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Child use and care articles - Safety guidelines

Artikel für Säuglinge und Kleinkinder - Sicherheitsleitfaden

Articles de puériculture - Conseils relatifs a la sécurité

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Child use and care articles - Safety guidelines

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This Technical Report was approved by CEN on 23 March 2004. It has been drawn up by the Technical Committee CEN/TC 252.

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Foreword

This document (CEN/TR 13387:2004) has been prepared by Technical Committee CEN/TC 252 “Child use and care articles”, the secretariat of which is held by AFNOR.

This document supersedes CR 13387 :1999

This is a revision of CR 13387 first published in 1999. It is a non-normative CEN publication which provides guidance information on common hazards that should be taken into consideration when developing safety standards for child use and care articles.

These guidelines deal with hazards that are common to child use and care articles. They have been drawn-up by a working group of experts set up by CEN Technical Committee, TC 252 Child use and care articles, with the prime objective of harmonizing the approach to hazard and risk assessment and prevention. The guidelines give recommendations on preventive safety measures to avoid injuries that could be caused by child use and care articles.

The standards being drafted by CEN/TC 252 are for child use and care articles intended for children from birth to 48 months of age who form a very vulnerable group in society. Up to 18 months of age the development of knowledge takes place through the combined use of sensory and motor skills, i.e. children learn to see, hear, taste, smell and feel. Their movements are aimed at achieving familiarity with their environment. As children become older they achieve increased muscular control and balance. Even up to 48 months of age children are unpredictable in their behaviour. Special consideration has to be given to the fact that these children cannot understand how to avoid risks and thus are involuntarily exposed to them.

Child use and care articles constitute a group with large variations between the different products. However many safety hazards associated with this diverse group of products are very similar. These guidelines identify many of these safety hazards and give details that enable similar safety principles to be applied to the drafting of standards across the group of products.

The described measures are based upon safety requirements in existing standards and in standards under development for different groups of articles within the scope of CEN/TC 252.

Where similar safety issues have been applied in standards that have either been developed or are under development by CEN/TC 52 (safety of toys), CEN/TC 136 (safety of playground equipment) and CEN/TC 207 (safety of children’s nursery furniture), these have also been taken into consideration when drafting this document.

The information given in these guidelines reflects the current state of the art. Standards and regulations will continuously be developed. Other sources may also provide useful information for the reader. Some of the test methods offered have yet to be fully validated.

Introduction

These guidelines present safety specifications and test methodology relating to hazards that are common to child use and care articles. A common approach to product information is also considered.

The general safety philosophy given in section 1 is based on the premise that child use and care articles should be designed to be safe.

Detailed safety information is given in the following sections:

— chemical hazards (section 2);

— mechanical hazards (section 3);

— thermal hazards (section 4);

— product information (section 5).

These guidelines contain two annexes and a bibliography:

— Annex A contains anthropometric data and details of the abilities of children from birth to 48 months of age;

— Annex B describes a risk assessment procedure;

— bibliography of reference literature.

How to use these guidelines

The safety specifications and test methods given are intended to give guidance and to lead to consistency when writing safety standards for child use and care articles. In addition, these guidelines can assist those with a general professional interest in child safety.

The safety specifications detailed do not constitute an exhaustive set of specifications that can be directly applied to all child use and care articles. As subsequent sections explain, their applicability to particular products should be decided by experts. When analysing the hazards and risks associated with child use and care articles, the need to balance the reduction of hazards and risk with the capability for manufacture and use of the product should be considered.

There may also be alternative means of achieving similar levels of safety that are not envisaged in these guidelines.

In these guidelines a rationale is given for a particular hazard explaining the potential hazard to the child. Wherever possible, requirements, test equipment and test methods are given which can be used when drafting standards. It should be noted that the terminology in these guidelines is not that required for standards, and that the word *shall* has to be used in standards, not *should* as given in these guidelines.

A general safety philosophy is given in section 1 of these guidelines.

Chemical hazards are addressed in section 2. The chemical properties associated with the use of, and availability to, materials for the construction, coating and/or packaging of child use and care articles that may damage a child's health are considered.

Mechanical hazards are addressed in section 3. “Mechanical hazard” is a general designation for physical factors which may give rise to injury due to the mechanical properties of products or parts of products.

Thermal hazards are addressed in section 4. “Thermal hazard” is a general designation for the combustible properties of materials and/or their ability to conduct high and low temperatures which may give rise to injuries from burns and scalds.

Product information is addressed in section 5.

Annex A provides tables of anthropometric data and abilities of children from birth to 48 months of age. It presents a compilation of data in current literature. Only sources that explain the method by which the measurements were taken, and of which the sample size was large enough to give reliable results, have been selected.

Annex B describes an outline risk assessment procedure.

The Bibliography contains a list of reference literature and lists the standards that have been considered when drafting these guidelines.

These guidelines do not cover hazards related to acoustics. The sensitivity of children to loud noise is basically unknown. There are scientists who hold the opinion that, since the auditory canal in children is smaller than in adults, there is a difference in amplification which makes children more sensitive to high frequency sounds. Impulse sounds are especially hazardous since permanent damage to hearing may occur after only one exposure to high peak sound levels.

The products on the current work programme of CEN/TC 252 emit little or no noise. However, in the event of a product emitting a potentially hazardous level of noise, requirements to reduce the risk of damage to hearing due to high continuous and/or impulse noise levels given in EN 71-1 may be used. Child use and care articles that are manifestly designed to emit noise should not be capable of harming a child’s hearing. The related restrictions according to the EU-legislation for occupational noise should not be exceeded.

The diagram in Figure 1 may be used as a structure for the understanding and use of these guidelines. The suggested sequence is:

a) Consider the safety philosophy:

   — read and understand the general safety philosophy given in section 1.

b) Undertake a risk analysis:

   — conduct a risk analysis following the procedure outlined in Annex B;

   — for additional guidance refer to ISO/IEC Guide 50;

   — identify the potential for injury associated with the product e.g. injury statistics and surveillance systems, research studies, recalls, complaint data etc.

c) Establish the ability/age range of the child using the product:

   — establish an ability/age range for the child who uses the product;

   — consult the anthropometric data in Annex A;

   — for additional information consult other sources of data e.g. CHILDATA.

d) Consult the hazard categories in sections 2 to 4:

— consider the chemical hazards identified in section 2 and select any relevant requirements and test methodologies;

— consider the mechanical hazards identified in section 3 and select any relevant requirements and test methodologies;

— consider the thermal hazards identified in section 4 and select any relevant requirements and test methodologies.

e) Consult the product information in section 5:

— determine the wordings for markings, purchase information and instructions for use.

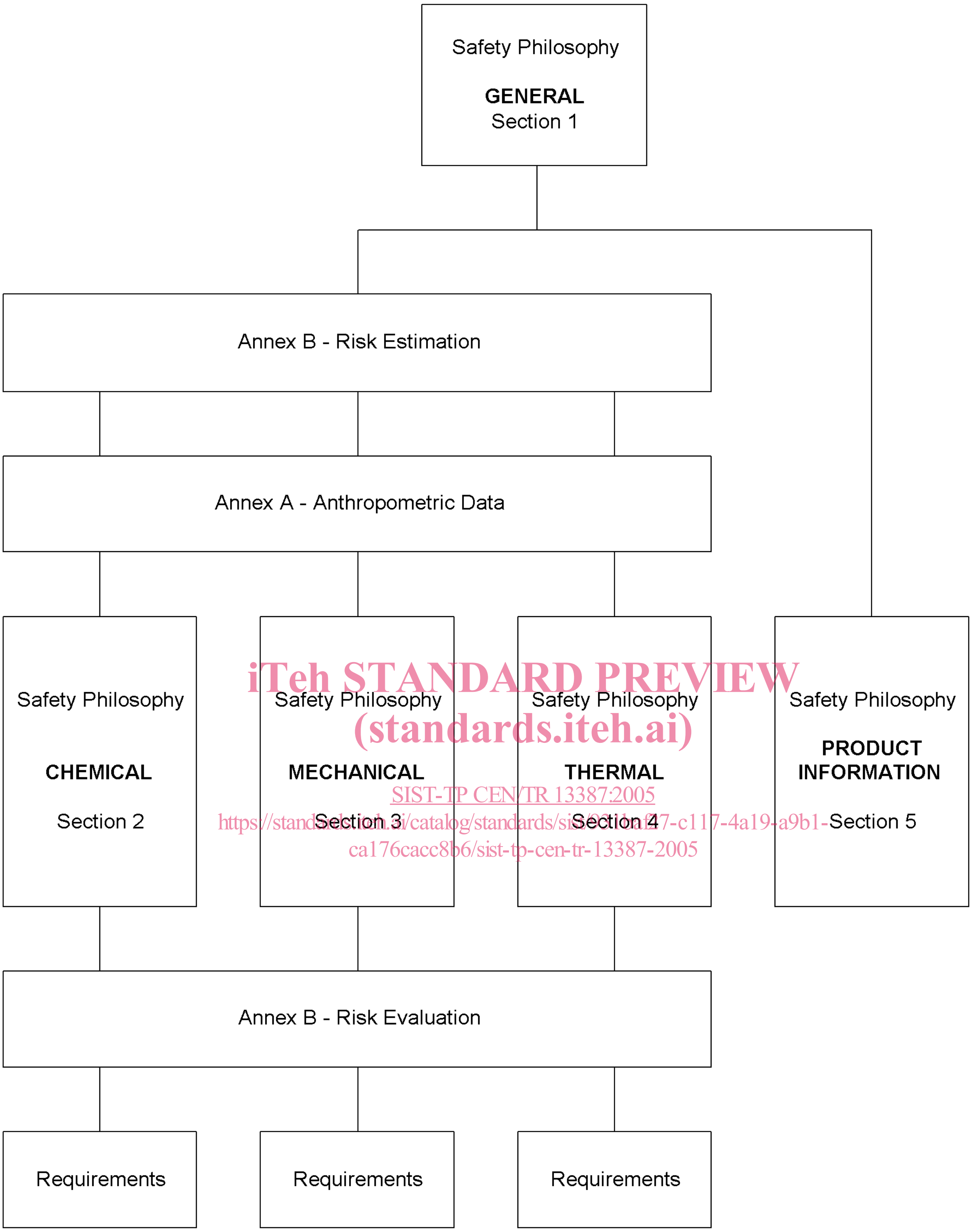

Figure 1 — Structure for the use of this report

General safety - Contents list

1 General safety

Safety is often a balance between being safe from injury and the other demands of a child use and care article, for example, ensuring that the item is fit for purpose as well as meeting consumers' needs and expectations.

Attention should be paid to:

— the child's stage of development (ability, weight, age, etc.);

— the intended or foreseeable use of the product, bearing in mind a child's unpredictable behaviour. This unpredictable behaviour exposes children to injury in ways that differ from those of adults, making children a particularly vulnerable group in society;

— the hazard presented by the product in the environmental circumstances under which the product and the child come into contact with each other.

Where the function of a product or part of a product changes by virtue of its use and is beyond the scope of child use and care articles, appropriate requirements should be applied. For example, toys attached to child use and care articles shall comply with appropriate toy safety requirements.

These recommendations are not exclusive and attention is drawn to the importance of ensuring that all potential hazards relevant to the product are fully addressed e.g. hygiene, the effects of electrical power etc., where other safety standards may apply.

1.1 Terms/definitions used in the report

Terms and definitions specifically related to chemical, mechanical and thermal hazards and also for product information are given in the relevant clauses.

1.1.1 Terms identical to those given in the definitions in CEN/CENELEC Memorandum no 9.

Harm: physical injury and/or damage to health or property.

Hazard: a potential source of harm or a product characteristic which could lead to injury.

Intended use: the use of a product, process or service under conditions or for purposes in accordance with specifications and instructions provided by the supplier (including information for publicity purposes).

Risk: the probable rate of occurrence of a hazard causing harm and the degree of severity of the harm.

Safety: freedom from unacceptable risk of harm. (It should be understood that young children cannot be expected to appreciate risk adequately. Risks generally considered by society as acceptable have to be taken into account when referring to the safety of children).

1.1.2 Common terms/definitions

Hazard characterisation: the quantitative evaluation of the nature of the adverse health effects following exposure to a risk source(s).

Hazard identification: the identification of a risk source(s) capable of causing adverse effect(s).

Risk analysis: the investigation of available information to identify hazards and to estimate risks.

Risk assessment: the evaluation, including the identification of the related uncertainties, of the likelihood and severity of an adverse effect(s) following exposure under defined means to a risk source(s).

Reasonably: should, where appropriate, take account of the foreseeable use and unpredictable behaviour of children.

1.2 Built-in safety

Standards related to child use and care articles should always be formulated with children and their safety in mind and there is no doubt about their importance in reducing children's injuries.

Child use and care articles should be designed with the intention of making them safe. Hazards should be eliminated wherever possible. For cases where a hazard cannot be eliminated or sufficiently minimized – by design or safeguards – product related information should be given. However product related information should not be used as an alternative to safe design. "Built-in" safety, which does not require any further human action, is the most effective means of preventing accidents and injuries associated with products. This is best built-in at the design and manufacturing stages of product development so that no safety device or action is needed when the product is used.

If a safety device is needed, it should wherever possible, be one which works automatically without human intervention. Next in order of effectiveness is a safety device which requires a single action. Least effective is when safety has to be considered in relation to the product each time it is used.

1.3 Accident data

A basis for risk assessment is given in Annex B.

Accident and injury data such as EHLASS "European Home and Leisure Accident Surveillance System" and/or other equivalent information sources should be consulted.

The absence of an accident history cannot be a good reason for an automatic presumption of a low level of risk. Other factors should be taken into account, particularly when the possible severity of injury is high.

Appropriate data may not be available for many reasons, including the absence or ineffectiveness of a data collection system, the time delay in collating and presenting statistics, changes in product design and use conditions etc. For example, historical information related to a product or material used in a hot climate may not apply to its use in colder countries or vice versa.