



SLOVENSKI STANDARD SIST-V CEN Guide 16:2017

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Vodilo za obravnavanje kemikalij v standardih za proizvode, ki so pomembni za porabnike

Guide for addressing chemicals in standards for consumer-relevant products

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

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Foreword

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

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

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

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

The project consists of 3 key activities:

- Setting up of a multi-stakeholder panel of experts; [SIST-V CEN Guide 16:2017
https://standards.iteh.ai/catalog/standards/sist/ae561c4b-8ebf-492f-88fc-76227062793e/sist-v-cen-guide-16-2017](https://standards.iteh.ai/catalog/standards/sist/ae561c4b-8ebf-492f-88fc-76227062793e/sist-v-cen-guide-16-2017)
- Development of a guidance document including the preparation of a literature review report;
- Development of a strategy for the implementation of the guidance document.

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

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

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

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

Introduction

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

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

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

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

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

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

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

1 Scope

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

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

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

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

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

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

NOTE The Bibliography includes relevant CEN sector guidance documents.

2 Terms and definitions

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

2.1 article

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

[SOURCE: REACH, Article 3.3]

2.2 consumer-relevant article

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

3 Regulatory, normative and policy background

3.1 General

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

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

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

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

Recommendation:

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

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

3.2 Chemicals legislation

3.2.1 REACH Regulation

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

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

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

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

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

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

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

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

Recommendation:

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

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

3.2.2 CLP Regulation

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

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

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

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

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

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

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

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

Recommendation:

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

3.2.3 Other relevant chemicals legislation

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

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

Recommendation:

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

3.3 Relevant EU regulation for articles and associated standards

3.3.1 General considerations

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

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

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

Recommendation:

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

3.3.2 General Product Safety Directive (GPSD) and related standards

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

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

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

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

3.3.3 Toy Safety Directive (TSD) and related standards

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

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

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

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

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

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

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

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

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

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

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

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

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

- 7th Environmental Action Programme;