



ANEC TECHNICAL STUDY

**THE DEVELOPMENT OF SAFETY REQUIREMENTS AND
HAZARD-BASED STANDARDS
FOR CHILD USE AND CARE ARTICLES**

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CONTENTS

ABOUT ANEC	1
ACKNOWLEDGEMENTS	1
ABBREVIATIONS	1
EXECUTIVE SUMMARY	2
INTRODUCTION	4
Scope of this study	4
Target audience	4
Hazard-based approach to the development of standards	5
Structure of this document	5
Future development of CEN/TR 13387	6
European standards	7
SECTION I – THE DEVELOPMENT OF SAFETY REQUIREMENTS AND STANDARDISATION REQUESTS	8
The development of safety requirements	8
Issues associated with developing safety requirements	9
Hazard-based format for safety requirements	11
European Commission and EFTA standardisation requests	11
SECTION II – THE DEVELOPMENT OF HAZARD-BASED STANDARDS	13
Background to the development of hazard-based standards	13
Breadth of representation in the standards development process	14
SECTION III – DECIDING WHETHER A STANDARD SHOULD BE A “HARMONISED STANDARD”	15
OVERALL RECOMMENDATIONS	19
ANNEX A – THE DEVELOPMENT OF SAFETY REQUIREMENTS FOR INCLUSION IN STANDARDISATION REQUESTS	20
ANNEX B – THE DEVELOPMENT OF HAZARD-BASED STANDARDS FOR CHILD USE AND CARE ARTICLES	35
ANNEX C – PROPOSED AMENDMENTS TO CEN/TR 13387:2015	42
Introduction	42
Proposed amendment to TR 13387:2015-1 – NEW Clause 6	43
Proposed amendment to TR 13387:2015-1 – NEW Clause 7	44
Proposed amendment to TR 13387:2015-1 – NEW Clause 8	47

ABOUT ANEC

ANEC is the European consumer voice in standardisation, promoting, representing and defending the consumer interest in standardisation, conformity assessment and related legislation. It was established as an international non-profit association under Belgian law in 1995 and represents consumer organisations from the 28 EU Member States and 3 EFTA countries (Iceland, Norway and Switzerland) as well as the former Yugoslav Republic of Macedonia and Turkey. ANEC is funded by the EU and EFTA, while the national consumer organisations contribute in kind. Its Secretariat is based in Brussels.

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ABBREVIATIONS

ANEC	European Association for the Coordination of Consumer Representation in Standardization (often known as "The European consumer voice in standardisation")
BEUC	Bureau Européen des Unions de Consommateurs (usually known as "The European Consumer Organisation")
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CPSR	Consumer Product Safety Regulation
EFTA	European Free Trade Association
ESOs	European Standardisation Organisations (CEN, CENELEC and ETSI)
ETSI	European Telecommunications Standards Institute
GPSD	General Product Safety Directive 2001/95/EC
OJEU	Official Journal of the European Union
SECO	Secrétariat de Coordination pour la Normalisation (the predecessor organisation to ANEC)
SMEs	Small and medium-sized enterprises

EXECUTIVE SUMMARY

This study provides guidance on:

- the development of the safety requirements that form part of the standardisation requests from the European Commission to the European Standardisation Organisations (ESOs¹)(CEN, CENELEC and ETSI), related standardisation requests and subsequent standards for some child use and care articles using the hazard-based approach;
- the hazard-based approach using child use and care articles as an example;
- additions to CEN/TR 13387:2015 *Child use and care articles - General safety guidelines - Part 1: Safety philosophy and safety assessment* details of hazard-based standards, indicating how such standards can be formulated and the processes used in drafting standards in this format;
- additional wording for an informative annex of hazard-based standards that contains the potential rationale to enable a consistent approach across standards.

The document focuses primarily on products with which child might interact, particularly child use and care articles, all of which fall under the General Product Safety Directive (GPSD). The principles, notably a hazard-based approach – an approach that comprehensively and systematically identifies, assesses and addresses hazards and risks during the development of safety requirements and the drafting of standards – might also be relevant for products and services for adults and to those covered by other Directives.

It argues that adopting a hazard-based approach can ensure that the safety requirements that form part of standardisation requests are comprehensive and informed by appropriate data and information. It also emphasises the importance of ensuring that the levels of safety set out in safety requirements in standardisation requests are relevant to the significance of the hazards and risks and are defined by the GPSD committee whose role is to define the precise details of the requirements and test methods defined in the standard, not by the European Standardisation Organisations.

A wide range of stakeholders are involved in the standards development process which extends from the drafting of the standardisation request that can include general and/or detailed safety requirements, through the drafting of the standard itself, to the process whereby a decision is taken whether or not to publish reference to the standard in the Official Journal of the European Union, thus being a harmonised standard. The knowledge of stakeholders can be limited to their own part of the process. To address this, this document provides guidance on the whole process.

The document identifies the areas of specialist knowledge that are needed to draft safety requirements (Annex A). It also presents a method of systematically identifying, assessing the significance of and addressing hazards and risks associated with products (Annex A); outlines a standard format for hazard-based standards (Annex B); and presents proposals for the amendment

¹ A list of abbreviations is presented at the beginning of the document.

of CEN/TR 13387-1:2015 *Child use and care articles. General safety guidelines. Safety philosophy and safety assessment* so that it includes a comprehensive picture of hazards and risks (Annex C). It also includes a proposed mechanism for checking whether or not a standard covers the safety issues contained in the standardisation request.

It presents a series of recommendations intended to improve the development of safety requirements and the drafting of standards by using a hazard-based approach and in a hazard-based format, and the determination of whether or not a standard is suitable to become a harmonised standard. These recommendations can be summarised as follows:

- The hazard and risk matrix in Annex A should be used to support the identification, assessment and analysis of the safety requirements to be included in standardisation requests.
- The levels of safety set out in safety requirements in standardisation requests should be relevant to the significance of the hazards and risks and, especially when the risk of harm is high, should be defined by the GPSD committee, not by the European Standardisation Organisations.
- Safety requirements should be drafted in a hazard-based format to make the comparison of these requirements and the content of the standard easier.
- There should be broad representation on the expert panels responsible for drafting safety requirements to ensure that they have an understanding of all the issues that need to be included.
- CEN/TR 13387-1:2015 *Child use and care articles. General safety guidelines. Safety philosophy and safety assessment* should be amended in line with the recommendation presented in Annex B.
- The published standard should be audited by the expert panel to determine whether or not it fulfils the safety requirements, both in terms of completeness and the levels of safety provided. This determination should be undertaken systematically using the checklist presented in this report.
- A similar project covering age groups other than children should be undertaken to improve the preparation of safety requirements and standards for consumer products not specifically designed for children.

INTRODUCTION

This study provides guidance on:

- the development of the safety requirements that form part of the standardisation requests² from the European Commission to the European Standardisation Organisations (ESOs³)(CEN, CENELEC and ETSI), related standardisation requests and subsequent standards for some child use and care articles using the hazard-based approach;
- the hazard-based approach using child use and care articles as an example;
- additions to CEN/TR 13387:2015 *Child use and care articles. General safety guidelines. - Part 1: Safety philosophy and safety assessment* details of hazard-based standards, indicating how such standards can be formulated and the processes used in drafting standards in this format;
- additional wording for an informative annex of hazard-based standards that contains the potential rationale to enable a consistent approach across standards.

Scope of this study

This document focuses on products developed under the General Product Safety Directive, 2001/95/EC, (GPSD) as this Directive does not include detailed safety requirements. Other Directives, which cover narrow ranges of products, such as the Personal Protective Equipment Directive, Toy Safety Directive and the Low Voltage Directive, contain essential safety requirements so standardisation requests associated with such Directives can differ from those under the GPSD. However, the analytical approach outlined in this document could be used beyond the GPSD.

It focuses particularly on child use and care articles, the standards for which are handled by the technical committee CEN/TC 252, all of which fall under the GPSD. However, the principles, notably the hazard-based approach presented below, might also be relevant for products and services for adults.

Target audience

It is important that everyone involved in the process of standards development, from the initial stages of identifying the need for a standard through the development of standardisation requests and the drafting of the standard to the assessment of the adequacy of the standard, needs to have an understanding of the process. People involved in the different stages would be expected to have detailed knowledge of their own tasks but might not fully understand how these fit into the whole process.

² Standardisation requests used to be called "mandates" and are frequently still referred to by this term although strictly it is out of date.

³ A list of abbreviations is presented at the beginning of the document.

Hazard-based approach to the development of standards

An important aspect in the development of any standard for a product or service for anyone who interacts with it, adults or children, which includes requirements covering the minimisation of harm, is the need to be certain that all hazards are considered and that the risks associated with any hazards are addressed. This does not mean that all hazards and risks have to be eliminated, but they have to be controlled.

The expert panels that draft the safety requirements that form part of standardisation requests and the technical committees of the ESOs that draft or amend standards routinely analyse the hazards and risks associated with products and services. However, this analysis is not always done in a comprehensive, systematic way.

The so-called hazard-based approach described in this document provides a means of undertaking a comprehensive identification of hazards using different sources of data and information, an appraisal of the risks associated with each hazard identified, i.e. the likelihood that the hazard will result in harm and the severity of that harm, and an assessment of the significance of the hazards and risks to allow decision to be taken on how to address these in standards. The approach was initially developed and continues to be used in CEN TC/252, the committee responsible for child use and care articles. This committee is also responsible for the development and maintenance of CEN/TR 13387:2015 *Child use and care articles. General safety guidelines*.

The key elements of the hazard-based approach are its comprehensiveness and its systematic approach. The approach can be supported using Table 1 in Annex A of this document. The table can also provide a means of recording the decisions taken with regard to each hazard, improving the transparency of the process.

It is important to make a distinction between a hazard-based approach for assessing hazards and risks and a hazard-based format for the layout of a safety requirement or standard. The former ensures that the safety requirement or the standard is complete and, in terms of levels of safety, appropriate, whereas the latter is one means of setting out a standard, using the hazards as clause headings. It is possible to adopt a hazard-based approach and then set out the standard in other ways.

Structure of this document

This document presents an overview of the process, structured to reflect the three major stages:

- Development of safety requirements and standardisation requests (section I)
- Development of the standard, addressing the safety requirements of the standardisation request, using a hazard-based approach (section II)
- Consideration of whether or not the standard is suitable for referencing in the Official Journal of the European Union (OJEU), i.e. becomes a "harmonised standard" (section III)

The document includes three annexes, the first two of which are capable of being used as standalone tools for the European Commission and the technical committees (and their working groups) respectively:

Annex A - the development of safety requirements for inclusion in standardisation requests. This covers the issues that need to be considered when analysing what should be included in safety requirements – hazard and risk assessment – and provides a table to allow this process to be undertaken comprehensively and consistently. The principal audience for this Annex is the European Commission and particularly experts developing safety requirements.

Annex B – guidance on how to develop hazard-based standards, as increasingly used in the technical committee CEN/TC 252. This is written for members of technical committees drafting safety standards with hazard-based formats where products are designed specifically for children and also for products with which children will have contact.

Annex C – proposals for the amendment of CEN/TR 13387-1:2015 *Child use and care articles. General safety guidelines – Part 1: Safety philosophy and safety assessment* needed to incorporate the guidance presented in Annex B into the technical report. The content of this Annex is directed towards members of CEN/TC 252 and its working group responsible for the development of the TR. It also includes a proposed amendment to facilitate the systematic comparison of safety requirements contained in standardisation requests and the ways that they are addressed in standards.

As noted above, some audiences of this report will be aware of at least some, and occasionally all, of the issues presented here. However, it is important that the document and in particular the Annexes allow any reader to understand the issues and use the guidance presented effectively.

Future development of CEN/TR 13387

Although CEN/TR 13387:2015 *Child use and care articles. General safety guidelines* makes reference to hazard-based standards, it does not include details relating to the structure of such a standard. Annex C presents proposals for the amendment of CEN/TR 13387 Part 1 to accommodate these details. It also presents proposals for the basic wording for the rationales in the informative annex of a hazard-based standard, and a mechanism for auditing the link between the safety requirements in a standardisation request and in the standard.

European standards

According to the ESOs, a European standard is a document that provides rules, guidelines or characteristics for activities or their results, for common and repeated use. Standards are created by bringing together all interested parties including manufacturers, users, consumers and regulators of a particular material, product, process or service. CEN notes that everyone benefits from standardisation through increased product safety and quality as well as lower transaction costs and prices.

Standards are just one of CEN's deliverables. Others include Technical Specifications (TS), Technical Reports (TR) and Guides. CEN's 33 National Members work together to develop its publications.

Although most standards are initiated by industry, standardisation proposals can also come from consumers, Small and Medium-sized Enterprises (SMEs) or associations, or European legislators.

Standards developed at the request of European legislators (the European Commission) have a special status. A "harmonised standard" is a European standard adopted on the basis of a request (a standardisation request) made by the Commission for the application of Union harmonisation legislation. When such standards are published, if they are considered to fulfil the safety requirements set out in the standardisation request, they are listed in the Official Journal of the European Union as harmonised standards. Compliance with such standards provides presumption of conformity of products with the essential requirements relating to those products laid down in the relevant Union harmonisation legislation.

SECTION I – THE DEVELOPMENT OF SAFETY REQUIREMENTS AND STANDARDISATION REQUESTS

This section is particularly directed to people involved in the development of standardisation requests, particularly relating to child use and care articles, under the General Product Safety Directive (GPSD), especially the safety requirements contained therein. This is likely to include officials from the European Commission and Member States, and representatives from key organisations that attend the GPSD committee⁴, Consumer Safety Network⁵ and its expert groups.

It provides an introduction to the guidance presented in Annex A.

The development of safety requirements

The need for a standard can be identified by many bodies. The need is discussed in the Consumer Safety Network and, if the need for a standard is agreed, it is put into the rolling plan for standardisation under the GPSD. The products at the top of this list are considered for inclusion in the European Union's annual work programme for standardisation.

The Commission drafts an annual European Union work programme for standardisation setting out its priorities. It is adopted after broad consultation with stakeholders including European standardisation organisations and European stakeholder organisations receiving Union financing, including organisations representing consumers and SMEs.

At this stage, safety requirements for the product are drafted, by a small, expert panel convened on an ad hoc basis. Expert panels should comprise representatives from the key stakeholders: Member States, manufacturers, consumers, and other essential representatives. Panel members should have detailed knowledge of:

- the product (or similar products);
- an understanding of the ways in which children and others are likely to interact with the product;
- the numbers and nature of accidents and injuries associated with the product.

The hazard matrix (see Annex A) can be used as a basis for this systematic analysis when developing safety requirements but does not replace the need for political input, i.e. input at European Community level, and expert (technical) input.

⁴ If a standardisation request falls within the scope of the General Product Safety Directive, the Commission committee that leads the work is known as the GPSD committee. For topics that fall outside the GPSD, other sectoral committees take responsibility.

⁵ The Consumer Safety Network is a consultative experts group chaired by the European Commission and composed of national experts from the administrations of the EU Member States and EFTA members, and other European stakeholder organisations.

Issues associated with developing safety requirements

This section considers three issues that have concerned ANEC over a prolonged period linked to the development of the safety requirements incorporated into standardisation requests and offers solutions:

- The separation of the "political" decisions, i.e. those taken at European Community level by the legislators, and technical decisions to be taken by the ESOs.
- The use of a systematic approach to the identification of hazards to be included in safety requirements.
- The level of detail to be included in safety requirements.

The separation of the political and technical roles in developing safety requirements

ANEC and BEUC have expressed concern over the respective roles of the European Commission and the ESOs, calling for political decisions to be taken at the Commission level and not delegated to the ESOs. In May 2010, ANEC and BEUC published the joint position paper "Revision of the General Product Safety Directive: Key issues from a consumer perspective"⁶. Among other issues, it addressed the relationship between legislation and standardisation and considered it essential

"that political decisions which have a direct impact on the protection or welfare of consumers are taken at Community level"

while

"the role of standardisation should be limited to providing the technical means through which compliance with the political decision is achieved or evaluated".

ANEC and BEUC envisaged the establishment of legally binding safety requirements which would allow on a case-by-case basis decisions on what should be covered by the safety requirements and what should be left to the standards bodies. Even though this idea was not followed in the Commission proposal for a Consumer Product Safety Regulation (CPSR), which has not yet been approved, the basic problem remains: what requirements at what level of detail will be embedded in the standardisation requests and how much leeway should be given to the ESOs?

A systematic approach to identify hazards

ANEC has called for a more systematic procedure – the hazard-based approach, as described above - to support the identification of the hazards that should be included in safety requirements. To facilitate this, ANEC has adapted the hazard matrix presented in CEN/TR 13387-1:2015 *Child use and care articles. General safety guidelines. - Part 1: Safety philosophy and safety assessment* . This can be used by the Consumer Safety Network, the GPSD committee and/or the

⁶ ANEC-GA-2010-G-001

expert panels that are responsible for drafting safety requirements and standardisation requests.

Guidance on their systematic development is presented in Annex A, outlining the knowledge and information needed to undertake the task effectively and presenting a tool that can assist the process.

The level of detail to be included in safety requirements

There is the issue of the level of detail of the safety requirements that should be included in standardisation requests. The Commission has argued that if the safety requirements are too detailed, it can hinder the standards development process. However, ANEC and some Member States are concerned that drafting safety requirements in a shorter, more general manner could give too much leeway to ESOs, in whose work the business interest is often dominant, so undermining consumer protection.

On this topic, in the Consumer Safety Network paper *Working methods for setting requirements to be met by standards in the context of the General Product Safety Directive (CSN 11.03.2014, AP 3)*, the Commission suggested that:

"In certain cases it may be justified that the Commission makes a 'political choice' to further guide the expected outcome of the standardisation process, e.g. by including reference values or laying down certain prescriptive requirements."

Combining the three issues

The respective roles of the Commission and standards committees, the function of the hazard matrix, text for inclusion in the safety requirements and the technical solutions contained in the standard can be illustrated using the example of window locking devices:

- a) The hazard matrix (see Table 1 of Annex A) used by the expert panel highlights the need for the mechanical hazard "falls" to be addressed using window locking devices as children may pass through openings and might overcome the barrier function.
- b) The broader safety requirement (in Decision 2010/11/EU, which forms part of the standardisation mandate M/465) then states: "To fulfil their intended purpose, the devices must limit the opening distance between the frame and the casement to a maximum distance to effectively prevent the passage of a young child, bearing in mind, in particular, the developmental abilities and anthropometric measurements of children at different ages".
- c) The more detailed normative safety requirement (in the standard EN 16281 *Child protective products – Consumer fitted child-resistant locking devices for windows and balcony doors – Safety requirements and test methods*) specifies that the opening shall not exceed 89 mm and presents a related test procedure.

The role of the expert panel and the need for falls to be addressed is defined using the hazard matrix (example (a) above), while broader safety requirement as expressed in the safety requirements of the standardisation request (in the example above (b)) clearly instructs the technical standardisation committee to provide a technical solution (c). The broader safety requirement avoids being too prescriptive but also avoids giving carte blanche to ESOs. In principle, the requirement could be even directly enforced (to some extent) without any standard, e.g. when the locking device leaves a big gap between the frame and the casement in the engaged position, but this would not offer guidance to manufacturers and means of testing conformity with the requirement as provided by a standard.

The challenge is to strike the balance between safety requirements that are too vague, for example by stating that the standard should “take care of falls”, and too prescriptive by including, for example, what gap should be permitted.

Hazard-based format for safety requirements

When drafting the safety requirements, wherever possible, they should use the hazard-based format and order outlined in Annex B. Adopting this approach enables the experts drafting the technical standard to follow the standardisation request ensuring that all the relevant hazards are addressed. Additionally this assists when using the checklist outlined in Section III which can be used to determine whether the standard is suitable for referencing in the OJEU, thus becoming a harmonised standard.

European Commission and EFTA standardisation requests

Standardisation requests are the mechanisms by which the Commission and the secretariat of the European Free Trade Association (EFTA) request the European Standardisation Organizations (CEN, CENELEC and ETSI) to develop and adopt European standards in support of European policies and legislation.

This procedure involves several steps, set out in detail in Regulation (EU) No 1025/2012, often referred to as the Standardisation Regulation, especially Article 10. In summary, the steps are as follows:

- After consultation with the ESOs, European stakeholder organisations receiving Union financing and the GPSD committee, and internal Commission consultations, the draft standardisation request that includes the safety and other requirements to be met by the standard (or other deliverable) is voted on in the GPSD committee and adopted by the Commission.
- The standardisation request is submitted to the ESOs;
- When a standardisation request has been accepted, the relevant ESO Technical Body is entrusted with the task of undertaking the expected standardisation work, i.e. developing the standard.

Extract from Regulation (EU) No 1025/2012:

The Commission may ... request one or several European standardisation organisations to draft a European standard or European standardisation deliverable within a set deadline. European standards and European standardisation deliverables shall be market-driven, take into account the public interest as well as the policy objectives clearly stated in the Commission's request and based on consensus. The Commission shall determine the requirements as to the content to be met by the requested document [ANEC's underlining] and a deadline for its adoption.
(Article 10(1))

SECTION II – THE DEVELOPMENT OF HAZARD-BASED STANDARDS

This section is particularly directed to people involved in drafting mandated (and other) standards, namely members of the technical committees of the ESOs and their working groups. It provides an introduction to the guidance presented in Annex B.

Using a hazard-based format enables standards to be systematically checked to ensure that they clearly address the requirements of any associated standardisation requests and any other hazards that need to be addressed.

Background to the development of hazard-based standards

In 1990, SECO, ANEC's predecessor organisation, presented a paper to the CEN technical committee TC 252, responsible for child care and use articles, proposing that a hazard-based approach should be used when drafting the standards on their work programme. This proposal was accepted by the technical committee (TC) and a specific working group was formed with the purpose of drafting a Technical Report providing guidance on common hazards that should be taken into consideration when developing safety standards for child use and care articles.

The first edition, CEN Report CEN/CR 13387:1999 *Child use and care articles – Safety guidelines*, was published in 1999, having the prime objective of harmonising the approach to hazard and risk assessment, and prevention. ANEC had an active role in the drafting of this CEN Report. These safety guidelines were revised in 2004 (and published as a Technical Report (TR)) to take into account new products and also the standards that had already been produced by CEN/TC 252. The editing of CEN/TR 13387:2004 revision was undertaken by a member of the ANEC Child Safety Working Group.

A further revision of TR 13387 was published in 2015. One major change was to publish it in five separate parts: safety philosophy and risk assessment, chemical hazards, mechanical hazards, thermal hazards and product information. (See Annex B for further information.) ANEC drafted the hazard and risk assessment clause for the safety philosophy together with making an active input into other parts of the revision.

When the European Standard EN 1930:2000 *Child care articles. Safety barriers. Safety requirements and test methods* was being revised by CEN/TC 252 WG 4 for its five year review, ANEC proposed and it was accepted that the Working Group should change the existing format to one that identified the hazards being addressed together with the associated requirements and that an informative annex – the Rationales annex – should be included that would explain the reasons for the inclusion of these requirements.

Subsequently, CEN/TC 252 decided that where standards are being revised or new standards drafted they should wherever possible be produced in this hazard-based format.

Breadth of representation in the standards development process

The Standardisation Regulation calls for wide representation in the standards development process, including, in addition to national standards bodies, the key stakeholders noted below.

Extract from Regulation (EU) No 1025/2012 on European standardisation (Article 5):

European standardisation organisations shall encourage and facilitate an appropriate representation and effective participation of all relevant stakeholders, including SMEs, consumer organisations and environmental and social stakeholders in their standardisation activities. They shall in particular encourage and facilitate such representation and participation through the European stakeholder organisations receiving Union financing in accordance with this Regulation at the policy development level and at the following stages of the development of European standards or European standardisation deliverables:

- a) the proposal and acceptance of new work items;
- b) the technical discussion on proposals;
- c) the submission of comments on drafts;
- d) the revision of existing European standards or European standardisation deliverables;
- e) the dissemination of information of, and awareness-building about, adopted European standards or European standardisation deliverables.

SECTION III – DECIDING WHETHER A STANDARD SHOULD BE A “HARMONISED STANDARD”

The audiences for this section are the technical committee (or working group) that has developed the standard, and the appropriate Commission committee (the GPSD committee, Consumer Safety Network and/or the expert panel that initially developed the safety requirements in the standardisation request).

To decide on whether or not there should be reference to the standard in the Official Journal of the European Union, i.e. whether or not it should be a harmonised standard, an assessment of whether the general and specific requirements contained in the standardisation request have been appropriately addressed in the standard has to be made by the European Commission, Member States and the ESO.

Extract from Regulation (EU) No 1025/2012:

The European standardisation organisations shall inform the Commission about the activities undertaken for the development of the documents referred to in paragraph 1. The Commission together with the European standardisation organisations shall assess the compliance of the documents drafted by the European standardisation organisations with its initial request. *(Article 10(5))*

Where a harmonised standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation, the Commission shall publish a reference of such harmonised standard without delay in the Official Journal of the European Union or by other means in accordance with the conditions laid down in the corresponding act of Union harmonisation legislation. *(Article 10(6))*

To assist with this assessment and enhance the transparency of the process, the technical committee or working group (WG) responsible for the standard should audit the standardisation request and the standard to confirm that the safety requirements in both documents align, or that there is an adequate explanation of why the requirements in the standard differ from those in the standardisation request. This can be done using a checklist, an example of which is presented below. The completed checklist should be included as an informative annex in the standard. If the technical committee feels that it is not possible to address a safety requirement, an explanation for this should also be included in the informative annex.

Checklist for comparing safety requirements in the standardisation request with the requirements set out in the standard.

The table below should be annexed to the standard and then used by the expert panel to assist in determining whether the standard should become a harmonised standard.

Safety requirements in standardisation request XXXX	Related clauses in this standard	Reasons for partial or not addressing of safety requirement

One can argue that if a specific safety requirement is not fully addressed in a standard, and hence an explanation is inserted into the third column, the standard does not meet the standardisation request. However, in practice, there can be a variety of reasons why this mismatch may occur, for example:

- The development of test methods may be limited by time constraints in the CEN process;
- A lack of funding to develop test methods particularly those of a dynamic nature;
- Lack of available technical expertise;
- New designs of a product coming onto the market may make a subjective requirement more appropriate.

When mismatches between the standardisation request and the standard occur, it should be documented that these should be allocated to "Future work" and that the standard will be revised or amended accordingly.

To complete the circle, the standard should then be referred to the expert panel that developed the safety requirements which would consider whether or not it is appropriate for reference to the standard to be published in the OJEU. This consideration can be technical so it is appropriate to involve the expert panel in this process as it contains the necessary expertise. If necessary, the panel could seek input from the convenor of the TC or WG to explain why safety requirements have not completely fulfilled the expectations of the panel, for example by not being fully addressed or by being omitted from the standard. Although the final decision would not reside with the expert panel, it would have the knowledge and experience to take an informed decision on the adequacy of the standard and the way that it meets the safety requirements in the standardisation request. It could present its considered opinion and advice to the body where the final decision on referencing the standard in the OJEU is taken.

There is a broadly similar requirement in standards developed under other Directives, such as the Directive 89/686/EEC on personal protective equipment, in which there is a 'presumption of conformity' for the parts of the directive detailed in Annex ZA of each standard.

Worked example of the use of the checklist

Mandate: M/465 Standardisation mandate to CEN on the safety of consumer-fitted child-resistant locking devices for windows and balcony doors.

Standard: EN 16281:2013 Child protective products. Consumer fitted child resistant locking devices for windows and balcony doors. Safety requirements and test methods.

Commission Implementing Decision of 13 June 2014 on the compliance of European standard EN 16281:2013 for consumer fitted child resistant locking devices for windows and balcony doors with the general safety requirement of Directive 2001/95/EC of the European Parliament and of the Council and publication of the reference of that standard in the Official Journal of the European Union. (2014/358/EU).

This Decision formally confirmed that the Standard fulfils the Mandate and complies with the general safety requirement of Directive 2001/95/EC. Reference to the Standard was published in the OJEU, Volume 57, 14 June 2014.

Safety requirements in standardisation mandate M/465	Related clauses in the standard EN 16281	Reasons for partial or non-addressing of the standardisation request or other comments
Durability – repeated opening	5.5.2	
Ageing and exposure to all weather conditions	5.5.1	
Withstand accidental impacts without breaking	5.5.7	
Limit opening distance between frame and casement	4.2 and 5.5.4	
Small parts	5.2.4 and 5.2.8	
Sharp edges, shearing and scissoring	5.5.10	

Safety requirements in standardisation mandate M/465	Related clauses in the standard EN 16281	Reasons for partial or non-addressing of the standardisation request or other comments
Entrapment of fingers		Regarded as a very low risk issue by the technical committee when current designs of product were examined
Child panel test	4.1.2	
Information of supplier	4.7	
Inclusion of statement to read information	4.7	
Installation instructions	4.7	
Other safety related instructions	4.7	

OVERALL RECOMMENDATIONS

This document presents a series of recommendations intended to improve the development of safety requirements and the drafting of standards by using a hazard-based approach and in a hazard-based format, and the determination of whether or not a standard is suitable to become a harmonised standard. These can be summarised as follows:

- The hazard and risk matrix in Annex A should be used to support the identification, assessment and analysis of the safety requirements to be included in standardisation requests.
- The levels of safety set out in safety requirements in standardisation requests should be relevant to the significance of the hazards and risks and should be defined by the GPSD committee, not by the European Standardisation Organisations, especially when the risk of harm is high.
- Safety requirements should be drafted in a hazard-based format to make the comparison of these requirements and the content of the standard easier.
- There should be broad representation on the expert panels responsible for drafting safety requirements to ensure that they have an understanding of all the issues that need to be included.
- CEN/TR 13387-1:2015 *Child use and care articles. General safety guidelines. Safety philosophy and safety assessment* should be amended in line with the recommendation presented in Annex B.
- The published standard should be audited by the expert panel to determine whether or not it fulfils the safety requirements, both in terms of completeness and the levels of safety provided. This determination should be undertaken systematically using the checklist presented in this report.
- A similar project covering age groups other than children should be undertaken to improve the preparation of safety requirements and standards for consumer products not intended for children.

ANNEX A – THE DEVELOPMENT OF SAFETY REQUIREMENTS FOR INCLUSION IN STANDARDISATION REQUESTS

This guidance has been drafted to support the development by the European Commission’s Consumer Safety Network and its expert panels of safety requirements for consumer products⁷ for inclusion in standardisation requests falling under the GPSD. It clarifies the differences between the safety requirements in standardisation requests and the technical requirements set out in standards, and assists in the development of safety requirements in a structured way.

This annex focuses primarily on safety requirements for children’s products that fall under the GPSD. However, the principles set out are equally relevant to consumer products intended for all ages of users.

It assumes that when the need for a standard has been agreed at European Commission level, either as a result of the frequency and/or severity of accidents and associated injuries, the development of the safety requirements to be included in the standardisation request and subsequently addressed by a CEN/CENELEC technical committee will be assigned to a small expert panel comprising experts from key stakeholders. Expert panels are usually established by the GPSD committee or the Consumer Safety Network.

THE USE OF A HAZARD-BASED APPROACH

The so-called hazard-based approach to the development of safety requirements provides a means of undertaking a comprehensive identification of hazards using different sources of data and information, an appraisal of the risks associated with each hazard identified, i.e. the likelihood that the hazard will result in harm and the severity of that harm, and an assessment of the significance of the hazards and risks to allow decision to be taken on how to address these in standards.

The key aspects of the hazard-based approach are its comprehensiveness and its systematic approach.

⁷ The term “product” is used throughout this document. However, it should be regarded as shorthand for manufactured articles, processes, structures (e.g. playground equipment), services, the built environment or a combination of any of these with which consumers might interact.

EXPERT PANELS

Expert panels should comprise representatives from the key stakeholders: European Commission, ESOs, Member States, manufacturers, consumers, and other essential representatives. Panel members should have detailed knowledge of:

- the product (or similar products);
- an understanding of the ways in which children and others are likely to interact with the product;
- the numbers and nature of accidents and injuries or other harm associated with the product.

One benefit of using a small panel is the fact that it can be easier and quicker to draft documents in small forums.

THE RESPECTIVE ROLES OF EXPERT PANELS AND TECHNICAL COMMITTEES

It is important to understand and differentiate between the respective roles of expert panels and CEN/CENELEC technical committees.

The role of the **expert panel** is to act on behalf of the Consumer Safety Network to draft safety requirements for inclusion in a standardisation request, although the final decision on its content is taken by the GPSD committee. It should:

- identify the hazards that might be associated with a product, having regard for the people who are likely to interact with the product, all of whom might be at risk of injury. The identification of hazards should be undertaken in a structured way as described below.
- decide which hazards are the most significant, using whatever criteria it regards as appropriate, and that should therefore be addressed in the standards. This is discussed further below.
- define precise limit values or detailed specifications for some safety requirements when it is felt that they may significantly affect the health and/or safety of consumers and there is a possibility that they may not be adequately dealt with in technical committees. Such a requirement might be the maximum size of a gap through which a child could pass, the maximum quantity of a chemical to be permitted, or that a container should not be capable of being opened without a tool.
- define less prescriptive safety requirements for those hazards and risks that might result in less serious harm. In this case, the requirement might state, for example, that an edge should not be sharp without indicating exactly what this means, or that a container should resist opening by children without offering a solution.

In contrast, **CEN/CENELEC technical committees** should use the safety requirements as starting points to develop detailed requirements in product standards to address the hazards and risks and define test methods to verify conformity. They might choose to exceed performance levels defined in the safety requirements and cover topics not covered in standardisation requests.

HAZARD AND RISK ASSESSMENT

ISO/IEC Guide 50:2014. *Safety aspects – Guidelines for child safety in standards and other specifications* uses the following definitions:

A **hazard** is a potential source of harm, which can be injury or damage to the health of people, or damage to property or the environment.

Risk is the combination of the probability of occurrence of harm and the severity of that harm.

The first two stages in the process of hazard identification are closely linked. They are the identification of:

- likely users of the product and the characteristics that put them at risk; and
- possible and consequential hazards through a structured analysis.

This linkage results from the fact that the hazards are often associated with the characteristics of the users.

PRODUCT USERS

It would be more accurate to refer to people interacting with a product, rather than using it, as this is likely to extend beyond the “users”. For example:

- a baby or young child will sit in a highchair and may be regarded as the real “user”;
- the chair is likely to have been assembled by an adult;
- other children may handle the chair, play with or close to it, etc;
- adults are likely to clean it and disassemble it.

Many parties therefore interact with the product and may be at some risk. For brevity, these people are referred to in this document as “users”.

User characteristics

Identifying the characteristics of the users of a product that can lead to the presence or absence of a hazard requires, in particular, an understanding of child development, a characteristic that changes rapidly and can vary considerably between children of similar ages.

A detailed and extensive commentary on this topic is presented in ISO/IEC Guide 50:2014, chapter 5, and is summarised below.

Chronological age compared with developmental age

When considering the hazards and risks that children face, one should be aware that chronological age does not always match developmental age, i.e. children of the same chronological age might differ significantly in terms of their development.

For example, within a single narrow age range, some 12 month old babies may be able to walk while others are still crawling; and a small proportion of 4 year olds can open containers that are certified as child-resistant while the majority cannot.

Children's body size and anthropometry

The size of the whole body and key parts of it, body mass, distribution of mass (i.e. the position of their centre of gravity), etc. are important as they can impact on hazards such as product stability and strength, the possibility of falls, body, head and/or limb entrapment, etc.

To complicate the issue, a child measuring the 95th percentile in height may have a head that is at the 50th percentile and hand length in the 25th percentile.

Examples of the consequences of variations in anthropometric characteristics include:

- Young children have a large head compared with their body size. Their high centre of mass increases the likelihood of falls, e.g. from furniture or structures on which children might be sitting, climbing or standing. Children often fall directly onto their head.
- Another effect of the high centre of mass is that it also increases the likelihood of falling into pools, buckets, toilets, bathtubs, etc., into which children are bending or reaching, thereby increasing the risk of drowning.
- The relatively large head size means that it requires a much larger space to pass through than the rest of the body. Entrapment can occur when the body passes, feet first, through a gap through which the head cannot.

Motor development

Motor development refers to the maturation process of gross and fine movements and coordination. The development process includes changes from primary involuntary reflex actions to deliberate, goal-directed actions. Milestone achievements in the process include acquiring the strength and skill to support the head, crouch, sit up, roll over, crawl, stand, climb, rock, walk and run, and the ability to manipulate objects with hands and fingers. Until balance, control and strength have sufficiently developed, children are particularly at risk of falling and getting into unsafe positions from which they cannot escape.

Examples of the consequences of variations in motor development include the following:

- When lying down, babies can move to the edge of a surface and roll off, but be unable to lift themselves up. As a result, they can become wedged between products and suffer positional or compression asphyxia.
- Standing babies and toddlers can become entangled in cords, ribbons, or window dressings within their reach. When they sit or slump, the cords can tighten around their neck, resulting in strangulation.

- Climbing children can get clothing, accessories, and anything they wear (e.g. backpack) caught in furniture items or protrusions. If they cannot extricate themselves, they can hang.
- Children can fall from heights because they lose their balance or grip.
- From about age three months, infants placed to sleep on their backs can turn over and suffocate if the mattress or bedding is too soft.

Physiological development

There are many physiological functions that are developing in children. These include sensory functions, biomechanical properties, reaction time, metabolism and organ development.

Sensory development of children occurs over time. Visual development is slower than development of other senses. Even at the stage when most children have vision similar to that of adults, they might have narrower vision or have difficulty with depth perception. As a result, children will have difficulty recognizing hazardous situations.

The following are examples where incomplete physiological development can be a factor in injuries:

- Children's small body size and faster breathing rates result in their being particularly susceptible to potentially toxic substances such as medications, chemicals and plants.
- Children's biochemistry makes them susceptible to toxicity of chemicals, medications and plants not toxic to adults.
- The characteristics of children's skin, including its thinness, make it more vulnerable to thermal injury than among adults.
- Children's bones are not fully developed, resulting in different responses to mechanical forces.
- Children are more susceptible to harm from intense light sources.

Cognitive development

Children's stage of cognitive development determines their ability or inability to understand the consequences of their actions. Young children have limited ability to recognize hazards. They do not consistently and reliably anticipate or respond to harmful consequences of hazardous conditions. Thus, hazards obvious to adults are not so obvious for children.

At some stage in childhood, experience and teaching from parents and other carers begin to influence the child's behaviour, but this should not be relied upon when defining safety requirements.

Exploration strategies

From early infancy, children are driven by an inborn desire to explore. Children's exploration behaviour can be classified in terms of basic strategies which correspond to their emerging abilities. Since children experience a somewhat predictable sequence of physical and mental maturation, they also employ predictable patterns of exploratory behaviour. These exploratory behaviours can result in the child using products in ways that were not intended by the manufacturer.

One of the most frequently observed exploration strategies is object manipulation. In infancy, this often involves handling and mouthing objects simultaneously. Exploratory mouthing requires basic motor coordination (e.g. bringing one's hand to the mouth).

As children's sensory, motor, and cognitive skills improve, exploration of the environment gradually becomes more sophisticated. Children continue to explore objects including their own bodies. Inserting themselves into a large object or inserting small objects into their body cavities are common.

Adults understand that exploration is a process of "discovering the unknown" that involves risk. Children of every age face additional risk, due to their limited risk perception and decision-making ability, poor understanding of their own limitations and their physical and cognitive immaturity, all of which impact their capacity to avoid danger. While children are capable of perceiving some risk, they are not able to assess the risk involved in a potentially hazardous situation until they are capable of understanding consequences (cause and effect) at around 7 to 8 years old.

ISO/IEC Guide 50:2014, pp. 8-9, includes a detailed table providing examples of children's typical exploration strategies.

Adult characteristics

It is not just the characteristics of children that need to be taken into account when developing safety requirements. As the safety of children can depend strongly on the knowledge, behaviour and attitude of parents and other carers, it is important to have regard for adult characteristics such as familiarity with similar products, attitudes towards safety, the ability to operate a product correctly and consistently, and literacy, language, culture, etc. If a product's assembly, instructions for use and operation cannot be understood, children's safety can be compromised.

Additionally, the level of risk that adults are likely to associate with a product (i.e. its perceived danger) should be considered, together with the likely degree of supervision typically provided when the product is used.

Analysis of hazards and risks

This section considers a structured way of identifying hazards, considering their significance and deciding whether or not they should be included in safety requirements.

CEN/TR 13887:2015 *General safety guidelines - Part 1: Safety philosophy and safety assessment* presents three tables (tables 1-3) listing comprehensive lists of mechanical, thermal and other non-chemical hazards. These tables are intended for use by technical committees and have been adapted for use by expert panels in the analysis of hazards and risks for inclusion in safety requirements. (The assessment of chemical hazards is considered in CEN/TR 13387:2015 *Child use and care articles - General safety guidelines - Part 2: Chemical hazards* but not in tabular form. Addressing chemical hazards is a complex issue, partly as a result of the legislation associated with the use of chemicals.)

The three tables have been combined and adapted to support decision-making on whether hazards and risks warrant inclusion in safety requirements (table 1).

The use of the table requires that for each hazard listed, one should undertake:

- hazard identification – the collection and consideration of data and information that might indicate the presence or absence of a problem. The data and information can include, but is not limited to:
 - o accident and injury data. This can be challenging as it may not be routinely collected or readily available,
 - o investigations of case reports,
 - o complaint data,
 - o extrapolation of relevant data about hazardous characteristics from other similar types of products,
 - o information from RAPEX and product recalls,
 - o information on problems and actions in other jurisdictions.

It is important to remember that the absence of reported harm does not necessarily mean that there is no hazard, especially when products that new to the market are being considered.

The information used at this stage should be as objective as possible.

- hazard analysis – analysis of the significance of the harm reported. At this stage, the typical severity of the hazards identified is classified. For new products, it may be necessary to rely on expert opinion on the potential for harm.
- overall assessment of the level of risk, combining information on the presence of hazards, and the frequency and severity of any resulting harm. Judging whether a risk is low, medium or high can be subjective as one has to balance, for example, a high frequency of low severity events against rare but disabling or fatal events.

- decision on whether or not to include a hazard in a standardisation request's safety requirements, and if so whether or not to specify detailed requirements that have to be met in the standard.

With regard to the final item in this list, it is not sufficient simply to tick the appropriate box. If there is agreement that precise or detailed requirements need to be specified because of the high risk of severe harm and/or because of recognition of the need for the decision to be taken at Community level and not to be left to the ESO's technical committee, this should be noted and incorporated into the safety requirements.

An example of precise limit values or detailed specifications might be the maximum size of a gap through which a child could pass, the maximum quantity of a chemical to be permitted, or that a container should not be capable of being opened without a tool. In contrast, less prescriptive safety requirements might be that an edge should not be sharp without indicating exactly what this means, or that a container should resist opening by children without offering a solution.

Primary, secondary and consequential hazards

Table 1 assists in the identification of what might be termed the primary and secondary hazards. Primary hazards are those that might cause death or serious (e.g. disabling or long-lasting) injury. For example, falls from windows would be a primary hazard.

Secondary or consequential hazards can be associated with the protective device that is used to address the primary hazard. In the window falls example, if a device to restrict the window from opening more than a certain amount is used, this might lead to strangulation of a child who attempts to climb out of the restricted window, is able to get its body through the gap but is then held by the head as, for some young children, this can be larger than the body. Also, there is a need to remember that a window might be an escape route in the event of fire. Similarly, lacerations from sharp edges or choking from small parts could be associated with a poorly designed protective device.

These hazards will not be revealed by the hazard and risk matrix as this is intended to identify the primary hazards. To identify these secondary or consequential hazards, the user characteristics described above need to be considered with reference to the protective device and a second iteration through the list of hazards in table 1 after a potential solution is identified might be constructive.

The identification of secondary hazards needs to take place at the expert panel and technical committee stages. If the expert panel specifies a solution to address the primary hazard, for example by stating in the safety requirements that a standard for a window restrictor is required, it should consider whether there are any significant consequences of this.

The technical committee might need to identify hazards that might be less serious than those in the safety requirements and therefore not explicitly mentioned, and also consider whether there are any significant safety requirements not identified by the expert panel and/or mentioned in the standardisation request. It is important to remember that technical committees

might be better informed on potential solutions to problems as manufacturers often specialise in innovative solutions and can have wider knowledge of the product field thus being able to transfer knowledge from one area to another.

Table 1. Hazard and risk assessment table

Hazards	Hazard identification					Hazard analysis					Risk level	Inclusion in safety requirements?			Comments
	Accident and/or injury data	RAREX notifications	Product recalls	Reported incidents / accidents	Product reports	Expert opinion	Minor or reversible injuries	Serious and reversible, or minor and irreversible injuries	Serious and irreversible injuries	Death	L (low), M (medium) or H (high)	Hazard to be included in safety requirements in general terms	Hazard to be included in safety requirements. Precise requirement to be specified.	Hazard absent or not to be included in safety requirements	
MECHANICAL HAZARDS															
Hazards from gaps and openings:															
Entrapment of head and neck															
Entrapment of fingers															
Entrapment of limbs															
Hazards due to moving parts, i.e. shearing and compression															

Hazards	Hazard identification					Hazard analysis					Risk level	Inclusion in safety requirements?			Comments
	Accident and/or injury data	RAREX notifications	Product recalls	Reported incidents / accidents	Product reports	Expert opinion	Minor or reversible injuries	Serious and reversible, or minor and irreversible injuries	Serious and irreversible injuries	Death		L (low), M (medium) or H (high)	Hazard to be included in safety requirements in general terms	Hazard to be included in safety requirements. Precise requirement to be specified.	
Hazards due to crushing															
Hazards due to protrusions															
Entanglement in cords, ribbons and parts used as ties															
Ingestion hazards															
Choking hazards															
Hazards from plastic decals or sheeting															
Hazards from packaging materials															
Hazardous edges															

Hazards	Hazard identification					Hazard analysis					Risk level	Inclusion in safety requirements?			Comments
	Accident and/or injury data	RAREX notifications	Product recalls	Reported incidents / accidents	Product reports	Expert opinion	Minor or reversible injuries	Serious and reversible, or minor and irreversible injuries	Serious and irreversible injuries	Death		L (low), M (medium) or H (high)	Hazard to be included in safety requirements in general terms	Hazard to be included in safety requirements. Precise requirement to be specified.	
Hazardous points and wires															
Hazards from inadequate stability															
Hazards from inadequate structural integrity															
Hazards from inadequate protective barrier function															
Hazards from inadequate protective restraint systems															
Falling hazards due to footholds															
Hazard heights (falls)															

Hazards	Hazard identification					Hazard analysis					Risk level	Inclusion in safety requirements?			Comments
	Accident and/or injury data	RAREX notifications	Product recalls	Reported incidents / accidents	Product reports	Expert opinion	Minor or reversible injuries	Serious and reversible, or minor and irreversible injuries	Serious and irreversible injuries	Death		L (low), M (medium) or H (high)	Hazard to be included in safety requirements in general terms	Hazard to be included in safety requirements. Precise requirement to be specified.	
Hazards from moving or rotating objects															
THERMAL HAZARDS															
Hazards due to flash effect															
Hazards due to flame propagation															
Hazards due to melting behaviour of materials															
Hazards from contact with flames															
Hazards from hot or cold surfaces															
Hazards from hot or cold liquids or food															

Hazards	Hazard identification					Hazard analysis					Risk level	Inclusion in safety requirements?			Comments
	Accident and/or injury data	RAREX notifications	Product recalls	Reported incidents / accidents	Product reports	Expert opinion	Minor or reversible injuries	Serious and reversible, or minor and irreversible injuries	Serious and irreversible injuries	Death		L (low), M (medium) or H (high)	Hazard to be included in safety requirements in general terms	Hazard to be included in safety requirements. Precise requirement to be specified.	
Hypothermia or hyperthermia hazards															
OTHER HAZARDS (see note at end of table)															
Suffocation due to an enclosed space															
Hazards from noise															
Drowning hazards															
Hazards from suction caps															
Electric shock hazards															
Radiation hazards															

Hazards	Hazard identification					Hazard analysis					Risk level	Inclusion in safety requirements?			Comments
	Accident and/or injury data	RAREX notifications	Product recalls	Reported incidents / accidents	Product reports	Expert opinion	Minor or reversible injuries	Serious and reversible, or minor and irreversible injuries	Serious and irreversible injuries	Death		L (low), M (medium) or H (high)	Hazard to be included in safety requirements in general terms	Hazard to be included in safety requirements. Precise requirement to be specified.	
High intensity or concentrated light															
Biological hazards															
Explosion hazards															
Inadequate information															

Note: Chemical hazards have not been included in the table as they require a different approach. Reference should be made to CEN/TR 13387-2:2015 *Child use and care articles – General safety guidelines – Part 2: Chemical hazards* for details.

ANNEX B – THE DEVELOPMENT OF HAZARD-BASED STANDARDS FOR CHILD USE AND CARE ARTICLES

The aim of this annex is to provide a tool for members of technical committees when drafting mandated and other safety standards for consumer products that fall under the General Product Safety Directive (GPSD), especially child use and care articles covered by CEN/TC 252, the technical committee responsible for such products. Using a hazard-based format enables standards to be checked to ensure that they clearly address the requirements of any associated standardisation requests and hazards which need to be addressed.

CEN/TC 252 has decided that where standards are being revised or new standards drafted they should, wherever possible, be produced in this hazard-based format.

The format is not restricted to CEN/TC 252 standards. It is also a suitable approach for other safety standards covered by the GPSD, whether a product is designed specifically for children or where children would come into contact with a product.

The hazard-based approach and format

The so-called hazard-based approach to the development of safety requirements provides a means of undertaking a comprehensive identification of hazards using different sources of data and information, an appraisal of the risks associated with each hazard identified, i.e. the likelihood that the hazard will result in harm and the severity of that harm, and an assessment of the significance of the hazards and risks to allow decision to be taken on how to address these in standards. The key aspects of the hazard-based approach are its comprehensiveness and its systematic approach.

The use of the hazard-based approach to develop a standard facilitates the presentation of the standard in a hazard-based format.

The use of CEN Technical Report TR 13387 *Child use and care articles - General safety guidelines*

CEN/TR 13387, first published in 1999 and then revised in 2004, has been further revised to incorporate additional requirements and test methods and to clarify some issues (TR 13387:2015). It has also been decided to separate TR 13387:2015 *Child use and care articles - General safety guidelines* into five discrete parts:

TR 13387 - Part 1 Safety philosophy and safety assessment;

TR 13387 - Part 2 Chemical hazards;

TR 13387 – Part 3 Mechanical hazards;

TR 13387 – Part 4 Thermal hazards;

TR 13387 – Part 5 Product information.

By separating the TR into parts any revisions or additions to a particular part will be quicker to carry out.

The aim of TR 13387 has been to address, wherever possible, a similar hazard in a similar way in any standard both by having similar requirements and test methods and also to provide information as to the rationale for particular requirements.

It should be noted that the hazards and requirements in TR 13387:2015 are specified for children up to 48 months of age. ISO/IEC Guide 50:2014 *Safety aspects – Guidelines for child safety in standards and other specifications* provides information on hazards for children up to 14 years of age. Both of these documents are extremely useful when taking the hazard-based approach.

STRUCTURE OF A HAZARD-BASED STANDARD

A hazard-based standard is separated into a **Normative section** and **Informative Annexes**, one of which contains the **Rationales** for the inclusion of requirements in the normative section of the standard

The **Normative section** of the standard includes the scope, normative references, terms and definitions, test equipment, general requirements and product information. The remainder of the standard covers at least the following hazards, including associated safety requirements and any applicable test methods, dependent on the nature of the product:

- Chemical hazards
- Thermal hazards
- Mechanical hazards

Other hazards which do not fit into the above groups, particularly where a product is not designed specifically for a child, such as electric shock and radiation, may need to be addressed. Additional information can be found in ISO/IEC Guide 50:2014.

Relevant clause numbers in the normative section are given in the rationales.

Where a rationale is included for a specific requirement a brief explanation is normally provided to cover the nature of the hazard together with any additional explanations for requirements related to a particular product. Although these hazards are primarily concerned with child care products, they can be applied to safety standards where children may use or come into contact with a product.

For the most commonly occurring hazards the brief explanations which form the basis of the requirements for the Normative part of the standard and the associated rationales are as follows:

Chemical hazards

Chemical safety is a complex issue and one covered by a range of legislative measures.

Babies and young children spend a considerable amount of time both mouthing and chewing. It is important that the quantities of certain elements, which may have a harmful effect if a child has access for mouthing and chewing, should be limited.

Harmful substances, such as medicines, cleaning products and other household chemicals, should be supplied in child-resistant packaging.

For further information on chemical hazards see TR 13387:2015 Part 2 and ISO/IEC Guide 50:2014 Clause 7.10.

Mechanical hazards

Mechanical hazards are defined in TR 13387:2015 Part 3 as physical factors which may give rise to injury due to the mechanical properties of a product or parts of a product.

Entrapment hazards

Entrapment occurs when a child becomes trapped in a static gap.

Specific hazards for entrapment of a child's head, neck, fingers, limbs, feet and hands should be considered depending on the product and the age of the child.

For further information see TR 13387:2015 Part 3 Clause 5 and ISO/IEC Guide 50:2014 Clause 7.2.1

Hazards from moving parts

Hazards from moving parts are related to products with rigid components which can cause crushing and shearing either to the whole or parts of a child's body.

For further information see TR 13387:2015 Part 3 Clause 6

Hazards where products are designed to fold

Products that have mechanisms to enable them to fold for storage, e.g. a travel cot, or to make transportation easier, e.g. a buggy in the boot of a car, should be designed with locking mechanisms to secure the product in the erected position for use. Any locking mechanisms should be sufficiently complex to avoid inadvertent release by the child using the product.

For further information see TR 13387:2015 Part 3 Clauses 7 and 8

Entanglement hazards

Where products have cords, ribbons and narrow fabrics that are sufficiently long to encircle a child's neck or have loops that can pass over a child's head, there is a risk of strangulation and their length and width should be limited.

The use of monofilament threads which will not break in use, if wound around a child's finger for example, can cause the blood supply to be restricted and should not be used in child care products.

Children's clothing and jewellery can be snagged on protrusions with the risk of strangulation (see Hazardous edges and projections)

For further information see TR 13387:2015 Part 3 Clause 9 and ISO/IEC Guide 50:2014 Clauses 7.6 and 7.7

Hazards from small objects

Choking occurs when a child's internal airways are blocked by small objects and its breathing is impeded so that air cannot pass into the lungs and brain damage can occur.

Ingestion hazards result from small objects passing into the child's digestive system which could cause toxic contamination, an internal blockage or laceration.

All components of a product should either be sufficiently large so that they cannot be swallowed by a child and small components should be securely attached to the product.

For further information see TR 13387:2015 Part 3 Clauses 10 and 12 and ISO/IEC Guide 50:2014 Clause 7.7

Suffocation hazards

When a child's mouth and nose are blocked simultaneously, air cannot pass into the child's lungs and brain damage can occur.

Plastic labels, transfers etc. should be securely attached to a product or be sufficiently small so that they will not cover both the mouth and nasal airways.

Non air-permeable packaging should either be sufficiently thick so that it cannot mould to child's face, or should be provided with ventilation holes.

For further information, see TR 13387:2015 Part 3 Clause 11, ISO/IEC Guide 50:2014 Clause 7.5 and TR 16353:2012 *Packaging - Safety guidelines for flexible plastic packaging to minimize the risk of suffocation to children*.

Hazardous edges and projections

Sharp corners, edges, burrs and projections can cause lacerations or abrasions to a child's skin and sharp points could puncture a child's skin or eye.

Children's clothing or jewellery around its neck can become snagged on projection and cause strangulation (see Entanglement)

For further information see TR 13387:2015 Part 3 Clause 13 and ISO/IEC Guide 50:2014 Clause 7.2.2 and 7.2.3.

Hazards from inadequate structural integrity

The poor choice of materials can result in inadequate strength and durability for the lifetime of the product.

Any major failure of the structure of a product could cause injury to a child, for example as a result of a fall, crushing injury or entrapment.

For further information see TR 13387:2015 Part 3 Clause 14 and ISO/IEC Guide 50:2014 Clause 7.2.5

Hazards from inadequate protection

Products that restrict a child's access, contain a child within a specific environment or limit a child's movement, provide a protective function. If this function is inadequate, injuries can occur.

Where bars are used to "contain" a child they should be spaced so that a child cannot pass between them and not have footholds which a child can use for climbing.

Where a child restraint is used in a product, it should be securely attached to the product and also designed so that a child cannot undo or wriggle free from it.

Where a product gives the perception of having a protective function, such as toy helmets and toy sunglasses, it should provide adequate protection.

For further information see TR 13387:2015 Part 3 Clause 15 and ISO/IEC Guide 50:2014 Clauses 8.2 and 8.4

Hazards from inadequate stability

Products should be sufficiently stable to prevent them tipping over.

For further information see TR 13387:2015 Part 3 Clause 16 and ISO/IEC Guide 50:2014 Clause 7.2.4

Hazardous heights

Falls from a height can result in internal injuries and fractures.

For further information see ISO Guide 50:2014 Clause 7.3

Thermal hazards

Flammability and burning hazards

If a product should come close to or be in contact with an ignition source the rate of spread of flame should be sufficiently low so that the carer can remove a child before injury occurs.

Flash effect occurs where a flame spreads across the surface of a material without the substrate burning.

For further information see TR 13387:2015 Part 4 Clauses 3.2 and 3.5 and ISO/IEC Guide 50:2014 Clauses 7.8 and 7.9

Hazards from hot and cold surfaces

If surfaces that are too hot or cold they can cause burns to a child's skin and mouth and should be covered to limit contact.

For further information see TR 13387:2015 Part 4 Clause 3.3 and ISO/IEC Guide 50:2014 Clause 7.9.1

Hazards from hot fluids

Children are at risk from scalds if they have access to hot fluids.

For further information see TR 13387:2015 Part 4 Clause 3.4 and ISO/IEC Guide 50:2014 7.9.2

Hyperthermia and hypothermia

Overheating, hyperthermia, is a rise in a child's core temperature which can occur if a child is in a hot environment or with products that cause heat build-up such as duvets.

Hypothermia is a lowering of the child's core temperature.

For further information see TR 13387:2015 Part 4 Clause 3.6 and ISO/IEC Guide 50:2014 Clause 7.9.4

Hazards from noise

Children will have a longer life exposure to noise than adults and their ears may be more susceptible to sound pressures that are too high.

For further information see ISO/IEC Guide 50:2014 Clause 7.13

Drowning hazards

Immersion in water can lead to drowning as even short periods of lack of air can cause brain damage.

For further information see ISO/IEC Guide 50:2014 Clause 7.4

Biological hazards

Young children have less resistance/immunity than adults. Products should be designed to facilitate cleaning together with instructions for cleaning. Any filling materials should be clean and free from infestation.

For further information see ISO/IEC Guide 50:2014 Clause 7.14

Product Information

Product information should contribute to avoiding hazards to a child and is not intended to compensate for design deficiencies but is a means for the supplier to communicate with the user.

Markings on the product such as warnings should be permanent.

Information enabling the purchaser to make an informed choice, including any age limitations, should be provided.

Instructions for use, including at least safety, assembly, installation, operation, storage, maintenance and repair where applicable, should be provided.

For further information see TR 13387:2015 Part 5, ISO/IEC Guide 50:2014 Clause 8.6 and CEN/CENELEC Guide 11:2006 *Product information relevant to consumers. Guidelines for standard developers.*

ANNEX C – PROPOSED AMENDMENTS TO CEN/TR 13387:2015

Introduction

CEN/TR 13387:2015 *Child use and care articles - General safety guidelines* defines hazards from which children may need protection in child use and care articles. It only makes reference to hazard-based standards and does not give any guidance as to how such standards should be constructed. It is proposed that an additional Clause 6 of Part 1: Safety philosophy and safety assessment is added as an amendment to address this omission.

Although TR 13387:2105 contains much detail concerning the rationales for the inclusion of the detailed requirements given in standards it is proposed that a Clause 7 of Part 1 is added which gives the basic wording for the rationales in the Informative Annex of the hazard-based standards.

When a standard has been developed as a result of a request from the European Commission in a standardisation request, it normally contains general and/or specific safety requirements. To support the decision on whether or not there should be reference to the standard should be included in the Official Journal of the European Union, i.e. it should be a harmonised standard, an assessment of the requirements contained in the standardisation request and the ways that they are addressed in the standard has to be made. To assist with this, the technical committee or WG responsible for the standard should audit the standardisation request and the standard to confirm that the standard meets the requirements specified in the standardisation request. This can be done using the model checklist presented in a new Clause 8 of TR 13387, leading to an informative annex. If the technical committee or working group (WG) feels that it is not possible to address a safety requirement, either fully or partially, an explanation for this should also be included in the annex. This approach also assists with the transparency of the process.

Proposed amendment to TR 13387:2015-1 – NEW Clause 6

6. Hazard-based standards

6.1 Structure of a hazard-based standard

The standard is separated into a **Normative section** and **Informative Annexes**, one of which contains the Rationales for the inclusion of requirements in the standard.

6.2 Normative section

- Scope
- Normative references
- Terms and definitions
- Test Equipment
- General requirements and test methods
- Chemical hazards (see TR 13387:2015 Part 2 for details)
- Mechanical hazards (see TR 13387:2015 Part 3 for details)
- Thermal hazards (see TR 13387:2015 Part 4 for details)
- Other hazards
- Product information, including markings, warnings, purchase information and instructions for use (see TR 13387:2015 Part 5 for details)
- Informative annexes, one of which contains the Rationales for the inclusion of requirements in the standard.

Each hazard being addressed will have the associated safety requirements together with any applicable test methods.

The Normative section has references to the associated clauses in the Informative Annex for the Rationales.

Proposed amendment to TR 13387:2015-1 – NEW Clause 7

There are many approaches to writing Rationales. Providing the main purpose of explaining the reason for the inclusion of requirements is achieved any approach is acceptable.

The purpose of the proposal below is to link the wording of the Rationales to that given in the separate parts of TR 13387:2015.

7. Basic wording for the Rationales in the Informative Annex

In addition to the basic wording to be included, there should be reference to the relevant clause(s) in the normative section of the standard.

The wording presented below provides basic examples of the text that could be used in Rationales. Additional wording specifically relating to the product and the relevant hazards should also be included.

7.1 Chemical hazards TR 13387:2015 Part 2

Babies and young children spend a considerable amount of time both mouthing and chewing. It is important that quantities of certain elements, which may have a harmful effect if a child has access for mouthing and chewing, should be limited

7.2 Mechanical hazards TR 13387:2015 Part 3

7.2.1 Entrapment hazards Clause 5

Entrapment occurs when a child becomes trapped in a static gap and does not have the ability to extract itself

7.2.2 Hazards from moving parts Clause 6

Hazards from moving parts occur with rigid components which can cause crushing and shearing hazards either to the whole or parts of the child's body.

7.2.3 Hazards with products designed to fold Clause 7

Products that fold should be designed to avoid unintentional folding in use.

Products that have mechanisms to enable them to fold for storage or transportation should be designed with locking mechanisms to secure the product in the erected position for use. Any locking mechanism should be sufficiently complex to avoid release by the child using the product.

7.2.4 Hazards due to inadvertent release of attachment mechanisms Clause 8

Products that can attached to other products should be designed to avoid crushing, entrapment, falling or suffocation during use due to unintentional release.

7.2.5 Entanglement hazards Clause 9

Where products have cords, ribbons and narrow fabrics that are sufficiently long to encircle a child's neck or have loops that can pass over the child's head there is a risk of strangulation.

Monofilament threads should not be used in child use and care products

7.2.6 Choking hazards Clause 10

Choking occurs when a child's internal airways are blocked and its breathing is impeded so that air cannot pass into the lungs.

7.2.7 Suffocation hazards Clause 11

When a child's external airways, its mouth and nose are blocked simultaneously, air cannot pass into the child's lungs and brain damage can occur.

7.2.8 Ingestion hazards Clause 12

Ingestion hazards result from small components passing into the child's digestive system which could cause toxic contamination or an internal blockage or laceration.

7.2.9 Hazardous edges and projections Clause 13

Sharp edges, burrs and projections could cause lacerations or abrasions to a child's skin. Sharp points could puncture a child's skin or eye.

7.2.10 Structural integrity Clause 14

Any major failure of the structure of a product could cause injury to a child.

7.2.11 Protective function Clause 15

Products that restrict a child's access, contain a child within a specific environment or limit a child's movement, provide a protective function.

7.2.12 Hazards associated with stability Clause 16

Products should be sufficiently stable to prevent them tipping over

7.3 Thermal hazards TR 13387:2015 Part 4

7.3.1 Flammability and burning hazards Clause 3.2

If a product should come close to or be in contact with an ignition source the rate of spread of flame should be sufficiently low so that the carer can remove a child before injury occurs.

Flash effect occurs where the flame spreads across the surface of material without the substrate burning.

7.3.2 Hazards from hot and cold surfaces Clause 3.3

Contact with a child's skin or mouth where surfaces are too hot/too cold will cause burns.

7.3.3 Hazards from hot and cold liquids or food Clause 3.4

Children are at risk from scalds if they have access to hot liquids or food

7.3.4 Hazards from contact with flames Clause 3.5

Flames are an obvious hazard to adults but may be an attraction to children.

7.3.5 Hyperthermia and hypothermia Clause 3.6

Overheating, hyperthermia, is a rise in a child's core temperature.

Hypothermia is a lowering of the child's core temperature.

Proposed amendment to TR 13387:2015-1 – NEW Clause 8

8. Relationship between the requirements in the standard and the safety requirements in standardisation request XXXX

There should be an Informative Annex in the Standard linking the safety requirements presented in the standardisation request that required the development of this standard with the requirements set out in the standard.

Where an aspect of the safety requirements has not been fully addressed or has not been addressed at all, the table should include an explanation of why this is the case.

Safety requirements in standardisation request XXXX	Related clauses in this standard	Reasons for partial or not addressing of safety requirement

One can argue that if a specific safety requirement is not fully addressed in a standard, and hence an explanation is inserted into the third column, the standard does not meet the standardisation request. However, in practice, there can be a variety of reasons why this mismatch may occur, for example:

- the development of test methods may be limited by time constraints in the CEN process;
- a lack of funding to develop test methods particularly those of a dynamic nature;
- lack of available technical expertise;
- new designs of a product coming onto the market may make a subjective requirement more appropriate.

When mismatches between the standardisation request and the standard occur, it should be documented that these should be allocated to "Future work" and that the standard will be revised or amended accordingly.

The table can be used by the expert panel that developed the safety requirements in the standardisation request to consider whether or not the standard should become a harmonised standard. It could present its considered opinion and advice to the body where the final decision on referencing the standard in the OJEU is taken.