scientific Opinion on the hazard assessment of endocrine disruptors" which was published in March 2013 and fed into the review process. The document is available at:
http://www.efsa.europa.eu/en/efsajournal/pub/3132.

Furthermore, in June 2014, the EC Directorate-General for Health and Consumer Protection (DG SANCO) and the Directorate-General for the Environment (DG ENV) launched a public consultation as part of an on-going initiative to define criteria to identify Endocrine Disruptors as required by the PPPR and BPR regulations. As set out in the European Commission roadmap "Defining criteria for identifying Endocrine Disruptors" (accessible via the link http://www.mychemicalmonitoring.eu/news/658ebb22-523f-49d1-a9d8-5caf11a03d90/European__roadmap_on_Endocrine_Disruptors_criteria) and due to the potential socio-economic impact linked to the identification of such criteria, the Commission has carried out an impact assessment (IA) to analyse different options for defining the criteria for the identification of endocrine disruptors.

In June 2016 the Commission presented the long awaited "scientific criteria" for EDCs in the field of plant protection products and biocides. The package included:

— a Communication providing an overview of the scientific and regulatory context;

— an Impact Assessment Report which presents the state of science regarding different criteria to identify endocrine disruptors, and provides information on possible consequences;

— two draft legal acts – one under the Biocidal Products legislation, the other under the Plant Protection Products legislation – which set the criteria to identify endocrine disruptors.

[1] EC: European Commission. Communication from the commission to the council and the European Parliament: Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife. COM(1999) 706 final, 17.12.1999 Brussels, Belgium; 1999, 31.

All documents can be accessed via the following link:
http://ec.europa.eu/health/endocrine_disruptors/policy/index_en.htm

In essence the Commission supported the WHO definition mentioned above and did not see the need for the introduction of additional categories of EDCs based on the different strength of evidence, nor the need for taking into account "potency" as an element of hazard characterization (both options were subject of a public consultation conducted between September 2014 and January 2015). The Commission advocates "*a concept of a reasonable evidence ("biological plausibility") to determine causality*". However, it remains unclear what precisely this is. Not surprisingly the Commission publications stimulated a lively debate, particularly related to the strength of evidence required to determine an endocrine mode of action or an adverse effect. The Commission presented several revised criteria but did not receive sufficient support by the Member States. By April 2017 the final adoption of the criteria was still pending.

REACH serves as the overarching legislative framework regulating EDCs. In particular, REACH requires an authorization for substances with endocrine disrupting properties, for which there is scientific evidence of probable serious effects to human health or the environment and which give rise to an equivalent level of concern as CMR, PBT and vPvB substances. The Commission is currently reviewing the way EDCs are authorized under REACH (Risk/Socio-economic considerations).

Several other pieces of EU legislation include specific provisions related to EDCs, including some regulating the marketing and use in products.

The CLP Regulation, which entered into force on 20 January 2009 and transposes the UN Globally Harmonized System for Classification and Labelling[2] into EU law, enables the identification and categorization of most known adverse effects relevant for human health and the environment. These include the main adverse human health effects expected to be caused by endocrine disruptors. Under the CLP Regulation, the relevance of adverse effects observed in animal studies is based on the mode of action of the substance, but without explicitly considering endocrine disruption specifically.

The Regulations regulating the placing on the market of plant protection products (Regulation (EC) 1107/2009 (PPPR)) and biocidal products (Regulation (EU) 528/2012 (BPR)) also include legal requirements for the use of EDCs. Both texts, under Annex II/Section 3.6.5 and Article 5 respectively, state that substances with endocrine disrupting properties, that may cause adverse effects in humans or are identified as EDCs under the REACH Regulation, shall not be approved for the respective use. Article 19(4) of the BPR adds that biocidal products with endocrine disrupting properties shall not be placed on the market for use by the general public. Both instruments also required the Commission to adopt scientific criteria to identify substances with endocrine disrupting properties by no later than end of 2013.

Furthermore, a legislative proposal for a Regulation on medical devices envisaged to replace existing legislation on general medical devices and *in vitro* diagnostic medical devices was presented by the European Commission in 2012 (see 1.16.3). The Council and European Parliament reached an agreement and endorsed a compromise text in June 2016. According to this text, the use of EDCs (included in the Candidate list or satisfying the EDC criteria relating to the BPR adopted by the Commission) in certain medical devices in a concentration exceeding 0,1 %, is allowed "when justified". Justification criteria are given and guidelines are envisaged to be published by the Commission. If the threshold of 0,1 % is exceeded the devices must be labelled. Publication is expected in April 2017. Here again, criteria for the identification of EDCs would be needed (to be reviewed in final version).

For cosmetic products, the legally required review of the Cosmetics Regulation with regard to substances with endocrine-disrupting properties may take place, once agreed criteria are available.

---

[2] The document can be accessed at
http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev02/English/03e_part3.pdf

The Water Framework Directive (Directive 2000/60/EC) also lists substances proven to have endocrine disrupting properties and which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment. A "priority list" of 146 substances was prepared for further evaluation for their role in endocrine disruption. More details on the priority list can be found here:
http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm.

Other sectoral EU legislation (e.g. on Occupational Safety and Health, on Pharmaceuticals and on Food Contact Materials) regulate EDCs together with other chemicals on a case by case basis, with no specific provisions related to EDCs.

2.6 Combination effects of chemicals

Even though, for humans and the environment, the actual exposure situation of mixtures of several different chemicals is complex, chemical risk assessment is generally made for each chemical alone. Within the EU, current regulatory approaches to the assessment of chemicals focus on the evaluation of individual chemicals. The assessment includes safety margins to take account of uncertainties including among other exposure to many different chemicals. Concerns have been raised about the need to address the combination effects of multiple chemicals from different sources and pathways in a more systematic way.

In 2007, DG Environment initiated a study entitled 'State of the Art Report on Mixture Toxicity' in order to review the current scientific knowledge and regulatory approaches on the toxicity derived from mixture components. The study is available at:
http://ec.europa.eu/environment/chemicals/effects/pdf/report_mixture_toxicity.pdf.

Upon the completion of this study (2009), the Council of Environment Ministers invited[3] the Commission to assess existing legislation on the issue and also to suggest appropriate modifications and guidelines. On 31 May 2012 the Commission expressed to the Council its view that EU laws set strict limits for the amounts of particular chemicals allowed in manufactured products, however the potentially toxic effects of these chemicals in combination are rarely examined. The Commission Communication on Combination effects of chemicals (chemical mixtures) is available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52012DC0252.

Adding to this, the Commission engaged to identify priority mixtures to be assessed and make certain that different pieces of EU legislation deliver consistent risk assessments for such priority mixtures. The new Commission approach is based on the latest opinion of three independent non-food scientific Committees (SCHER[4], SCHENIHR[5] and SCSS[6]) which produced the report entitled "Toxicity and Assessment of Chemical Mixtures", available at:
http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_155.pdf as well as on the "State of the Art Report on Mixture Toxicity", accessible via the link:
http://ec.europa.eu/environment/chemicals/effects/pdf/report_mixture_toxicity.pdf.

In REACH, the combination effects of chemicals in consumer products are not addressed within its scope despite its explicit aim to "*ensure a high level of protection for human health and the environment*".

NOTE Annex I of REACH requires to take into account combined exposure in the chemical safety assessment which relates to different exposure routes and uses of single substances.

---

[3] Through the adoption of "conclusions on the combination effects of chemicals", available at http://register.consilium.europa.eu/pdf/en/09/st17/st17820.en09.pdf

[4] Scientific Committee on Health and Environmental Risks

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

[6] Scientific Committee on Consumer Safety

However, the regulation on plant protection products (Regulation (EC) 1107/2009 (PPPR)), requires that plant protection products *"shall not have any harmful effects on human health, including vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available*", thus, taking account of combined effects. Similarly, Regulation (EC) 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin requires to take into account "*the possible presence of pesticide residues arising from sources other than current plant protection uses of active substances, and their known cumulative and synergistic effects, when the methods to assess such effects are available*".

Based on these regulatory provisions EFSA launched a number of projects aimed at developing a related risk assessment methodology not limited to pesticides and contaminants but looking at the issue more broadly. In July 2013 a report entitled "International Frameworks Dealing with Human Risk Assessment of Combined Exposure to Multiple Chemicals" was published:
http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3313/epdf

In October 2016 EFSA launched another initiative called "MixTox" to propose methods for carrying out risk assessment for multiple chemicals from a variety of sources:
http://www.efsa.europa.eu/en/press/news/161024

Also Regulation (EU) No 528/2012 concerning biocidal products (BPR) requires to take into account cumulative or synergistic effects in the evaluation of biocidal products. In this context ECHA published a "Transitional Guidance on mixture toxicity assessment for biocidal products for the environment" in May 2014:
http://www.echa.europa.eu/documents/10162/15623299/biocides_transitional_guidance_mixture_toxicity_en.pdf

2.7 Exposure to single substances via different routes and from different sources

Different terminology has been used for considering exposure to single substances via different routes and from different sources. This is sometimes called "cumulative" exposure. REACH uses the terms "concomitant", "combined" or "aggregated" exposure. A publication by the German Federal Environmental Agency (UBA) highlighted different uses of terms in the legal context: "*Basic principles for the development of a concept for environmental exposure assessments of single substances released from multiple uses under REACH*" (UBA Text 63/2011). The text is available here:
http://www.umweltbundesamt.de/publikationen/basic-principles-for-development-of-a-concept-for

Combined exposure to chemicals is addressed in various sections of the REACH "Guidance on Information Requirements and Chemical Safety Assessment". In particular, Part E: "Risk Characterisation" states (E.3.5 Step 5):

— *"In situations where the same person is potentially exposed to the same substance in the same setting via different routes of entry into the body or from different products containing the same substance, exposure scenarios reflecting these concomitant exposures should be assessed in the exposure estimation. These scenarios – typically related to workplaces and aggregated exposure for consumers – need specific attention in the risk characterisation step" (see Section E.3.5.1).*

— *In addition, humans are exposed at work, from consumer products and via environmental exposures. It should be considered in which cases it is relevant to make risk characterization for such scenarios, representing exposure from all sources. Typically it is most relevant to combine consumer exposures with indirect exposure of humans via the environment.*

— *In special cases, where exposure occurs to a substance as well as to several very closely related and similar acting chemical substances (e.g. different salts of a metal or closely related derivatives of organic substances), the exposure evaluation and risk characterization should reflect this aspect. If data are available the exposure assessment should also include a scenario concerning this combined exposure. One way to conduct risk characterization for combined exposure to closely related*

analogues could be to add exposures and to use a toxicological descriptor from a representative substance among the analogues. If data do not allow for a quantitative assessment, an attempt should be made to address the issue in a qualitative way".

Further guidance is given in Section E.3.5.1. of the REACH guidance mentioned above.

2.8 Nanomaterials

Nanomaterials are substances or materials manufactured or used at a very small scale, with a nanometre being one-billionth the size of a metre. In the EU, the nano-scale has been legally set arbitrarily at the range from approximately 1 nm to 100 nm in size in at least one dimension. The use of nanotechnology is expanding rapidly, so a large number of products containing nanomaterials are already found on the European market including consumer products. These products range from batteries, coatings and antibacterial clothing to food and cosmetic products.

The first official EC Communication published in 2004 defined a "European strategy for nanotechnology: European policy on Nanomaterials" and a follow-up action plan for the period 2005-2009. The Communication talked about the development of nanotechnology in a "safe and responsible manner", adhering to ethical principles and studying potential health, safety or environmental risks in order to prepare for possible regulation. The nanotechnology strategy is available at http://ec.europa.eu/research/industrial_technologies/pdf/policy/nano_com_en.pdf, the action plan is accessible via: http://ec.europa.eu/research/industrial_technologies/pdf/policy/nano_action_plan2005_en.pdf.

As part of the proposed actions in the Strategy, the European Commission adopted a code of conduct for responsible nanosciences and nanotechnologies research, available at: http://ec.europa.eu/research/industrial_technologies/pdf/policy/nanocode-rec_pe0894c_en.pdf

In 2008, the EC also adopted a Communication on regulatory aspects of nanomaterials: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:en:PDF.

As a follow up, the EC proposed a first definition of nanomaterials in a 2011 Commission Recommendation in order to be able to identify nanomaterials from other materials. With an intention to provide unambiguous criteria to identify materials for which special regulatory provisions might apply, the Recommendation built upon the scientific basis for the definition provided by the then Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in a report published in 2010: http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_030.pdf.

The Recommendation definition is currently under review, following a series of studies delivered by the European Commission's Joint Research Centre (JRC). The Recommendation can be found here: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011H0696 and the final of three JRC studies on the revision of the definition can be found here: https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/towards-review-ec-recommendation-definition-term-nanomaterial-part-3-scientific-technical?search

In all those communications, the EC states that nanomaterials are sufficiently and adequately regulated by existing chemicals legislation, particularly through REACH and CLP. Chemical substances in nanoform (nanomaterials) are considered to meet the definition of a chemical "substance"[7] and thus are regulated under REACH, although the text contains no specific provisions related to the different sizes of material. REACH requires nanomaterials to be registered if the annual manufactured/imported quantity is equal to or over 1 tonne. Nanomaterials are not considered as separate substances[8] and, a manufacturer or importer is responsible for registering the nanomaterial substance together with the

[7] A substance definition under REACH addresses chemicals in whatever size, shape or physical form

[8] But as substances in a certain form

corresponding bulk material (if it exists) in the same registration procedure/ dossier and under the same chemical identity registers. The quantity of the bulk and nanomaterial is decisive for the calculation of the aforementioned tonnage threshold and it is only in cases where no corresponding bulk material is manufactured or imported by the same registrant, that the nanomaterial shall be registered separately. For material quantities exceeding 10 tonnes a year, a chemical safety report shall be prepared.

In October 2012, the Commission adopted a "Communication on the Second Regulatory Review on Nanomaterials" which describes the Commission's plans to review EU law, including REACH, and their application in order to ensure nanomaterials are adequately addressed to ensure their safe development and use. The Communication can be accessed at:http://ec.europa.eu/research/industrial_technologies/pdf/policy/communication-from-the-commission-second-regulatory-review-on-nanomaterials_en.pdf.

The Communication was accompanied by a "Staff Working Paper on nanomaterial types and uses", including safety aspects and providing an overview of the benefits and risks of nanomaterials on the market. The document is available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0288:FIN:EN:PDF.

In this Second Regulatory Review the Commission indicated its intention to launch an impact assessment "*to identify and develop the most adequate means to increase transparency and ensure regulatory oversight*". This reflected the wish of the European Parliament and several Member States to implement notification requirements for all nanomaterials. However, the Commission has later decided against an EU nanomaterial registry. Instead, it has opted to task the European Chemicals Agency (ECHA) to develop a nanomaterial observatory.

The Second Regulatory Review was followed by the launch of a review of the REACH Regulation in February 2013, which can be consulted at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0049:FIN:EN:PDF.

The Commission recommends that the REACH registration and proof of safe use for nanomaterials is based on a case by case approach, and that each type of nanomaterial is clearly described. Following the REACH review publication, a public consultation was initiated by the Commission in May 2013, as part of an impact assessment, related to how the annexes of REACH could be amended to ensure that nanomaterials are registered more clearly under REACH and that the safe use of nanomaterials is adequately demonstrated within the registration dossiers. It is not clear when the Commission will provide its official proposal for these revisions, although the original intention was to do so to be able to meet the final REACH registration deadline of 2018. This deadline can no longer be met, given the timeline for EU co-decision procedures. A third regulatory review on nanomaterials is currently underway, anticipated to be completed by late 2016.

Although no amendments have been made so far to the legal text of REACH to incorporate nanomaterials, the European Chemical Agency (ECHA) updated its guidance to include nanomaterials and set up a webpage on nanomaterials under REACH, the CLP Regulation and the BPR, and accessible at: http://echa.europa.eu/regulations/nanomaterials.

Also IUCLID (a software to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances) was updated to report nanoform specific information. More information on IUCLID is available at: https://iuclid6.echa.europa.eu/home

Under the CLP Regulation, there is an obligation to notify ECHA any substances in the forms as placed on the market, including nanomaterials, which meet the criteria for classification as hazardous, independent of the annual tonnage quantity limit. Finally, since 2012 and by the time that this document is drafted, seven substance registrations and eighteen CLP notifications refer to "nanomaterial" as the form of the substance in voluntary fields.

Different pieces of legislation also address nanomaterials in products, with no particular consistency, as summarized in Table 13.

Table 13 —Overview of current EU legislation in various sectors making reference to nanomaterials

Legislation	EU legislation	Definition[a]	Label[b]	Guidance
Products:				
Biocides	(EU) No 528/2013	Yes	Yes	No
Cosmetics	(EC) No 1223/2009	Yes	Yes	Yes
Medical devices	COM (2012) 542 final (proposal)	Yes	Yes	No
Plant protection products	(EC) No 1107/2009	No	No	Yes
Chemicals:				
REACH	(EC) 1907/2006	No	No	Yes
Classification, labelling and packaging (CLP)	(EC) 1272/2008	No	No	No
Occupational health and safety	89/391/EEC: 98/24/EC: 2004/37/EC: EC 1907/2006:	No	No	No

[a] 'Yes' signifies that the legislation includes a definition of nanomaterial.

[b] 'Yes' signifies that the legislation requires indication of the use of nanomaterials on the product label.

Under the BPR and for biocidal products and treated articles placed on the market, Member States are required to submit[9] to the Commission a report every 5 years on the implementation of the Regulation with a specific focus on the use and potential risk of nanomaterials in biocidal products.

Under the EU Cosmetics Regulation 1223/2009, some conditions apply on the use of nanomaterials ingredients in cosmetic products. In addition to being the first piece of legislation to include a "nanomaterial" definition, the Cosmetics Regulation requires that industry submit notification of all cosmetic products containing nanomaterials, six months before placing them on the market. It also requires that all nanomaterial ingredients are identified on the product label (ingredient name followed by the prefix "nano" in brackets).

2.9 Food contact materials

In July 2012, the Commission published a Roadmap concerning "Food Contact Materials - Specific provisions for materials other than plastics – implementing measure". The roadmap foresees the followings:

— Recent food scarce originating from food packaging led to criticism by Member States, Industry and the European Parliament on the lack of EU specific legislation for materials other than plastics.

— Recent years have shown food scares due to substances originating from food packaging. Those cases concerned substances originating from other materials than plastics. Lack of knowledge of substances used in these materials exists at EU and national level. In a huge number of cases their safety has not been assessed at EU or national level or by industry itself.

— The initiative should focus on the safety of these other materials and in particular those for which there is a high risk from transfer of its constituents into food (printing inks, coatings, silicones, adhesives, rubber, metals, paper and board and combinations of materials).

— In the feedback of inspectors in the training sessions on "Better training for safer food" it was mentioned that only when specific parameters, criteria or limits are available in legislation or guidance against which compliance can be assessed, inspectors are able to verify compliance.

— The lack of harmonized specific rules at EU level is seen by industry as a barrier to trade. Those industry areas for which no harmonized rules exist at EU level feel disadvantaged over the other areas. Demonstration of safety of the materials to customers becomes more difficult when criteria for safety are not established.

— National provisions are often differing between MS. Divergent rules thus trigger multiple testing leading to additional costs for industry.

— The questions received by industry operators situated in Third Countries substantiate that the absence of EU harmonized specific requirements is misunderstood as no obligation on the safety of the food contact materials.

The Roadmap intended to "*focus on the safety of these other materials and in particular those for which there is a high risk from transfer of its constituents into food (printing inks, coatings, silicones, adhesives, rubber, metals, paper and board and combinations of materials)*". The foreseen Impact Assessment, planned to be initiated in September 2012 and accompanied by a public consultation in the second half of 2013, has been put on hold.

In 2016, the European Parliament's Research Service (DG EPRS) published an in-house supporting study "Food Contact Materials Regulation (EC) 1935/2004. European Implementation Assessment Study". In this survey the majority of participating stakeholders (across businesses, consumers, environmental and health NGOs, researchers, as well as Member States' competent authorities) expressed support for specific measures at EU level for the FCMs that are not yet harmonized at EU level. The study can be downloaded here:
www.europarl.europa.eu/RegData/etudes/STUD/2016/581411/EPRS_STU(2016)581411_EN.pdf

This study formed the basis for the adoption of a (non-legislative) resolution on the "Implementation of the Food Contact Materials Regulation" in October 2016. It calls on the Commission to:

— adopt specific measures for those 13 materials not yet regulated at EU level;

— prioritize the drawing-up of specific EU measures for paper and board, varnishes and coatings, metals and alloys, printing inks and adhesives;

— to consider the so-called 'cocktail effect' or the effect of multiple concurrent and cumulative exposures from FCMs and other sources when determining migration limits;

— to ensure that harmful substances phased out under REACH are also phased out in FCMs;

— to ban BPA in all FCMs;

— to develop a legislative proposal introducing lower limits for the release of cadmium and lead in the Council Directive 84/500/EEC on ceramics;

and believes that nanomaterials should be subjected to authorization for use not only in plastic materials but in all FCM materials. The resolution is available here: http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P8-TA-2016-0384

2.10 Materials in contact with drinking water

Many materials in contact with drinking water (but not all) fall in the scope of the CPR. As pointed out in 3.15., this Regulation does not allow to establish performance requirements for construction products or form a framework for a European certification system for this group of products.

On the other hand, Article 10 of Council Directive 98/83/EC on the quality of water intended for human consumption (Drinking Water Directive, DWD) requires Member States "*to take all measures necessary to ensure that no substances or materials for new installations used in the preparation or distribution of water intended for human consumption or impurities associated with such substances or materials for new installations remain in water intended for human consumption in concentrations higher than is necessary for the purpose of their use and do not, either directly or indirectly, reduce the protection of human health provided for in this Directive*". The Directive is currently under review.

In 1999, a Regulators Group for Construction Products in contact with Drinking Water (RG-CPDW) was established by the Commission (DG Enterprise). Its task was to develop a common European approach to the assessment and certification of materials in contact with drinking water. As a result, a proposal for the establishment of a "European Acceptance Scheme for Construction Products in contact with Drinking Water (EAS)" was published in 2005. Its main elements include:

— Provision of full information on the composition of materials making up the product;

— Compliance of these materials with agreed Positive Lists (organic substances), Composition Lists (metallic materials) and Approved Constituents Lists (cementitious materials);

— Initial type-testing of the product by way of a suite of tests applied as appropriate to cover:

  (a) Organoleptic aspects (odour, flavour and turbidity)

  (b) General hygiene (including TOC and chlorine demand)

  (c) Toxic substances (including DWD parameters, list substances and unsuspected substances)

  (d) Enhancement of microbial growth.

The scheme was intended to cover construction products used in the drinking water supply system from the point of treatment up to the consumer taps. After completion of the EAS proposal, the Commission decided that it would not be possible to implement the 'full global EAS' due to 1) the lack of an adequate legal basis for such a scheme, with the CPR only providing a basis for harmonized test methods but not the setting of common requirements for all MS, and 2) the lack of organization and resources within the Commission for the central operation of a single scheme operating at the European level.

In the absence of a European regulatory basis, 4 Member States (FR, GE, NL and UK) joined forces to harmonize their existing approval schemes (see 3.5).

In June 2014 the Commission launched a consultation concerning the "Quality of Drinking Water in the EU" with a view to identifying the need to revise the EU Drinking Water Directive (Council Directive

98/83/EC on the quality of water intended for human consumption). The questionnaire included *inter alia* questions related to materials in direct contact with drinking water. An analysis of the responses showed that there was strong support for harmonized European rules for water supply materials. The draft report "Analysis of the public consultation on the quality of drinking water" is accessible here: http://ec.europa.eu/environment/consultations/water_drink_en.htm

An evaluation report supporting the revision of the EU Drinking Water Directive was published in May 2016: http://www.safe2drink.eu/wp-content/uploads/2016/07/DWD-evaluation-report-Main.pdf

This was followed by a Commission Staff Working Document "Refit Evaluation of the Drinking Water Directive 98/83/EC" published in December 2016. It states: "*Asked about the necessity to regulate certain aspects of drinking water at EU level, a majority across all respondents (74%) voted for a harmonized regulation of the materials in contact with drinking water*". The document can be obtained here: http://ec.europa.eu/environment/water/water-drink/pdf/SWD_2016_428_F1.pdf

2.11 Emissions to indoor air

As in the case of materials in contact with drinking water, there is no suitable legal framework limiting the release of substances to the indoor air in the EU. The CPR is not an instrument that can allow to establish harmonized performance requirements for construction products, and there exists no legal instruments for other products causing indoor emissions, such as indoor textiles (e.g. carpets or curtains), furniture, paints, plastics materials, products emitting fragrances (air fresheners), or printers.

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 reports on indoor quality issues were published from 1988 (29 so far). A complete list can be found here: http://www.aivc.org/resources/collection-publications/european-collaborative-action-urban-air-indoor-environment-and

Of primary importance are the reports dealing with a possible harmonization of existing national voluntary and regulatory schemes in Europe with the aim to develop a common approach. These include:

— ECA Report No 24: "Harmonisation of indoor material emissions labelling systems in the EU - Inventory of existing schemes (2005)",

— ECA Report No 27: "Harmonisation framework for indoor products labelling schemes in the EU (2012)",

— ECA Report No 29: "Harmonisation framework for health based evaluation of indoor emissions from construction products in the European Union using the EU-LCI concept (2013)".

In particular, ECA Report No 27 describes the consensus achieved by the parties involved on a harmonized framework for the evaluation of indoor emissions including "common core" and "transitional criteria". Common core criteria are those for which consensus has already been achieved and can be applied Europe-wide, whereas transitional criteria are those for which consensus is still to be reached and these continue to be applied locally during a transitional period. The proposed criteria include:

Core criteria:

— total amount of Volatile Organic Compounds (TVOC);

— elimination of volatile CMR substances (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.

The emission testing should be based on harmonized European Standards prepared by CEN/TC 351 "Construction Products - Assessment of release of dangerous substances", when available (until then ISO 16000- series may be used subject to additional conditions). Measurement should take place on day 3 and day 28.

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). 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, some actors involved formed the "EU-LCI Working Group" including representatives from authorities, university, research institutes and industry. The Group aimed to derive and recommend EU-wide harmonized health-based reference values for the assessment of product emissions based on the LCI-concept. With time this group became a Sub-group of the "Expert Group on Dangerous Substances" within the larger committee structure of the "EC Advisory Group on Construction Products". Its website includes:

— 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.

In addition to these agreed EU-LCI values, the website includes a list of substances with insufficient data (which will not be progressed until further data are available), a EU-LCI Master list (with all the substances identified requiring an EU-LCI value) and a EU-LCI Working list (with substances currently being progressed).

The lists can be downloaded from: https://ec.europa.eu/growth/sectors/construction/eu-lci_en

The regulatory situation in some MS is covered below.

Apart from construction products, a number of other products can emit substances to the indoor air. These include laser printers, home textiles (such carpets, curtains), cleaning agents, air fresheners, personal care products, and others. Some of those were addressed in a Commission funded project called EPHECT (**E**missions, **E**xposure **P**atterns and **H**ealth **E**ffects of **C**onsumer Products): https://sites.vito.be/sites/ephect/Pages/home.aspx

2.12 EU Scientific Committees

The Scientific Committees of the European Commission play a key role in advising the Commission on matters relating to consumer safety, public health and the environment including chemical issues. The following three Scientific Committees in the non-food area started their work in March 2009:

— Scientific Committee on Consumer Safety (SCCS);

— Scientific Committee on Health and Environmental Risks (SCHER);

— Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).

All three Committees have published opinions on chemicals in consumer products. The opinions of SCCS, SCHER and SCENIHR are accessible via the following link:
http://ec.europa.eu/health/scientific_committees/index_en.htm

The number of Committees has been reduced to two (merging of SCHER and SCENIHR) in 2016:

— Scientific Committee on Consumer Safety (SCCS);

— Scientific Committee on Health, Environmental and Emerging Risks (SCHEER).

The European Food Safety Authority (EFSA) also operates a Scientific Committee and several Scientific Panels. An overview is given here: http://www.efsa.europa.eu/en/efsawho/scpanels

The EFSA Journal is an open-access, online scientific journal that publishes the scientific outputs EFSA:
http://www.efsa.europa.eu/en/publications/efsajournal

2.13 EU Export Helpdesk Database

DG TRADE has developed a database to inform potential exporters from 3rd countries about applicable rules which be complied with. It also includes information on chemicals related legislation. An exporter can enter a product code (10 digits) and find, among other information, the list of compulsory EU import requirements applying to his product. The information may in principle also be useful for European producers.

The website of the EU Export Helpdesk and the database are accessible under the following links:
http://exporthelp.europa.eu/thdapp/index.htm?newLanguageId=EN and
http://exporthelp.europa.eu/thdapp/display.htm?page=form%2fform_MyExport.html&docType=main&languageId=en

3 Relevant national regulation, policy developments and initiatives

3.1 General strategies

Some Member States have indicated that they consider the current legislative framework regarding chemicals in general and, in particular, chemicals in (some) consumer products insufficient. As an example, KemI, the Swedish Chemicals Agency, issued a comprehensive report “Improved EU rules for A Non-Toxic Environment” in March 2012 (KemI report 1/12). Among others, KemI calls upon improvement the protection of children by assuring that articles children come in contact with are safe and to introduce new EU rules on chemicals in textiles:
http://www3.kemi.se/Documents/Publikationer/Trycksaker/Rapporter/Summary_1_12.pdf

An “Action plan for a toxic-free everyday environment 2015-2020” was published by KemI in June 2014 (following a first one for the period 2011-2014). The Action Plan identifies three major challenges to address, such as chemicals in food, drinking water and consumer products as well as the exposure of children and young people to harmful chemicals. KemI has been asked by the government to assess whether there is any scope for the country to introduce new restrictions, at the national level, without infringing EU single market rules. More information can be found here:
http://www.kemi.se/en/about-us/our-work/action-plan-for-a-toxic-free-everyday-environment

The Danish government also presented its 2014-2017 Chemicals Action Alan, which includes, *inter alia*, a focus on consumer products, and, in particular, those used routinely by children and young persons, such as toys, textiles, and electronic equipment. Better information provision to consumers is also part of the programme: http://kemikalieindsatsen.dk/english/giftfrie-produkter/#anchor1

3.2 Endocrine Disrupting Chemicals (EDCs)

Member States such as France, Sweden, Denmark, Belgium and Austria, have already taken initiatives with regard to EDCs in products at national level. Most of the measures taken concern the use of Bisphenol A and are briefly presented below.

France

In early 2014, France launched a national strategy on endocrine disrupting chemicals (SNPE) where the following specific actions were proposed:

— to remove, within the EU REACH system, Bisphenol A (BPA) from thermal paper (used in cash-till receipts) for the whole of Europe and encourage voluntary phase-out in France;

— to speed up the substitution of BPA in toys, and measures controlling phthalates in toys;

— to request the review of five suspected EDCs during the course of 2014 (followed up by 10 more in the next two years) and if these substances are found to be EDCs, to propose them for further regulatory action under the relevant EU legislation (REACH, PPPR and BPR).

The five main components of the strategy were built upon the support for research, the stimulation of innovation, the strengthened expertise through analysis of suspected EDCs, the promotion of this approach at European level, and, the improvement of information for citizens, including stressing the need for international standards on labelling.

Adding to the above, France prohibited the use of BPA in food contact materials (for children under three years) in 2013 and in all food contact materials from 1st January 2015. However, in late 2015, France's Constitutional Council overturned the ban on the use of BPA in food containers destined for the export market. The ban on sale and import of the substance in France itself remains.

Denmark

A ban on Bisphenol A in food contact materials for children under the age of three has been in place in Denmark since 2010, while a further ban on four phthalates (DEHP, DBP, DIBP and BBP) was proposed and then decided against in 2015. Instead, Denmark has worked to introduce an EU-level ban. Based on the Danish proposal, ECHA has submitted a restriction proposal for the four phthalates under REACH in April 2016 (see also 1.1.1.4).

Sweden

A ban on Bisphenol A in varnishes and coatings used in the packaging of food for children under the age of three is in place in Sweden since 2013.

Belgium

A ban on Bisphenol A in food contact materials and in plastic articles such as spoons and plates for children under the age of three is in place in Belgium since 2013.

Austria

A ban on Bisphenol A in baby's teething rings and pacifiers is in place in Austria.

3.3 Nanomaterials

Despite the existence of different pieces of EU legislation covering nanomaterials in products, various Member States opted for stricter rules on nanomaterials in products. Many initiatives related to the voluntary reporting of products containing nanomaterials.

France

Within the authority of the 2009 Environment Act and under the *Grenelle II* Law, France established a compulsory reporting system (*Déclaration des substances à l'état nanoparticulaire*) where companies shall report the following information:

— identity of the registrant;

— identity of the substance (chemical identification of the substance, particle size distribution by number, agglomeration, aggregation, surface, etc.);

— quantity of nanoparticle substance produced;

— distributed or imported, uses;

— identity of professional users.

In addition, provisions for protecting information and safeguarding confidentiality are also addressed. Since 2013, the annual declaration of the production, distribution and import of nanomaterials, with a minimum threshold of 100 g, is managed by the French Agency for Food, the Environment and Occupational Health and Safety (ANSES). Reports (in French) are available here: https://www.r-nano.fr

Belgium

In February 2014, Belgium established a database of substances in the nanoform concerning preparations and products present on the Belgian market, and which could be potentially harmonized with other national databases (e.g. France or Denmark). Although naturally-occurring nanoparticle substances and industrial processing by-products fall outside the scope, the registry is set to be operational by 1 January 2016 and bulk materials (mixtures) will have to be registered from 2017 onwards. Further information is available here:
http://www.health.belgium.be/en/environment/chemical-substances/nanomaterials/register

Denmark

Denmark introduced a mandatory national nano register with reporting requirements for producers/importers on mixtures and articles containing nanomaterials, following a product-focus characteristic rather than nanomaterial-only identification. The registry became operational on 20 June 2014 and the first reports were due by 30 August 2015. The reporting obligation exempts many product groups: food materials, feed, drugs, medical equipment, cosmetic products, pesticides and waste. Further information can be found here: http://eng.mst.dk/topics/chemicals/nanomaterials/the-danish-nanoproduct-register

Sweden

KemI, the Swedish Chemicals Agency, was mandated by the Swedish government to explore the reporting requirements of a national registry for nanomaterials. The proposal was presented in December 2015, setting out reporting on nanomaterials that have been intentionally added to a product, regardless of concentration. The document including an English summary can be found here:
http://www.kemi.se/en/news-from-the-swedish-chemicals-agency/2015/the-swedish-chemicals-agency-proposes-reporting-requirements-for-nanomaterials

3.4 Food contact materials

An EFSA Scientific Cooperation (ESCO) Working Group was set up in February 2010 with a view to collect evaluations concerning non-plastics materials in contact with food available in Member States, to prepare inventory lists of evaluated substances and to classify them according to the way they were evaluated (guidelines, risk assessment background), to identify gaps and strengths in different approaches, to establish the principles of setting the priorities for further evaluations, and to identify the most knowledgeable experts in the field, who could be mobilised in case of further need.

Substances which had been used for the manufacturing of paper and board, printing inks, coatings, rubber, colorants, wood, and cork, and evaluated at national level, were inventoried. The final ESCO inventory list contains 2800 entries.

The "Report of ESCO WG on non-plastic Food Contact Materials" was published in July 2011. A revised version was made available in March 2012. The study and a compiled list of substances in an Excel file can be found here: http://www.efsa.europa.eu/en/supporting/pub/139e.htm

A draft German legislation on printing inks ("Twenty-First Regulation amending the Consumer Goods Regulation") was notified to the Commission after many years of discussion in July 2016. It applies to printed food contact materials and articles (e.g. packaging, napkins, cardboard cups, paper plates) and stipulates a list of substances that are permitted to be used in printing inks involved in the manufacture of food contact materials and articles (a positive list) including permissible maximum limits for the transfer of substances onto foods. Other substances may be used where the printing does not come into direct contact with the foodstuff provided said substances do not migrate to foodstuffs from the printing inks (i.e. transfer 'not detectable' = 0,01 mg/kg of foodstuff). CMR (carcinogenic, mutagenic and reprotoxic) substances may not be used if no safety assessment is available that justifies their use or the derivation of limit values for transfer to foodstuffs and, hence, facilitates inclusion in the positive list.

The notification text and the draft Ordinance are available here: http://ec.europa.eu/growth/tools-databases/tris/en/index.cfm/search/?trisaction=search.detail&year=2016&num=333&mLang=EN

The Swiss legislation concerning packaging inks is based on similar principles:
https://www.blv.admin.ch/blv/de/home/gebrauchsgegenstaende/materialien-in-kontakt-mit-lebensmitteln/verpackungen.html#-1672431083

3.5 Materials in contact with drinking water

In the absence of a European legal basis for materials in contact with drinking water, 4 Member States (FR, GE, NL and UK) join forces to (gradually) harmonize their existing approval schemes. The co-operation started in 2007 and was formalized in 2011. Portugal has been granted the status of Candidate Member, and other MS are expected to join.

The following documents describing the current status of the discussion have been published:

- Metallic materials:
  - Part A – Procedure for the acceptance;
  - Part B – 4MS Common Composition List;
- Organic Materials:
  - Positive Lists for Organic Materials;
  - Combined positive List of organic Substances in Contact with Drinking Water;
- Cementitious Products:
  - Assessment of Cementitious Products in Contact with Drinking Water.

More information including the documents listed above can be obtained here:
http://www.umweltbundesamt.de/en/topics/water/drinking-water/distributing-drinking-water/approval-harmonization-4ms-initiative

3.6 Emissions to indoor air

In Germany, a compulsory approval scheme for certain construction products emitting substances to the indoor air was introduced in 2006. Approvals are granted by Deutsches Institut für Bautechnik, DIBt. The following product groups are currently covered:

— Resilient, textile and laminate floor coverings (EN 14041);

— Wood flooring (EN 14342);

— Screed materials (EN 13813);

— Surfaces for sports areas - Indoor surfaces for multisports use (EN 14904);

— Modular tiles for flooring and stairs (EN 15285);

— Associated coatings, adhesives and underlays;

— Decorative wall coverings (EN 15102).

The emissions are evaluated using a scheme developed by the "Committee for Health-related Evaluation of Building Products" ("Ausschuss für die gesundheitliche Bewertung von Bauprodukten", AgBB). The latest edition was published in February 2015. Most important criteria:

— TVOC value after 3 days ≤ 10 mg/m^3, after 28 days ≤ 1,0 mg/m^3;

— Carcinogens of categories 1A and 1B may not exceed a concentration of 0,01 mg/m^3 after 3 days, 0,001 mg/m^3 after 28 days (unless a threshold and a LCI-value can be determined);

— Sum of the SVOC concentrations ≤ 0,1 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 ≤ 0,1 mg/m^3.

Links to the documents providing more detail can be found here:
http://www.umweltbundesamt.de/en/topics/health/commissions-working-groups/committee-for-health-related-evaluation-of-building

The Belgian Royal Decree for emissions from construction products, which is applicable from January 2015, establishes threshold levels for the emissions to the indoor environment from floor coverings, floor covering adhesives and surface coatings for wooden flooring. It follows essentially the German approach (though there are some exceptions such as lower limits for toluene or acetaldehyde). Information on the Belgian legislation can be found here: http://www.health.belgium.be/en/health-impact-construction-products#article

Since January 2010, in France, the emissions of four CMR substances (trichloroethylene, benzene, bis(2-ethylhexyl) phthalate and dibutyl phthalate) from construction product shall be less than 1 µg/m^3 each after 28 days.

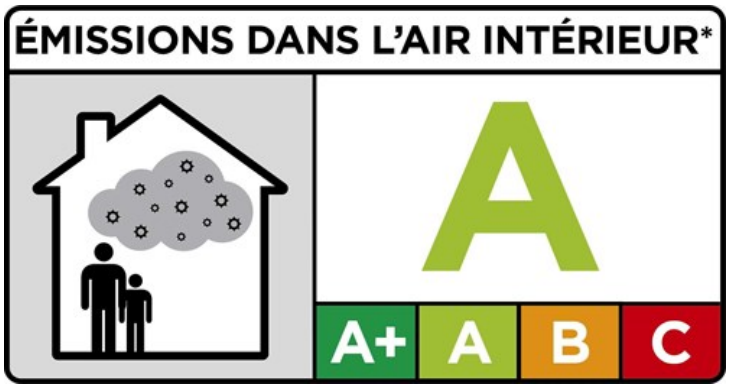
Construction products, decoration and furnishing products in France are to be labelled using an emissions classification on the basis of emissions tests from January 2012. It covers a broad range of products including floor coverings, paints and varnishes, windows and doors, wall and ceiling panelling. A non-exhaustive list of covered and non-covered products is available here (in French):
http://www.logement.gouv.fr/IMG/pdf/liste_indicative_etiquetage_cov_janvier_2016.pdf

The emission classes are as follows (µg/m³):

Classes	**C**	**B**	**A**	**A+**
TVOC	**> 2 000**	**< 2 000**	**< 1 500**	**< 1 000**
Formaldehyde	> 120	< 120	< 60	< 10
Acetaldehyde	> 400	< 400	< 300	< 200
Toluene	> 600	< 600	< 450	< 300
Tetrachloroethylene	> 500	< 500	< 350	< 250
Xylene	> 400	< 400	< 300	< 200
1,2,4-Trimethylbenzene	> 2 000	< 2 000	< 1 500	< 1 000
1,4-Dichlorobenzene	> 120	< 120	< 90	< 60
Ethylbenzene	> 1 500	< 1 500	< 1 000	< 750
2-Butoxyethanol	> 2 000	< 2 000	< 1 500	< 1 000
Styrene	> 500	< 500	< 350	< 250

Further details including test methods and emission scenarios as well as the design of the label can be found in the French legislation (in French):
https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000023991852&categorieLien=id

The label looks like this:



Following a request from the Swedish government, KemI has developed a proposal for Swedish rules on emission of construction products alongside Germany, France and Belgium which was presented on 1st December 2015:
http://www.kemi.se/en/news-from-the-swedish-chemicals-agency/2015/the-swedish-chemicals-agency-proposes-legislation-regarding-hazardous-substances-in-construction-products

3.7 Textiles

Sweden has repeatedly asked for implementation of EU legislation for textiles. KemI published two studies on chemicals of concern in textiles. The first one published in 2013 (KemI Report 3/13 - Hazardous chemicals in textiles) included a list of substances used in the textile industry that may remain in the finished textile products. It also included a proposal for an EU regulation. In this report, the Textile Fibre Regulation (No 1007/2011) was presented as the main regulatory option to be considered, but other alternative ways to regulate chemicals in textiles are also discussed. It was proposed to restrict chemicals primarily based on their intrinsic properties using the hazard classification and thresholds according to the CLP regulation. A procedure for setting specific limits on a

case-by-case basis was also foreseen. This report can be found here:
http://www3.kemi.se/Documents/Publikationer/Trycksaker/Rapporter/Rapport-3-13-textiles.pdf

A second report (KemI Report 6/14 – "Chemicals in textiles – Risks to human health and the environment") was published in October 2014. The study included three main parts:

— An overview of textile consumption in the EU and Sweden;

— A screening study with the aim to identify hazardous substances/groups of substances of potential concern to human health and the environment;

— A literature study of data on exposures and effects related to hazardous substances in textile.

Approximately ten percent of the identified 2 400 textile-related substances are considered to be of potential concern for human health. These substances include direct azo dyes, acid azo dyes, and fragrance. The identified direct-type dyes have properties that are associated with an increased risk of cancer and developmental effects, whereas the identified acid-type dyes and fragrances have properties that are associated with an increased risk of allergy. EU legislation was called for to cover risks from substances in textile articles. A comprehensive annex lists the substances of concern including their classification. The study can be downloaded here:
http://www3.kemi.se/Documents/Publikationer/Trycksaker/Rapporter/Report6-14-Chemicals-in-textiles.pdf

Following a request from the government, KemI is looking at measures to handle risks with chemicals in textiles in its third textile report. The report was published in December 2015:
http://www.kemi.se/en/news-from-the-swedish-chemicals-agency/2015/the-swedish-chemicals-agency-proposes-new-eu-legislation-on-textiles

The Swedish Chemicals Agency recommended that the Swedish Government initiate the development of specific product legislation concerning textiles within the EU.

The Dutch Institute of Public Health and the Environment (RIVM) published a report on the same topic in February 2015 (RIVM Report 2014-0155 – "Hazardous substances in textile products"). RIVM developed a prioritization method for substances in textiles that are registered in REACH, based on their hazard characteristics. Prioritization depends on the use of the substances, e.g. only in the production process or present in textile article. The classification of the substances into categories, such as carcinogen or skin sensitization, and potency were also included for prioritization. This method identified 788 individual substances, 32 of which had the highest priority scores. Most substances with a high priority were dyes and flame retardants. An in-depth assessment was performed for ten of the high-priority substances. Information available in the REACH registration dossier was not specific enough to perform a risk assessment. The study can be downloaded here:
http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2015/februari/Hazardous_substances_in_textile_products

3.8 Information on chemicals in articles

The German UBA recently published a study entitled "Enhancement of the REACH requirements for (imported) articles - Options for improvement of the chemicals regulation" (April 2015) which can be downloaded here: http://www.umweltbundesamt.de/en/publikationen/enhancement-of-the-reach-requirements-for-imported

Among other issues, UBA addresses options for enhancement of the REACH information requirements for SVHC and other chemicals in articles. The study proposes 3 regulatory options:

— introduction of a standardized communication format for articles (regulatory option 1);

— labelling requirements for SVHC (and possibly other substances) (regulatory option 2);

— extension of the communication requirements to other substances (regulatory option 3).

A standardized communication format for SVHC in articles (developed in another UBA study) is shown in the annex. It includes 4 major headlines:

— information on article and manufacturer (article, manufacturer, contact);

— substance information (substance name, EC Number, CAS Number, SVHC property or properties in accordance with REACH regulation, classification in accordance with CLP regulation, concentration in product or its part, amount in product, function of the substance);

— instructions for safe use;

— instructions for safe disposal.

This template may be a suitable starting point for a chemicals declaration form in the context of the present study. It seems appealing to consider a broadening of its scope in line with the proposed option 2, i.e. to include all substances complying with the criteria of Art. 57 REACH (a) to (e) (i.e. CMRs cat. 1A and 1B + PBTs + vPvBs) without the need to be included on the candidate list or even to go further and to include other hazard classes such as CMRs cat. Two or respiratory and skin sensitizing substances.

4 Voluntary specifications, standards and guidance documents

4.1 EU Ecolabel criteria

Regulation (EC) No 66/2010 on the EU Ecolabel lays down rules for the establishment and application of the voluntary EU Ecolabel scheme. The scheme is intended to promote products which have a high level of environmental performance through the use of the EU Ecolabel. The Regulation requires that the criteria which products shall comply with in order to bear the EU Ecolabel are based on the best environmental performance achieved by products on the Community market (i.e. should be awarded to the best 10 % - 20 % of the products available).

Consolidated versions of the Regulation can be found here: http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:32010R0066

4.1.1 Key elements of the Ecolabel Regulation relevant for chemicals in articles

Article 6 of the Regulation provides “General requirements for EU Ecolabel criteria”. Paragraph 6 and 7 contain requirements relating to chemicals:

“*6. The EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR, in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures([2]), nor to goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency([3]).*

7. For specific categories of goods containing substances referred to in paragraph 6, and only in the event that it is not technically feasible to substitute them as such, or via the use of alternative materials or designs, or in the case of products which have a significantly higher overall environment performance compared with other goods of the same category, the Commission may adopt measures to grant derogations from paragraph 6. No derogation shall be given concerning substances that meet the criteria of Article 57 of Regulation (EC) No 1907/2006 and that are identified according to the procedure described in Article 59(1) of that Regulation, present in mixtures, in an article or in any homogeneous part

of a complex article in concentrations higher than 0,1 % (weight by weight). Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 16(2)".

Additional chemical provisions are included in the criteria for specific product groups.

Specific criteria are available for the following articles (other products not listed):

— personal care products: absorbent hygiene products;

— clothing and textiles: textile products, footwear;

— electronic equipment: imaging equipment, personal, notebook and tablet computers, televisions;

— coverings: wooden floor coverings, hard floor coverings, textile floor coverings (discontinued);

— furniture and bed mattresses: furniture, bed mattresses;

— household appliances: electrically driven, gas driven or gas absorption heat pumps, water-based heaters;

— other household Items: sanitary tapware, flushing toilets and urinals;

— paper products: converted paper, newsprint paper, printed paper, copying and graphic paper, tissue paper.

An overview of the products covered by the Regulation and subject to specific criteria can be found here: http://ec.europa.eu/environment/ecolabel/products-groups-and-criteria.html

Exclusion of substances based on Hazard (H) Statements is a key element of the product specific rules. Typically, the following substance exclusions are found in the criteria (former Risk (R) phrases in brackets):

Carcinogenic, mutagenic or toxic for reproduction (CMR)	
Category 1A and 1B	**Category 2**
H340 May cause genetic defects (R46)	H341 Suspected of causing genetic defects (R68)
H350 May cause cancer (R45)	H351 Suspected of causing cancer (R49)
H350i May cause cancer by inhalation (R49)	
H360F May damage fertility (R60)	H361f Suspected of damaging fertility (R62)
H360D May damage the unborn child (R61)	H361d Suspected of damaging the unborn child (R63)
H360FD May damage fertility. May damage the unborn child (R60, R60/61)	H361fd Suspected of damaging fertility. Suspected of damaging the unborn child (R62/63)
H360Fd May damage fertility. Suspected of damaging the unborn child (R60/63)	H362 May cause harm to breast fed children (R64)
H360Df May damage the unborn child. Suspected of damaging fertility (R61/62)	

Acute toxicity	
Category 1 and 2	**Category 3**

H300 Fatal if swallowed (R28)	H301 Toxic if swallowed (R25)
H304 May be fatal if swallowed and enters airways (R65)	
H310 Fatal in contact with skin (R27)	H311 Toxic in contact with skin (R24)
H330 Fatal if inhaled (R23/26)	H331 Toxic if inhaled (R23)
	EUH070 Toxic by eye contact (R39/41)

Specific target organ toxicity (STOT)	
Category 1	**Category 2**
H370 Causes damage to organs (R39/23, R39/24, R39/25, R39/26, R39/27, R39/28)	H371 May cause damage to organs (R68/20, R68/21, R68/22)
H372 Causes damage to organs (R48/25, R48/24, R48/23)	H373 May cause damage to organs (R48/20, R48/21, R48/22)

Respiratory and skin sensitization	
Category 1	
H317: May cause an allergic skin reaction (R43)	
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled (R42)	

Hazardous to the aquatic environment	
Category 1 and 2	**Category 3 and 4**
H400 Very toxic to aquatic life (R50)	H412 Harmful to aquatic life with long-lasting effects (R52/53)
H410 Very toxic to aquatic life with long-lasting effects (R50/53)	H413 May cause long-lasting effects to aquatic life (R53)
H411 Toxic to aquatic life with long-lasting effects (R51/53)	

Hazardous to the ozone layer	
H420 Harms public health and the environment by destroying ozone in the upper atmosphere (R59)	

The substance exclusions based on H-statement may apply generally or with respect to certain categories of substances (e.g. colourants or flame retardants) or both. The thresholds may be based on general and specific concentration thresholds determined in accordance with Article 10 of the CLP Regulation or other limits. Alternatively, it is simply stated that the classified substances shall not be used unless derogations are granted.

In view of the comprehensive requirements included in some of the product criteria only some key observations are made in the following sections.

4.1.2 Personal care products

The criteria for **absorbent hygiene products** (Commission Decision 2014/763/EU) comprise disposable baby diapers, feminine care pads, tampons and nursing pads (also known as breast pads).

Criterion 2. "Fluff pulp", Criterion 3. "Man-made cellulose fibres (including viscose, modal, lyocell, cupro, triacetate) and Criterion 4 "Cotton and other natural cellulosic seed fibres" include production related chemical requirements such as exclusion of chlorine gas for bleaching (limit for AOX emissions), exclusion of optical brighteners and colouring agents (including fluorescent whitening agents), emissions to air and water (COD, phosphorous (P) and sulphur (S) compounds, NOx).

Criterion 5. "Plastic materials and superabsorbent polymers" provides that the contents of lead, cadmium, hexavalent chrome and related compounds shall be lower than 0,01 % (100 ppm) of the mass of each plastic material and synthetic polymer used in the product. Additives used in plastics in concentration above 0,10 % by weight shall not be classified with any of the listed hazard statements. Some restrictions apply to superabsorbent polymers (e.g. exclusion of acrylamide, residual monomers with listed H statements above 1 000 ppm, max. 10 % water-soluble extracts).

Criterion 6. "Other materials and components" excludes colophony resins, diisobutyl phthalate, diisononyl phthalate and formaldehyde from adhesives (a limit of 100 ppm, additional provisions for formaldehyde). The product and any homogeneous part of it shall not be dyed (some derogations apply). Several requirements apply to fragrances: products marketed as designed and intended for children as well tampons and nursing pads shall be fragrance-free, fragrance shall be manufactured and handled following the code of practice of the International Fragrance Association (IFRA), any fragrance used shall also comply with Criterion 7. on excluded or limited substances or mixtures regardless of the concentration in the final product, fragrances and ingredients of the fragrance mixtures that are identified as established contact allergens of special concern by the Scientific Committee on Consumer Safety as well as the fragrances whose presence, in accordance with Annex III to the Cosmetics Regulation is required to be indicated in the list of ingredients shall not be used, the use of nitromusks and polycyclic musks is not allowed and some labelling provisions are given. Nanosilver particles shall not be intentionally added to the product or to any homogeneous part or material of it.

Criterion 7. "Excluded or limited substances or mixtures" addresses excluded or limited substances and mixtures based on the text of Article 6 of the Ecolabel Regulation and, respectively, the tables with H statements and R phrases (indicated above). The standard text for concentration thresholds is given (generic or specific concentration limits determined in accordance with Article 10 of the CLP Regulation, 0,1 % for PBTs, vPvBs and substances of equivalent concern).

4.1.3 Clothing and textiles

The Ecolabelling criteria for **textile products** (Commission Decision 2014/350/EU) are comprehensive and only a short summary is given below.

Criterion 13 refers to a "Restricted Substance List (RSL)" included in Appendix 1 (9 pages). The requirements relate to various production stages in the textile supply chain:

(a) fibre and yarn spinning (readily biodegradable substances)

(b) bleaching and pre-treatment (no chlorine bleaching)

(c) dye houses (no halogenated carriers, no azo dyes that may cleave to aromatic amines listed in Appendix 2 which also gives an indicative list of azo dyes that may cleave to these aryl amines, no dyes with CMR or sensitizing properties, indicative lists of CMR dyes and sensitizing dyes are also included in Appendix 2, no chrome mordant dyes, restrictions for metal complex dyes based on copper, chrome and nickel)

(d) printing processes (provisions for dyes and pigments in line with (c) above, max. 5 % VOCs in printing pastes, no plastisol additives)

(e) finishing processes (no incorporation of biocides such as triclosan into fibres, restrictions of halogenated compounds for anti-felting and shrink resistance, no fluorinated water, stain and oil repellent treatments, exclusion of listed flame retardants – HBCDD, polybrominated diphenylethers, PBBs, TEPA, TRIS, TCEP, SCCP –, restriction for antimony trioxide (derogation from ban based on H351)).

(f) all production stages (exclusion of SVHC in line with Article 6 text of Regulation, readily biodegradable surfactants, softeners and complexing agents required, exclusion of substances used in auxiliaries such as alkylphenols and alkylphenolethoxylates (APEOs))

(g) the final product (restrictions for N,N-Dimethylacetamide (derogation from SVHC ban, 0,001 % - 0,005 %), restrictions for formaldehyde (16 ppm – 75 ppm), only authorized biocides allowed, limits for extractable metals, ban of 8 phthalates, exclusion of PFOA or any of its higher homologues for outdoor clothing, metal limits for metal accessories, phthalate exclusions for plastic accessories). Some of the requirements (e.g. extractable metals, formaldehyde) contain different limits depending on the type of use: products for babies and children under 3 years old, all products that are in direct contact with the skin, garments with limited skin contact and interior textiles (similar to Oeko-Tex® Standard 100)

Criterion 14 covers additional requirements concerning the "Substitution of hazardous substances used in dyeing, printing and finishing". It disallows substances applied to fabrics and knitted panels during dyeing, printing and finishing processes which remain on the final product if they meet the hazard criteria listed in the tables indicated above unless they have been specifically derogated and subject to derogation conditions (listed in Table 6).

In addition, there are some fibre specific requirements, e.g. pesticide residues in cotton (Criterion 1(c)), or ectoparasiticide concentrations in wool (Criterion 3(a)). Also some workplace emissions are covered.

The criteria for **footwear** (Commission Decision (EU) 2016/1349) provide restrictions for extractable metals similar to those for textile products. Additional requirements address 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 use of flame retardants is allowed only for certain types of personal protective equipment with an incorporated flame retardant function to ensure safety at work. The phthalates DIHP, DHNUP, DMEP, DIPB, DEHP, DBP, BBP, DPP (n-, iso-, or mixed), DIPP, DnHP) are restricted 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 %). A list is included of solvents which shall not be used in any mixtures or formulations for the processing of component materials (leather, textiles, coated leather and textiles, plastics) and in adhesives used during the final product assembly (no limits). Various limits for the content of free formaldehyde are set. Listed N-Nitrosamines shall not be detectable in rubber. Fluorinated water, stain and oil repellent treatments must not be used, including perfluorinated and polyfluorinated carbon treatments. Alkylphenols and alkylphenol ethoxylates (APE) are limited in leather, textiles and coated fabrics. Limits for 18 PAHs are given for textiles or leather materials and coatings with individual limits for the 8 PAHs restricted in REACH as well as a total limit value for all 18 substances (1 mg/kg for footwear for children, 10 mg/kg for all other footwear). Further restrictions cover substances such as C10-C13 chloralkanes (SCCP),, azo dyes, CMR and sensitizing dyes, metal containing dyes and biocides.

4.1.4 Electronic equipment

The criteria for **imaging equipment** (Commission Decision 2013/806/EU) includes restrictions on indoor emissions (Criterion 5) which addresses TVOC, benzene, styrene, not identified single VOC substances, ozone and dust (the last 2 only for electro-graphic (EP)-printing). The general exclusion rules for chemicals given in the text of the Regulation apply. The list of substances with H statements as above with the exception of H420 (ozone) is given. The limits are based on general and specific concentration thresholds determined in accordance with Article 10 of the CLP Regulation. For PBTs, vPvBs and substances of equivalent concern a 0,1 % limit applies. A list of derogations is also given (e.g. articles or homogeneous parts of articles with weight below 25 g, inks, toners and cartridges). Mercury

or its compounds shall not intentionally be added to light sources used in imaging equipment (Criterion 8). Additional requirements apply to substances in ink and toners (Criterion 12). These cover mercury, cadmium, lead, nickel or chromium-VI-compounds, azo dyes and biocides.

The criteria for **personal, notebook and tablet computers** (Commission Decision (EU) 2016/1371) include i the usual substance bans based on certain H statements, as well as some specific restrictions for indicated sub-assemblies and component parts. Certain exemptions from the restrictions in Article 4(1) of the ROHS Directive listed in its Annex III do not apply (relating to the use of lead solder in small-scale servers, cadmium in electrical contacts or use of mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps). Other provisions restrict or exclude organotin stabilizers, azo dyes that may cleave to the carcinogenic aryl amines, other colourants included in the IEC 62474 declarable substances list, PAHs (the sum total concentration of the 18 listed PAHs not greater than 10 mg/kg), biocidal products intended to provide an anti-bacterial function as well as arsenic and its compounds (0,005 %). Derogations for the use of hazardous flame retardants, plasticisers, additives, coatings, cathode materials, solvents and salts are also given.

The criteria for **televisions** (Commission Decision 2009/300/EC) include limits for mercury (75 mg up to screen sizes of 40 inches and 99 mg above). Further limits cover heavy metals (in line with ROHS Directive) and flame retardants (excluding CMRs and substances with aquatic toxicity). Reactive flame retardants are excluded, i.e. those which upon use change their properties (i.e. are actually not contained in the final product in a concentration > 0,1 %) such that the identified R-phrases above no longer apply.

4.1.5 Coverings

The criteria for **wood-, cork- and bamboo-based floor coverings** (Commission Decision (EU) 2017/176) includes apart from general exclusions based on hazard classifications limits for recycled materials (metals, chlorine, fluorine, pentachlorophenol (PCP) and tar oils (benzo(a)pyrene)) . The treatment of wood, cork and/or bamboo of the floor coverings with biocidal products is not permitted. Several restrictions apply to substances or mixtures used in the manufacture of floor coverings (such as paints, adhesives, coatings, resins or surface treatment products). This includes biocides, halogenated organic compounds, azidirin and polyaziridins, heavy metals (lead, cadmium, chrome (VI), mercury, arsenic and selenium), VOC content,phthalates and flame retardants. The release of dangerous substances in the use stage is limited as regards formaldehyde (in principle 50 % or 65 % of E1 values, alternatively Californian or Japanese specifications) and VOCs (TVOC, TSVOC, R-values for LCI substances, carcinogens).

The criteria for **hard floor coverings** (Commission Decision 2009/607/EC) exclude the addition of substances or preparations based on the list of R phrases or H statements (see above). Lead, cadmium and antimony (or any of their compounds) are limited in glazes (0,5 %, 0,1 % and 0,25 %). There is a limitation of the presence of asbestos and polyester resins (10 %) in the materials. Several requirements apply to the release of substances from finishing and production processes (e.g. particulate matter, SO_2, NOx, etc.). The release of dangerous substances from glazed tiles in the use stage is limited (Pb: 80 mg/m^2, Cd: 7 mg/cm^2).

The criteria for **textile coverings** (Commission Decision 2009/967/EC) are no longer valid as the product group is discontinued (but the provisions may be still interesting). In the section on raw materials, they exclude the use of substances or preparations for the manufacture of the product based on the list of R phrases or H statements (see above). In addition, there are some fibre-specific requirements such as the exclusion of insecticides (organochlorine, organophosphorous and others) for wool, polyamide, polyester and polypropylene. Antimony in the polyester fibres shall not exceed 260 ppm. Lead-based pigments shall not be used. Requirements for backing apply if latex foam contributes to more than 5 % of the total weight of the carpet: there are limits for extractable heavy metals (antimony 0,5 ppm, arsenic 0,5 ppm, lead 0,5 ppm, cadmium 0,1 ppm, chromium 1,0 ppm, cobalt 0,5 ppm, copper 2,0 ppm, nickel 1,0 ppm, mercury 0,02 ppm), a VOC limit (0,5 mg/m^3), metal complex dyes based on copper, lead, chromium or nickel shall not be used, no chlorophenol (salts and esters) shall be

present in concentrations exceeding 0,1 ppm, except mono- and di-chlorinated phenols (salts and esters) which shall not exceed 1 ppm, the concentration of butadiene shall not exceed 1 ppm, the concentration of N-nitrosamines shall not exceed 0,001 mg/m^3, tin in organic form shall not be used, CFCs, HCFCs, HFCs or methylene chloride shall not be used as (auxiliary) blowing agents, vulcanized foams shall not be used for back coating and the concentration of formaldehyde shall not exceed 30 ppm as measured with EN ISO 14184-1. Alternatively, it shall not exceed 0,01 mg/m^3 as measured with the chamber test.

Another series of requirements is included in the section on the production of all materials. There is a substance exclusion based on a list of R phrases or H statements. In addition there are specific exclusions for flame retardants (only reactive flame retardants may be used in the product, in case of FRs with certain R phrases or H statements a maximum of 0,1 % residue of the original form is allowed), plasticizers (phthalates with certain R phrases or H statements are excluded, additionally DNOP (di-n-octyl phthalate), DINP (di-isononyl phthalate), DIDP (di-isodecyl phthalate) are not permitted in the product), several auxiliaries for textile fibres treatment are banned (Alkylphenolethoxylates (APEOs), linear alkylbenzene sulfonates (LAS), bis(hydrogenated tallow alkyl) dimethyl ammonium chloride (DTDMAC), distearyl dimethyl ammonium chloride (DSDMAC), di(hardened tallow) dimethyl ammonium chloride (DHTDMAC), ethylene diamine tetra acetate (EDTA), and diethylene triamine penta acetate (DTPA)), restrictions for dyes and pigments apply (exclusion based on a list of R phrases or H statements, azo dyes shall not be used that may cleave to any one of the listed aromatic amines, a list of dyes is banned, dyes and pigments containing lead (Pb), cadmium (Cd), mercury (Hg) or chromium (chromium total) or Cr(VI) shall not be used, the limit value for the total heavy metal content of a fitted carpet is 100 mg/kg.

4.1.6 Furniture and bed mattresses

The criteria for **furniture** (Commission Decision (EU) 2016/1332) also exclude the use of substances or preparations for the manufacture of the product based on the list of R phrases or H statements (see above). Extractable heavy metals are restricted in leather, textiles and coated fabric covering materials as well as in upholstery padding materials similar to the limits included in ecolabel criteria for textile products. Additional restrictions apply to certain heavy metals included in paints, primers and varnishes based on cadmium, lead, chromium VI, mercury, arsenic or selenium, at concentrations exceeding 0,010 % for each individual metal and heavy metals in plastic additives that contain cadmium, chromium VI, lead, mercury or tin compounds. Chrome mordant dyes are not allowed. 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). Excluded are essentially already banned flame retardants in polyurethane (PUR) foam. The phthalates DBP, DNOP, DEHP, BBP, DIDP, DINP are restricted in polyurethane (PUR) foam in furniture for children less than 3 years old (sum 0,01 %). A list of solvents is given which shall not be used (no limits given) in any mixtures or formulations for the processing of component materials (leather, textile or coated fabric materials). The limits for VOC emissions from latex and PUR foams are identical with the ones set in the EU ecolabel criteria for bed mattresses. 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 also defined. In addition, formaldehyde emission limits are provided for emissions from wood-based panels as well as content limits for leather, textile and coated fabrics. Perfluorinated and polyfluorinated substances compounds shall not be impregnated into furniture upholstery covering material finishes in order to impart water, stain and oil repellent functions. In addition to the individual concentration limits for 8 PAHs restricted under REACH (1 mg/kg), the sum total concentration limit for the 18 PAHs listed shall be lower than 10 mg/kg (including in addition to rubber or plastic components covered by REACH also textiles or leather materials and coatings). The criteria include limits for residues of individual listed pesticides (0,04 ppm each) in latex foams which include at least 20 % natural latex. Some provisions are related to biocides.

The criteria for **bed mattresses** (Commission Decision 2014/391/EU) include a comprehensive set of chemical requirements under a number of different headings. The most relevant ones are listed below:

Criterion 1. "Latex foam" includes lists of restricted substances including limits (chlorophenols, heavy metals, pesticides, butadiene), emission limits for specified volatile organic compounds (including total VOC) and provisions for dyes.

Criterion 2. "Polyurethane (PUR) foam" includes lists of restricted substances including limits (biocides, heavy metals, plasticizers, toluenediamine (TDA), methylenedianiline (MDA), tinorganic substances and others), emission limits for specified volatile organic compounds (including total VOC), provisions for dyes, total chlorine content of isocyanates and a ban of halogenated organic compounds as (auxiliary) blowing agents.

Criterion 5. "Textiles (fabrics and fibres used as mattress cover and/or filling materials)" covers – apart from a reference to requirements covered by criterion 7 (flame retardants), 8 (biocides), 9 (plasticizers) and 10 (hazardous substances) - auxiliaries used in preparations and formulations (alkylphenols, alkylphenolethoxylates (APEOs) and their derivatives, as well as other substances), surfactants, fabric softeners and complexing agents in wet processes (biodegradabilty), bleaching of pulp, yarns, fabrics and end products (limitations regarding chlorine bleaching), dyes (excluding halogenated dyeing accelerants (carriers), azo dyes that may cleave to aromatic amines that are known to be carcinogenic (including and indicative list of azodyes), CMR dyes, potentially sensitizing dyes and limiting chrome mordant dyes and metal complex dyes), extractable metals, water, stain and oil repellents (exclusion of fluorinated treatments, non-fluorinated treatments shall be biodegradable and non-bioaccumulative) and wastewater discharges from wet processing.

Criterion 6. "Glues and adhesives" does not allow the use of organic solvents.

Criterion 7. "Flame retardants" excludes listed substances (e.g. some polybrominated diphenyl ethers, hexabromocyclododecane, TCEP).

Criterion 8. "Biocides" requires to use only authorized substances under the Biocidal Products Regulation and excludes the use of certain substances during the transportation or storage of the product.

Criterion 9. "Plasticizers" excludes listed phthalate plasticizers.

Criterion 10. "Excluded or limited substances and mixtures" includes the standard text with H statements. However, here we can find a lot of derogations including derogation conditions (e.g. for antimony trioxide, nickel, dyestuffs for dyeing and non-pigment printing, flame retardants, optical brighteners, water, dirt and stain repellents, auxiliaries, glues and adhesives).

Criterion 11. "Emission of specified volatile organic compounds" includes limits for formaldehyde, other aldehydes, VOCs (total), SVOCs (total) and volatile carcinogenic substances cat. 1A and 1B (measurement after 7 days or 28 days).

4.1.7 Household appliances

The criteria for **electrically driven, gas driven or gas absorption heat pumps** (Commission Decision 2007/742/EC) establish only a requirement for the global warming potential (GWP) of the refrigerant (GWP value > 2 000 over a 100-year period). The requirements for heavy metals and flame retardants are in line with regulatory requirements (ROHS).

The criteria for **water-based heaters** (Commission Decision 2014/314/EU) contain several emission limits. Apart from the general chemical provisions included in the Ecolabel Regulation there are no further restrictions for chemicals.

4.1.8 Other household Items

The criteria for **sanitary tapware** (Commission Decision 2013/250/EU) include chemical requirements in the following criteria:

Criterion 2. "Materials in contact with drinking water" requires that metallic materials in contact with drinking water used in sanitary tapware shall be listed in the positive list 'Acceptance of Metallic Materials for Products in Contact with Drinking Water' as given in the Appendix. If the metallic materials are not included in this positive list, results of test conducted in accordance with the approach for 'Adding Materials to the Composition List within a Category of Materials', as described in the Appendix, and using the EN 15664-1 standard, shall be submitted. In addition, existing national regulatory provisions apply, of course. It appears that the approach by the group of 4 MS (see above) has been used.

Criterion 3. "Excluded or limited substances and mixtures"" includes the standard text with H statements and a derogation including derogation conditions for nickel in stainless steel.

The criteria for **flushing toilets and urinals** (Commission Decision 2013/641/EU) include in Criterion 3. "Excluded or limited substances and mixtures" only the standard text with H statements and derogations for articles with weight below 25 g, homogeneous parts of complex articles with weight below 25 g, nickel in stainless steel of all types and electronic components (which are in compliance with the provisions set out in Article 4 of Directive 2011/65/EU (ROHS).

4.1.9 Paper products

The criteria for **converted paper** (Commission Decision 2014/256/EU) include criteria for three main categories of products: envelopes, paper carrier bags and stationery paper products such as folders, binders, notebooks or pads.

Criterion 1 consists of Part A for paper substrates and Part B for board substrates. Paper substrates shall comply with the corresponding Ecolabel criteria for copying and graphic paper or for newsprint paper (see below). The requirements for board substrates include a variety of production related emission limits (e.g. COD, Sulphur, NOx, Phosphorous or AOX) and addresses excluded or limited substances and mixtures based on the text of Article 6 of the Ecolabel Regulation and, respectively, the tables with H statements and R phrases (indicated above). The standard text for concentration thresholds is given (generic or specific concentration limits determined in accordance with Article 10 of the CLP Regulation, 0,1 % for PBTs, vPvBs and substances of equivalent concern). Additional requirements include: exclusion of chlorine gas as a bleaching agent, no alkylphenol ethoxylates or other alkylphenol derivatives as addition to cleaning chemicals, de-inking chemicals, foam inhibitors, dispersants or coatings, a limit of 100 ppm for the total quantity of residual monomers present in coatings, retention aids, strengtheners, water repellents or chemicals used in internal and external water treatment based on H statements and R phrases (for acrylamide a limit of 700 ppm applies), surfactants used in de-inking shall be ultimately biodegradable, biocides shall not be bio-accumulative (limit log Pow < 3,0 or BCF ≤ 100), exclusion of azo dyes that may cleave to any of the listed aromatic amine (in line with REACH Annex XVII), exclusion of dyes or pigments based on lead, copper, chromium, nickel or aluminium with the exception of copper phthalocyanine dyes or pigments and restricted impurities of (ionic) metals in the dye stuffs.

The criteria for **newsprint paper** (Commission Decision 2012/448/EU) and for copying and graphic paper (Commission Decision 2011/332/EU) follow essentially the same approach.

The criteria for **printed paper** (Commission Decision 2012/481/EU) build upon the criteria for newsprint paper and for copying and graphic paper (i.e. one of these criteria has to be fulfilled). Thus, the criteria just address the printing, coating and finishing processes of the paper components and the non-paper components of the printed paper product and provide requirements for the finished product.

Criterion 2 covers excluded or limited substances and mixtures based on the text of Article 6 of the Ecolabel Regulation and, respectively, the tables with H statements and R phrases (indicated above). Some derogations are granted (i.e. toluene for use in rotogravure printing processes where a closed or encapsulated installation or recovery system, or any equivalent system, is in place to control and monitor fugitive emissions and where the recovery efficiency is at least 92 %. UV varnishes and UV inks classified H412/R52-53 are also exempted from this requirement). The standard text for concentration

thresholds is given (generic or specific concentration limits determined in accordance with Article 10 of the CLP Regulation, 0,1 % for PBTs, vPvBs and substances of equivalent concern). Biocides that are classified H410/R50-53 or H411/R51-53 are granted a derogation provided they are not be bio-accumulative (limit log Pow < 3,0 or BCF ≤ 100). Restrictions are given for washing agents used for cleaning in printing processes and/or sub-processes that contain aromatic hydrocarbons, alkyl phenol ethoxylates, halogenated solvents and phthalates. Heavy metals or their compounds shall not be used in printing inks, toners, inks, varnishes, foils and laminates: cadmium, copper (excluding copper-phthalocyanine), lead, nickel, chromium VI, mercury, arsenic, soluble barium, selenium, 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. There are also provisions for emissions to water and air during production.

The criteria for **tissue paper** (Commission Decision 2009/568/EC) comprise sheets or rolls of tissue paper fit for use for personal hygiene, absorption of liquids and/or cleaning of soiled surfaces. Apart from emissions to air and water it covers requirements on hazardous chemical substances in chapter 4 including the following: exclusion of chlorine gas as a bleaching agent, exclusion of the addition of alkylphenol ethoxylates or other alkylphenol derivatives to cleaning chemicals, de-inking chemicals, foam inhibitors, dispersants or coatings, required biodegradability of surfactants in de-inking formulations for recycled fibres, exclusion of bio-accumulative biocides, a limit of 0,7 % for the (sum of the) chloro-organic substances epichlorohydrin (ECH), 1,3-dichloro-2-propanol (DCP) and 3-monochloro-1,2-propanediol (MCPD) used as wet strength aids, exclusion of softeners, lotions, fragrances and additives of natural origin which meet the classification as hazardous to the environment, sensitizing, carcinogenic or mutagenic (or are assigned the corresponding R phrases) and exclusion of fragrances which shall be labelled in accordance with the Cosmetics Directive (now Regulation) on a product/packaging (concentration limit 0,01 %). In addition, chapter 5 “Product Safety” contains further chemical requirements for products made from recycled fibres or mixtures of recycled and virgin fibres including restrictions for formaldehyde (1 mg/dm2), glyoxal (1,5 mg/dm2) and PCP (2 mg/kg) in tissue paper as well as restrictions for azo dyes that may cleave to any of the listed aromatic amines and exclusion of dyes based on Cd or Mn.

4.1.10 Remarks on the EU Ecolabel criteria

The EU Ecolabel criteria are a key reference point for establishing chemical requirements for products. The exclusion of chemicals based on hazard classification (e.g. CMR) or related H sentences (the formerly used R phrases should no longer be used as the transitional period in which their use was allowed has expired) is simple (does not require sophisticated risk assessments) and easy to check for a manufacturer (based on safety datasheets). General exclusions based on hazard classifications seem to be difficult to enforce. Substances, which are classified as CMR (harmonized or self-classified) comprise hundreds of compounds. However, analytical procedures focus on certain distinct substances and do not allow to detect a whole range of substances covered by hazard classes. Hence, in practice a mix of hazard based exclusions (for the most hazardous substances such as CMR) and substance specific limits seem warranted.

More recent Ecolabel criteria generally use a threshold of 0,1 % for substances included in the Candidate List for SVHCs as well as for substances with certain H statements It should be noted, however, that compliance with this limit does not necessarily mean that the product is safe.

4.2 Selected national ecolabel criteria

4.2.1 Global Ecolabelling Network (GEN)

The Global Ecolabelling Network (GEN) is a non-profit association of third-party, environmental performance recognition, certification and labelling organizations founded in 1994 to improve, promote, and develop the “ecolabelling” of products and services. Ecolabelling means so-called Type 1 labels as defined by the ISO 14024 standard. GEN currently has twenty-6 members and three associate members operating ecolabelling programs around the world. However, it should be noted that there are

many other labels (partly focusing just on a limited number of issues), which are not member of this network. The website of the organization is accessible under: http://www.globalecolabelling.net/

The website provides an overview of existing product criteria by country and by product type (though some links to the criteria do not work or some criteria are not available in English).

From a European perspective, the schemes operated in Germany and in the Nordic countries seem the most relevant.

4.2.2 German Blue Angel

The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety owns the Blue Angel eco-label which was created in 1978. It is verified by RAL GmbH and awarded on the basis of criteria, developed by the Federal Environment Agency and the Independent Environmental Label Jury.

The website of the Blue Angelis accessible via the following link: https://www.blauer-engel.de/en

The following criteria seem relevant for the purpose of the current study:

— RAL-UZ 5 “Sanitary Paper Products made of Recycled Paper”;

— RAL-UZ 14 “Recycled Paper”;

— RAL-UZ 30a “Products made from Recycled Plastics”;

— RAL-UZ 35 “Wallpapers and Woodchip Wall Coverings primarily made of Recycled Paper”;

— RAL-UZ 38 “Low-Emission Furniture and Slatted Frames made of Wood and Wood-Based Materials”;

— RAL-UZ 56 “Recycled Cardboard”;

— RAL-UZ 65 “Unbleached Paper Filters for Use with Hot or Boiling Water”;

— RAL-UZ 67 “Lead-free products”;

— RAL-UZ 72 “Printing and Publication Papers”;

— RAL-UZ 76 “Low-emission Composite Wood Panels”;

— RAL-UZ 78a “Computer”;

— RAL-UZ 78b “Key Boards”;

— RAL-UZ 78c “Monitors”;

— RAL-UZ 87 “Low-Energy Hand Driers”;

— RAL-UZ 106 “Mobile Phones”;

— RAL-UZ 117 “Low Emission Upholstered Furniture”;

— RAL-UZ 119 “Mattresses”;

— RAL-UZ 120 “Elastic Floor Coverings”;

— RAL-UZ 125 “Baby Phone”;

— RAL-UZ 127 “Digital Projectors”;

— RAL-UZ 128 “Textile Floorcoverings”;

— RAL-UZ 129 “Low-Noise and Low-Pollutant Garden Tools”;

— RAL-UZ 131 “Digital cordless phone”;

— RAL-UZ 132 “Low-Emission Thermal Insulation Material and Suspended Ceilings for Use in Buildings”;

— RAL-UZ 133 “Water boilers, electric kettles”;

— RAL-UZ 134 “Auto-Off Power Strips and Socket Adapters”;

— RAL-UZ 136 “Coffee Machines for Household Use”;

— RAL-UZ 138 “Refrigerators”;

— RAL-UZ 139 “Household Gas cooker and gas-fired cooking appliances”;

— RAL-UZ 140 “External Thermal Insulation Composite Systems (ETICS) “;

— RAL-UZ 142 “Household Energy Meters”;

— RAL-UZ 143 “Electric Ovens for Household Use”;

— RAL-UZ 144 “DVD-Recorder, DVD-Player, Blu-ray Disk-Player”;

— RAL-UZ 145 “Television Sets”;

— RAL-UZ 146 “Compact Hi-Fi Systems”;

— RAL-UZ 147 “Household Cooker Hoods”;

— RAL-UZ 148 “Low-emission upholstery leathers”;

— RAL-UZ 149 “Microwave Ovens”;

— RAL-UZ 150 “Voice over IP”;

— RAL-UZ 152 “Household Dishwashers “;

— RAL-UZ 154 “Textiles”;

— RAL-UZ 155 “Shoes”;

— RAL-UZ 156 “Flooring Underlays”;

— RAL-UZ 157 “Energy-Efficient and Water-Saving Hand-Held and Overhead Shower Heads “;

— RAL-UZ 158 “E-Book Reader”;

— RAL-UZ 159 “Textile Toys”;

— RAL-UZ 160 “Router “;

— RAL-UZ 167 “Toasters”;

— RAL-UZ 171 “Office Equipment with Printing Function (Printers, Copiers, Multifunction Devices)”;

— RAL-UZ 174 “Data Shredders “;

— RAL-UZ 175 “Hair Dryers“;

— RAL-UZ 176 “Low-Emission Floor Coverings, Panels and Doors for Interiors made of Wood and Wood-Based Materials”;

— RAL-UZ 177 “Recycled Toner modules“;

— RAL-UZ 180 “Sanitary tapware”;

— RAL-UZ 181 “Household Tumble Dryers”;

— RAL-UZ 183 “Telephone Systems “;

— RAL-UZ 188 “Household Vakuum Cleaner”;

— RAL-UZ 195 “Printed matters“;

— RAL-UZ 196 “Set-Top Boxes”;

— RAL-UZ 200 “Writing Utensils and Stamps”;

— RAL-UZ 205 “Office Equipment with Printing Function (Printers and Multifunction Devices)”.

4.2.3 Nordic Ecolabel (“Swan”)

The Nordic Ecolabel is the official ecolabel of the Nordic countries and was established in 1989 by the Nordic Council of Ministers. The choice of criteria is made by the Nordic Ecolabelling Board with representatives from each country.

The website of the Nordic Ecolabel is accessible via the following link: http://www.nordic-ecolabel.org/

In addition, there are national websites of the 5 national offices (Denmark, Finland, Iceland, Norway and Sweden).

The following criteria seem relevant for the purpose of the current study:

— 001 “Primary batteries”;

— 003 “White goods”;

— 005 “Tissue paper”;

— 008 “Remanufactured OEM toner cartridges”;

— 010 “Construction and facade panels”;

— 015 “Imaging equipment”;

— 019 “Compost bins”;

— 023 “Sanitary products”;

— 029 “Floor coverings”;

— 030 “Rechargeable batteries”;

— 031 “Furniture and fitments”;

— 039 “Textiles, hides/skins and leather”;

— 040 “Machines for Parks and Gardens”;

— 041 “Printing companies, printed matter, envelopes and other converted paper products”;

— 047 “Disposables for food”;

— 048 “Computers”;

— 049 “Grease-proof paper”;

— 052 “Closed Toilet Systems”;

— 057 “Office and hobby supplies”;

— 059 “Heat pumps”;

— 062 “Windows and Exterior doors”,

— 071 “TV and Projector”,

— 073 “Outdoor furniture and playground equipment”,

— 078 “Stoves”;

— 086 “Durable resistant wood for outdoor use”;

— 088 “Candles”;

— 089 “Small houses, apartment buildings and pre-school buildings”;

— 095 “Toys”;

— 098 “Disposable bags, tubes and accessories for health care”.

4.2.4 Remarks on the national ecolabel criteria

Criteria included in national ecolabelling schemes are a useful complement to the EU Ecolabel criteria, as it covers additional product categories and include requirements that often go beyond the corresponding European ones.

4.3 Activities in the field of textiles and leather

4.3.1 Oeko-Tex® Standard 100

The Oeko-Tex® Standard 100 for textile products of all types was established in 1992. It is operated by the International Oeko-Tex® Association, a union of 16 renowned institutes for textile research and testing in Europe and Japan, with representations and contact offices in over 60 countries worldwide. It runs also a certification scheme 'Sustainable Textile Production' (STeP) covering the sustainable textile production and the 'Made in Green' label which is a combination of the former two schemes.

The website of the Oeko-Tex® Association is accessible via the following link:
https://www.oeko-tex.com

The most recent limit values are accessible here: https://www.oeko-tex.com/en/business/certifications_and_services/ots_100/ots_100_limit_values/ots_100_limit_values.html

The related test methods can be found here: https://www.oeko-tex.com/en/business/certifications_and_services/ots_100/ots_100_test_methods/ots_100_test_methods.xhtml

4.3.1.1 Key elements of the Oeko-Tex® Standard 100

Oeko-Tex® Standard 100 is applicable for textile and leather products and articles of all levels of production, including textile and non-textile accessories. The standard is also applicable to mattresses, feathers and downs, foams, upholstery and other materials with similar characteristics. It also addresses non-textile and non-leather items.

There is a supplement which is applicable to special articles containing a large proportion of non-textile materials. The prerequisite is generally that there are significant textile components in the finished product. The supplement covers tents, curtain kits, roller blinds, chairs and couches, push chairs/prams, suitcases, bags, rucksacks, jewellery and watches, heated pillows and blankets and other textiles which can be heated, helmets, umbrellas and sunshades, pulse and blood pressure measuring devices with cuffs, toys, orthopaedic articles (bandages and orthotics) and personal protective equipment (PPE). The document which is available in the download section of the website identifies the applicable product category of the main document.

There are limits for 4 different product categories:

— Products for babies (product class I);

— Products with direct contact to skin (product class II);

— Products without direct contact to skin (product class III);

— Decoration material (product class I).

The limits cover the following:

— pH value;

— Formaldehyde;

— Extractable heavy metals;

— Heavy metals in digested sample;

— Pesticides;

— Chlorinated phenols;

— Phthalates;

— Organic tin compounds;

— Other chemical residues;

— Colorants;

— Chlorinated benzenes and toluenes;

— Polycyclic aromatic hydrocarbons (PAH);

— Biological active products;

— Flame retardant products;

— Solvent residues;

— Surfactant, wetting agent residues;

— PFC's, Perfluorinated Compounds;

— Colour fastness (staining);

— Emission of volatiles;

— Determination of odours;

— Banned fibres.

Individual substances for several substance categories are listed in Appendix 5.

Testing procedures are included in a separate document.

It should be noted that the standard generally excludes biological active products and flame retardant products with exception of treatments accepted by Oeko-Tex®. Lists of accepted treatments can be found on the website under Certified products/Active chemical products.

4.3.1.2 Remarks on the Oeko-Tex® Standard 100

Undoubtedly the Oeko-Tex® Standard 100 is a key reference document given that more than 100 000 products have been certified so far which means that the specification is widely accepted.

4.3.2 Oeko-Tex® Leather Standard

The Oeko-Tex ® Association launched a new scheme for leather goods which is applicable for certification from 2017. It follows a similar approach as the Oeko-Tex® Standard 100 for textile products. Details can be found here: https://www.oeko-tex.com/en/business/certifications_and_services/leather_standard/leather_standard.xhtml

4.3.3 Zero Discharge of Hazardous Chemicals (ZDHC) Programme

In 2011, a group of major apparel and footwear brands and retailers (such as Adidas, C&A, H&M, Jack Wolfskin, etc.) made a shared commitment to help lead the industry towards zero discharge of hazardous chemicals by 2020.

The website of the ZDHC programme is accessible via the following link:
http://www.roadmaptozero.com/index.php

A "Joint Roadmap" was published in 2011, a second version in 2013 and another update in 2015. The most interesting document is the "Manufacturing Restricted Substances List"(MRSL) published for the first time in 2014. It is a list of chemical substances banned from intentional use in facilities that process textile materials and trim parts in apparel and footwear (including 16 substance groups). The MRSL establishes acceptable concentration limits for substances in chemical formulations used within manufacturing facilities. Although it does not establish limits for products the document may be a useful complement to other information sources.

4.3.4 Apparel and Footwear International RSL Management Group (AFIRM)

The AFIRM initiative (including some of the ZDHC members) has published several versions of a "Restricted Substances List" (version 1 published in December 2015) which applies to final products. According to the FAQs on the website "Over 80 % of Oeko-Tex® content mirrors these RSLs" (Restricted Substance Lists), "but there are some specific differences".

The website of the AFIRM programme is accessible via the following link: http://www.afirm-group.com/

AFIRM members have yet to fully harmonized their approaches, hence the various companies have their own RSLs. Some of these can be directly accessed by clicking the company logos on the members' page of the AFIRM website (e.g. from Adidas, H&M, Levi Strauss and Co., etc.). In case of H&M the RSL contains also limits for non-textile products: http://www.hm.com/chemical-restrictions

4.3.5 CEN guidance documents related to textile and leather products

4.3.5.1 Textiles and textile products

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" provides a useful compilation of existing limits of chemicals in textiles covering REACH provisions, national legislation and voluntary specifications such as ecolabels. The authors suggest that "*the textile market follows the ethos of this Technical Report*". The document also mentions existing standardized test methods. Technical Reports are of purely informative nature, and are not normative.

Nevertheless, the document provides some general recommendations such as avoiding CMR chemicals, PBT and vPvB substances in amounts exceeding 0,1 % by weight of the whole product. The document identifies the textile materials likely to contain some of the substances discussed in the report.

Various categories of substances are also discussed including formaldehyde, chlorophenols, orthophenylphenol, heavy metals - antimony (Sb), arsenic (As), barium (Ba), cadmium (Cd), chromium (Cr), cobalt (Co), copper (Cu), lead (Pb), mercury (Hg), nickel (Ni), selenium (Se), flame retardants, colorants (CMR or sensitizing), sensitizing substances others than colorants, pesticides, herbicides and fungicides, chloroorganics including carriers (chlorinated benzenes, chlorinated toluenes and chlorinated naphthalenes), phthalates, organotin compounds, perfluorooctanesulfonates (PFOS) and perfluorooctanoic acid (PFOA), dimethylfumarate (DMFu), alkylphenolethoxylates (APEO), residual solvents and polycyclic aromatic hydrocarbons (PAH).

In addition, the report provides information on issues such as pH or colour fastness in relation to acidic and alkaline perspiration.

4.3.5.2 Footwear

CEN ISO/TR 16178:2012 "Footwear - Critical substances potentially present in footwear and footwear components (ISO/TR 16178:2012)" establishes a list of critical chemical substances potentially present in footwear and footwear components. The Technical Report describes the critical chemical substances,

their potential risks using a "critical substances category scale" (5 categories), the materials in which they can be found and the test method(s) which can be used to quantify them.

CEN/TR 16417:2016: "Footwear -Footwear industry guideline for substances of very high concern (Annex XIV of REACH)" is intended to provide information on the chemicals listed in the Candidate List and Annex XIV of the REACH Regulation and their usage and presence in the footwear industry. The document aims to help shoe manufacturers to collect mandatory information from suppliers regarding the content of these chemicals and, at same time, allow them to provide accurate information to their customers.

4.3.5.3 Leather

ISO 20137:2017 "Leather - Chemical tests - Guidelines for testing critical chemicals in leather" suggests to apply the available chemical test methods for leather. It provides 3 Tables addressing substances used by the leather industry with no legal restrictions for leather, as well as substances previously used by the leather industry (at present unlikely to be found in leather articles) and (restricted) substances previously used by the leather industry (presence of these substances in leather articles is only likely due to external conditions/contamination).

4.4 Activities of stakeholders other than industry

Apart from industry initiatives, there are also some civil society organisations, which have published lists of chemicals of concern that they feel shall be restricted, substituted or eliminated.

ChemSec, the International Chemical Secretariat, is a non-profit organization founded in 2002 by four environmental organisations (Swedish Society for Nature Conservation, WWF Sweden, Nature and Youth and Friends of the Earth Sweden). It has developed among other the so-called "SIN List" (Substitute It Now!) which is a list of hazardous chemicals fulfilling the official criteria for Substances of Very High Concern (SVHC) as defined in REACH. The aim of this list is "to spark innovation towards products without hazardous chemicals by speeding up legislative processes and giving guidance to companies and other stakeholders on which chemicals to start substituting".

The organization's webpage and the SIN list can be accessed under the following addresses:
http://chemsec.org/ and http://chemsec.org/what-we-do/sin-list

Furthermore, the European Trade Union Confederation (ETUC) published a "Priority List for REACH Authorisation", which last version is dated July 2010. This list can be accessed under the following link:
https://www.etuc.org/press/reach-etuc-updates-its-priority-list-authorisation#.VjI1Hpdc4sI

5 International developments

5.1 UNEP/SAICM Chemicals in products project

The Chemicals in Products (CiP) programme is a project of UNEP in support of the overall objective of the Strategic Approach to International Chemicals Management (SAICM), an international policy framework to promote chemical safety around the world. The CiP project was designed as a voluntary initiative aimed at businesses, organisations and other participants throughout the product life cycle and intended to engage all the stakeholders in the product chain, which includes those involved in raw material supply, component and product manufacture, distribution, retailing, use and end-of-life management. Each of these actors identified a need for information on chemicals in products and, under the chemicals in products programme, each would exchange chemical information with others in their product sector. The programme also recognizes the information needs of stakeholders who may not necessarily handle a product, such as Governments, non-governmental organisations and consumers, but which nonetheless require chemicals in products information.

The elements of the chemicals in products programme were formulated in such a manner as to allow stakeholders throughout the life-cycle of products to demonstrate their commitment to the sound

management of the chemicals contained in products as they are fabricated, transported, purchased and sell, used, becoming part of reuse systems and recycling operations for material recovery, and finally discarded as waste.

The first phase of the CiP project (2009 – 2012) aimed at assessing the situation globally and developing recommendations to bridge gaps in CiP information access and exchange. The second phase of the project (2012 – 2015) concentrates on developing a means to assist in bridging those gaps.

At the time of writing this document, a CiP programme pilot in the textiles sector involving supply chains in China is in its early stages (scheduled for 2014-2017). The main aim of this pilot project is to create a mechanism to link all the different players in the textile manufacturing industry and to provide information on the types of chemicals involved during a product's production phase.

Prior to its recent conference (October 2015), a "Proposal for a chemicals in products programme" (SAICM/ICCM.4/10) and a complementing "Guidance for stakeholders on exchanging chemicals in products information" (SAICM/ICCM.4/11) were circulated. These documents can be obtained here:

The fourth session of the International Conference on Chemicals Management (IC CM4) welcomed the "Chemicals in products programme" as a voluntary framework for all Strategic Approach stakeholders. IC CM4 also took note of the "Guidance for stakeholders on exchanging chemicals in products information", as a practical means of implementing the chemicals in products programme, and recognized the guidance as a living document that will evolve to address the needs of SAICM stakeholders and encouraged participants to consider the guidance in the implementation. More information can be found here: http://www.saicm.org/Home/tabid/5410/language/en-US/Default.aspx