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Child use and care articles - General safety guidelines - Part 2: Chemical hazards

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European foreword

This document (CEN/TR 13387-2:2015) has been prepared by Technical Committee CEN/TC 252 “Child use and care articles”, the secretariat of which is held by AFNOR.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes CEN/TR 13387:2004.

CEN/TR 13387 comprises the following five parts:

— Safety philosophy and safety assessment (CEN/TR 13387-1);

— Chemical hazards (CEN/TR 13387-2);

— Mechanical hazards (CEN/TR 13387-3);

— Thermal hazards (CEN/TR 13387-4);

— Product information (CEN/TR 13387-5).

CEN/TR 13387-2 should be used in conjunction with CEN/TR 13387-1.

The chemical part has been completely rewritten compared to the previous edition.

1 Scope

This Technical Report provides guidance information on chemical hazards that should be taken into consideration when developing safety standards for child use and care articles. In addition, these guidelines can assist those with a general professional interest in child safety.

2 Regulatory, normative and policy background

2.1 General

In Europe child use and care articles are covered by the Directive on general product safety (GPSD, Directive 2001/95/EC). This directive contains a general safety requirement and does not address chemical substances in particular. 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 phthalates in toys and child use and care articles and for dimethylfumarate (DMF) and both have been later incorporated into REACH. In addition, Member States can impose actions on products found unsafe.

Restrictions for several specific chemical substances can be found in Annex XVII of the Regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH, Regulation (EC) No 1907/2006) “relating to restrictions on the marketing and use of certain dangerous substances and preparations” as amended. If applicable to their type of product or material used, these provisions are to be followed by manufacturers of child care articles.

The Regulation on persistent organic pollutants (POP, Regulation (EC) No 850/2004) restricts production, placing on the market and use of chemical substances listed in Annex I of the regulation including constituents of articles. The provisions apply also to child care products.

Other regulatory provisions relating to chemicals may apply to certain products. For instance, drinking equipment is subject to the Regulation on materials and articles intended to come into contact with food (Regulation (EC) No 1935/2004) and plastics components of drinking equipment are regulated by the Regulation relating to materials and articles intended to come into contact with foodstuffs. A Directive covers the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers (Directive 93/11/EEC). Applicable regulation will have to be identified where relevant.

Another example of chemical provisions applicable to child care articles is the Directive on packaging and packaging waste (94/62/EC) which establishes among others limits for lead, cadmium, mercury and hexavalent chromium in packaging.

While not directly applicable to child care articles the Directive on the safety of toys (TSD, 2009/48/EC) is an important reference document addressing a product group with similar exposure characteristics and providing a high standard of safety in the field of products intended for children. Hence, specific guidance seems appropriate on how to make use of toys related chemical rules.

It is the intention of the present guidelines to complement existing legal obligations by providing some practical recommendations keeping in mind legal minimum requirements.

Environmental issues are moving in the spotlight. CEN has adopted a policy: the “CEN Approach on addressing environmental issues in product and service standards” calls for incorporation of environmental considerations when product or service standards are elaborated. These aspects are highly relevant in particular for chemicals as far as child care articles are concerned. Hence, this guide incorporates also recommendations in this regard.

2.2 REACH - Short summary

2.2.1 Registration

All chemical substances manufactured or imported in quantities greater than 1 tonne per year per manufacturer or importer shall be registered at the European Chemicals Agency (ECHA) unless they are exempted from the scope of registration. The registration obligations apply to the individual chemical substances, independently of whether they are on their own, in a mixture or in an article (when the chemical substance is intended to be released).

2.2.2 Authorization

Chemical substances with properties of very high concern may be subject to authorization before being allowed to be manufactured or used in the European Union. These are CMRs (carcinogenic, mutagenic and toxic for reproduction), PBTs/vPvBs (persistent, bio accumulating and toxic/very persistent and very bio accumulating chemical substances) and chemical substances identified as causing serious and irreversible effects to humans or the environment equivalent to the effects mentioned above. As a first step such chemical substances are incorporated in a so-called “candidate list” which is published and periodically updated by ECHA (twice a year in June and December). The candidate list is also known as the “SVHC list”. Finally, chemical substances identified as requiring authorization will be taken up in Annex XIV or REACH. These chemical substances cannot be placed on the market or used for manufacturing in Europe after a given date, unless an authorization is granted for their specific use, or the use is exempted from authorization.

For the current list of SVHC please consult the ECHA website.

2.2.3 Restrictions

REACH Annex XVII contained specific restrictions on 64 chemical substances or groups of substances by the end of 2014. These may apply to all uses of the substance or more specifically to certain product types or exposure scenarios. Some restrictions have particular relevance to child care and use articles such as the limits on total content for certain phthalate based plasticisers and total content limits for certain flame retardants in textiles where there is prolonged skin contact. Some entries, such as the total content restriction for cadmium in certain materials, may apply to child care and use articles where that material is used to make the finished product.

2.2.4 Articles

Articles within REACH are 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 consumer products including child use and care articles can be defined as articles. Chemical substances in articles do not need to be registered under REACH, except chemical substances in articles that are intentionally released if present in quantities greater than 1 tonne per manufacturer annually. This could be for example a product with a perfume scent. Chemical substances that are unintentionally released during use are not in scope for registration, like plasticizers migrating out of a product over time.

If articles contain chemical substances on the “candidate list” (SVHC list) in a concentration above 0,1 % (w/w), the supplier has to provide sufficient information (as a minimum the name of the chemical substance) to the recipient of the article to allow for safe use of the article. For consumers the information about these chemical substances in the article shall only be given upon request and within 45 days of the request. (Article 33 of REACH). This requirement is independent of the total tonnage of the chemical substance. No such requirement exists for other dangerous chemical substances in articles.

If a SVHC substance is present in a concentration above 0,1 % in the article and its import or manufacturing quantities are above 1 tonne in total per year per company, EU producers or importers of articles shall notify the ECHA of the presence of the SVHC substance. Such notification requirement does not exist for other dangerous substances in articles.

Chemical substances integrated in articles are neither subject to registration nor to authorization with the exception of chemical substances intended to be released. However, SVHC substances used in or for the manufacturing of articles in Europe may require authorization. Restricted chemical substances (REACH Annex XVII) cannot be used in articles in the EU, nor can they be present in any article imported into the EU.

2.2.5 Recommendations

Manufacturers and standardization bodies involved with child care and use articles should be aware of the developments in REACH and how they apply to the product category. Where the developments are deemed sufficiently protective of children there is generally no further need to elaborate a current or future standard unless the development of new scientific knowledge indicates otherwise. Where REACH covers child care and use articles in a limited way (in particular, imported articles) REACH should not be considered as a replacement for product specific chemical rules.

2.3 Toy Safety Directive and related standards

2.3.1 Short summary of Toy Safety Directive

The Toy Safety Directive (TSD) was published in June 2009 (Directive 2009/48/EC). Part III of Annex II contains the chemical requirements and are summarized below.

Chemical substances that are carcinogenic, mutagenic or toxic to reproduction (CMR) substances of category 1A, 1B or 2 under the Classification, Labelling and Packaging (CLP) Regulation (Regulation (EC) No 1272/2008) are only allowed in toys if certain conditions are 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.

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

Requirements on migration of 19 elements (aluminium, antimony, arsenic, barium, boron, cadmium, chromium (III), chromium (VI), cobalt, copper, lead, manganese, mercury, nickel, selenium, strontium, tin, organic tin, and zinc) replacing the previous migration restrictions on 8 elements (antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium). The migration limits are set for three different types of materials:

1) dry, brittle powder-like or pliable toy material,

2) liquid or sticky toy material and

3) scraped-off toy material.

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.

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

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 end of 2014 the substances tris (2-chloroethyl) phosphate (TCEP, CAS No 115-96-8), tris-monochloro-propyl phosphate (TCPP, CAS No 13674-84-5) and tris(1,3-dichloropropyl-2)phosphate (TDCP, CAS No 13674-87-8) are listed with a specific limit value of 5 mg/kg (content limit). In addition, bisphenol A (CAS No 80-05-7) is included with a limit of 0,1 mg/l (migration limit).

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. The manufactures shall furthermore, demonstrate that the toy complies with the requirements set in Annex II. The assessment shall be kept in the technical documentation.

2.3.2 Toy standards

The following standards dealing with chemical substances in toys relevant for child use and care articles are currently available:

2.3.2.1 Harmonized standards

— EN 71-3:2013, Safety of toys - Part 3: Migration of certain elements.

This standard contains migration limits and test methods for 19 elements (aluminium, antimony, arsenic, barium, boron, cadmium, chromium (III), chromium (VI), cobalt, copper, lead, manganese, mercury, nickel, selenium, strontium, tin, organic tin, and zinc).

— EN 71-12:2013, Safety of toys - Part 12: N-Nitrosamines and N-nitrosatable substances.

This standard contains limits and test methods for N-nitrosamines and N-nitrosatable substances for toys and parts of toys made from elastomers and intended for use by children under 36 months or intended to be placed in the mouth and finger paints for children under 36 months.

2.3.2.2 Non-harmonized standards

— EN 71-9:2005+A1:2007, Safety of toys - Part 9: Organic chemical compounds – Requirements;

— EN 71-10:2005, Safety of toys - Part 10: Organic chemical compounds - Sample preparation;

— EN 71-11:2005, Safety of toys - Part 11: Organic chemical compounds - Method of analysis;

The standards EN 71-9, EN 71-10 and EN 71-11 which do not provide a presumption of conformity to TSD requirements include limit values and test methods for certain organic chemical compounds such as:

— flame retardants;

— colorants;

— primary aromatic amines;

— monomers (migration);

— solvents (migration and inhalation);

— wood preservatives;

— preservatives;

— plasticizers (migration).

It should be noted, however, that EN 71-9, EN 71-10 and EN 71-11 cover only a small number of organic chemical substances. Consequently, the introduction of EN 71-9 includes the following sentence: “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”.

2.3.3 Recommendations

The applicable requirements in the Directive including generic CMR exclusions and standards dealing with chemical substances in toys should be considered when establishing requirements for child use and care articles. However, the limits should be checked and different values should be considered when e.g. the exposure and use profile is different compared to toys or if new scientific evidence suggests that the limits need to be changed.

It is also recommended to carry out an analysis of the chemical hazard that a child use and care article may present, as well as an assessment of the potential exposure to such a hazard.

Manufacturers and importers of as well as standard setting bodies for child use and care articles should monitor the revisions of the limit values given in the Toy Safety Directive and the adoption of specific limits for toys intended for use by children under 36 months or in other toys intended to be placed in the mouth. In addition, the developments within CEN/TC 52 should be taken into account. Manufacturers should consider the latest versions of limit values and test methods in the toys field if referenced in child use and care standards, as these are normally updated with some delay.

2.4 CEN Approach on addressing environmental issues in product and service standards

2.4.1 Short summary

The key objective of the “CEN approach on addressing environmental issues in Product and Services Standards” is to put in place a general framework to systematically address environmental issues in standardization in order to reduce the environmental impacts of products and services.

The document defines roles and responsibilities for the various parties involved including technical bodies of CEN, its Strategic Advisory Body on Environment (SABE) including the Environmental Helpdesk (EHD) and the Team on Environmental Issues in Standardization (ENIS), stakeholders and national standards bodies.

The framework consists of supporting tools (guidance documents, checklists, trainings, tailored environmental programmes for technical bodies, etc.) and mandatory elements (review of titles and scopes of TCs, inclusion of environmental issues in business plans, new work item proposals, formatted resolutions, agenda item on environmental issues). It is envisaged to provide specific guidance to TCs/WGs on specific issues including *inter alia* advice on the coverage of chemicals in product standards.

The functioning of the above is subject to monitoring by the relevant CEN groups and will be periodically reviewed.

2.4.2 Recommendations

If specific guidance on addressing chemical substances in product standards is made available by CEN’s advisory bodies on environmental issues it should be taken into consideration. Environmental concerns should be taken on board in the development of standards for child use and care articles, i.e. also environmental effects of chemical substances should be addressed. This means to not only consider human health but also environmental impacts, e.g. to eliminate PBTs or vPvB substances.

3 Basics of Chemical Safety Assessment (CSA)

3.1 General

The scope and limit of chemical substance restrictions in regulations and standards are most often based on a chemical safety assessment (CSA). This assessment determines the scope relevancy of the restriction (e.g. type of material, accessibility etc) and provides recommended safe limit value based on the exposure profile and use of a product or product group. To be able to adopt and adapt chemical substance restrictions for different types of child use and care articles it is important to understand the key aspects of a chemical safety assessment.

CSA is the process that identifies and describes the conditions under which the use and/or presence of a chemical substance could be considered 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 intrinsic properties of the chemical substance. The objective of the hazard assessment is to identify the hazards of the substance, assess their potential effects on human health and the environment, and determine, where possible, the threshold levels for exposure considered as safe (the so called no-effect levels).

The **exposure assessment** is the process of measuring or estimating the dose or concentration of the chemical substance to which humans and the environment are or may be exposed, depending on the use of the chemical substance and the use of products in which it is present.

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

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 relevant effect.

Risks are regarded as controlled when the potential exposure levels to the chemical substance are below the threshold levels which are considered as safe. For effects with no threshold levels, emissions and exposures have to be minimised or avoided for risks to be considered to be controlled.

In the following parts the main steps of a CSA are briefly explained and complemented by specific considerations for chemicals used in child use and care articles in particular.

3.2 Hazard assessment

The hazard assessment normally comprises the following steps:

1) Hazard Identification

Hazard identification is the determination of what hazards are associated with the chemical substance. The information on the types of hazard can come from the classification and labelling of the chemical substance or other available relevant toxicological and ecotoxicological information.

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 for the hazard identification.

ECHA has published 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 EU classifications.

Other relevant and available toxicological and ecotoxicological information on the intrinsic properties of a chemical substance not covered by the classification and labelling information can be found, for instance, in the publically available REACH registration dossiers as published on the ECHA website.

For example the toxicological properties of the chemical substance when exposed via dermal (skin) contact, oral contact or inhalation and the effect of the chemical substance if the exposure is short-term (acute) or long term (chronic) can be found in these dossiers.

2) Derivation of threshold levels

The derivation of threshold levels is the determination of the relationship between the hazard and the dose (exposure amount). In principle for almost every hazard there is a minimum dose under which no effect is expected anymore, a threshold level.

Several thresholds are available to be used in a chemical safety assessment.

Derived-No-Effect Level (DNEL)

The Derived No-Effect Level or DNEL is the level of exposure to the substance above which humans should not be exposed. The DNEL is typically based on the NOAEL(No-Observed-Adverse-Effect-Level) of a chemical substance, The NOAEL is the greatest concentration or amount of a substance, found by observation or experiment, which causes no statistically significant detectable adverse effect in the exposed population. The NOAEL is scaled by a safety factor, conventionally but not always of 100, to account for the differences between test animals and humans (factor of 10) and possible differences in sensitivity between humans (another factor of 10).

The lowest value available (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.

DNELs and DMELs can be found in publically available REACH dossiers or can be calculated based on available toxicological information.

Predicted-No-Effect Concentration (PNEC)

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).

PNECs can be found in publically available REACH dossiers or can be calculated based on available ecotoxicological information.