



Brussels, 9th July 2009
M/445 EN

**STANDARDISATION MANDATE ADDRESSED TO CEN AND CENELEC
WITHIN THE FRAMEWORK OF DIRECTIVE 2009/48/EC REVISING
DIRECTIVE 88/378/EEC CONCERNING THE SAFETY OF TOYS**

1. OBJECTIVE

This standardisation mandate requests CEN and CENELEC to revise existing European standards or draw up new European standards in order that they will meet the essential requirements of Directive 2009/48/EC that revises Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys.

2. BACKGROUND

2.1 The legal basis of the mandate

This mandate relates to Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the Safety of Toys, revising Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys.

Directive 2009/48/EC comes into force on 20 July 2009.

According to Article 10 of Directive 2009/48/EC, toys subject to the Directive must comply with the essential safety requirements set out, as far as the general safety requirement is concerned, in paragraph 2 of Article 10, and, as far as the particular safety requirements are concerned, in Annex II.

Article 13 of Directive 2009/48/EC states that toys which are in conformity with harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the requirements covered by those standards or parts thereof, set out in Article 10 and in Annex II.

The revised Directive focuses on enhanced safety requirements for toys, namely with regard to the use of chemicals in toys. The revised Directive also aims at updating

requirements on electrical properties and in physical and mechanical areas, such as choking risks and suffocation, as well as on flammability and hygiene

The main novelty of the revised Directive is the introduction of specific rules on CMR (carcinogenic, mutagenic, or toxic for reproduction) in toys. The revised Directive foresees that toys and components of toys or micro-structurally distinct parts of toys shall not contain CMR of categories 1A, 1B and 2, although derogations are foreseen, and nickel in stainless steel is exempted from these provisions as well as materials which are covered and comply with the provisions for food contact materials.

In order to take into account new scientific knowledge, the revised Directive provides for an update of certain chemical substances to be used in toys and lowers the limit values for these substances. The revised Directive replaces the reference to bioavailability (i.e. the soluble extract having toxicological significance) with “migration” as mentioned in the opinion of the scientific committee on toxicity, ecotoxicity and the environment (CSTEE).

The revised Directive foresees to complement provisions by requiring that warnings specify, where appropriate for safe use, user limitations such as minimum and maximum ages of the user or the ability of the user of toys or maximum or minimum weight of the users as well as the need to ensure that the toy is used under adult supervision. Toys shall not bear one or more warnings if they contradict the intended use of the toy as determined by virtue of their function, dimension and characteristics (Article 11). The warnings and when applicable the pictograms shall be preceded by the word Warning(s) (Article 11 and Annex V part B.1). It is furthermore foreseen to require some warnings which determine the decision to purchase the toys, such as those specifying the minimum and maximum ages for users and the other applicable warnings set out in Annex V, to appear on the packaging or be clearly visible before the purchase, including on-line purchase (Article 11).

The revised Directive foresees to extend the provisions on choking/asphyxiation. (Annex II.1.4.c) *“Toys and their parts must be of such dimensions as not to present risk of asphyxiation by closing off the flow of air as result of internal airway obstruction by objects wedged in the mouth or pharynx or lodged over the entrance to the lower airways.”* The revised Directive provides for additional requirements to prevent suffocation by internal airway obstruction to deal with the risk presented by new designs of toys such as those with suction cups. The internal airway obstruction risks shall be covered for all toys and not only for those intended for children less than 36 months and also for certain toy packaging.

(Annex II.1.4.d) *“Toys, which are clearly intended for children under 36 months, and their component parts and any of their detachable parts must be of such dimensions as to prevent their being swallowed or inhaled. This also applies to other toys which are intended to be put into the mouth, and their component parts and any of their detachable parts.”* The revised Directive foresees to extend the provisions of choking for those toys that are intended to be put in the mouth, such as toy instruments.

(Annex II.1.4.f) *“Toys contained within food or co-mingled with a food must have their own packaging. This packaging in its supplied condition must be of such dimensions as to prevent it being swallowed and/or inhaled.”* The revised Directive foresees the new requirement that i) toys should be marketed in a package separating them from the food items they are co-mingled with or contained in, ii) the packaging itself shall pass the ‘small parts cylinder test’.

(Annex II.1.4.g) *“Toy packaging as referred to in points 4e and 4f which is spherical, egg-shaped or ellipsoidal and any detachable parts of this, or of cylindrical toy packaging with rounded ends must be of such dimensions as to prevent it from causing airway obstruction by being wedged in the mouth or pharynx or lodged over the entrance to the lower airways.”* The revised Directive provides for additional requirements for packaging in which toys are contained (offered) for retail sale and for toys co-mingled with or contained in food. The requirements aim at ensuring that spherical, egg-shaped or ellipsoidal packaging does not pass through the template for small balls. As regards cylindrical toy packaging with rounded ends, only its detachable parts are covered by the requirement. Small plastic bags are not addressed. The requirements apply to toys intended for children of all ages.

(Annex II.1.4.h) *“Toys firmly attached to a food product at the moment of consumption in such a way that the food product needs to be consumed in order to get direct access to the toy shall be prohibited. Parts of toys otherwise directly attached to a food product shall fulfil the requirements set out in point 4c and 4d.”* The revised Directive foresees to ban toys that are firmly attached with foodstuffs in such a way that prior consumption of the food item is necessary to access to the toy itself, e.g. lollipops with a toy inside. Also parts of toys otherwise directly attached to a food product shall fulfil the requirements of asphyxiation risk caused by internal airway obstruction and choking risk. Examples are toy pacifiers with a candy nipple or toy lipsticks with a candy stick. As these toys are intended to be used in the mouth, the requirements shall be fulfilled regardless of the age of the child.

(Annex II.1.11) *“Activity toys shall be manufactured so as to reduce the risk of crushing or trapping of body parts or trapping of clothing and the risk of falls, impacts and drowning as far as possible. In particular, any surface thereof accessible for one or more children to play on shall be designed to bear their load.”* The revised Directive foresees inter alia that activity toys, when any surface thereof is accessible for one or more children to play on, shall be designed to bear their load. By load it is meant that the toy shall bear the mass of one or more children and support them during use. This applies to both static and dynamic forces.

(Annex II.V.2) *“A toy intended for children under 36 months must be designed and manufactured in such a way that it can be cleaned. A textile toy shall, to this aim, be washable, except if it contains a mechanism that may be damaged if soak washed.”* The revised Directive foresees that all toys intended for children under 36 months can be cleaned. The toy shall fulfil the safety requirements of the Directive after cleaning in accordance with the provisions of above mentioned paragraph and the manufacturer's instructions.

3. DESCRIPTION OF THE MANDATED WORK

The Commission requests CEN and CENELEC to check the existing body of standards for toys and, where necessary, to draw up new standards or to amend or revise the existing standards in order to ensure that they cover the scope and satisfy the essential safety requirements of the Directive 2009/48/EC.

The existing standards concerned by this mandate are the standards, the references of which have been published in the OJEU in support of Directive 88/378/EEC. This

mandate also concerns new and revised standards for toys to be adopted during the period leading up to the application of Directive 2009/48/EC.

The standardisation tasks covered by this mandate are as follows:

- Ø Make the necessary adjustments to standards to take account of the fact that Directive 2009/48/EC revised Directive 88/378/EEC with the effect that new definitions and warnings have been introduced, in particular the definition of activity toys and design speed and warnings for toys in food, imitations of protective masks and helmets, packaging for fragrances, toys intended to be strung across a cradle, toy scooters, toy bicycles and skateboards;
- Ø Ensure that the standards take account of the new physical and mechanical, chemical, electrical, hygiene and flammability requirements;
- Ø In particular, make the necessary adjustments to standards to take account of the fact that the Directive 2009/48/EC contains new requirements, to limit the maximum values both for impulse noise and continuous noise emitted by toys in order to adequately protect children from the risk of impairment of hearing;

The revised directive foresees that more stringent and comprehensive standards should be established to limit the maximum values for noise levels for all toys that emit sound, both due to high continuous noise and to impulse noise. The measurement result is as a rule to be given as the highest value recorded. The emission of sound pressure levels should not impair children's hearing and should be revised taking into account that children are the most vulnerable age group and that their auditory channel is smaller than in adults.

- Ø Address the hazard presented by books made of cardboard and paper in order to cover adequate testing. The requirements must in particular ensure that there is no choking risk as regards books intended for children less than 36 months;
- Ø Ensure that the harmonised standards intended to support Directive 88/378/EEC fully satisfy the relevant essential safety requirements of the revised Directive or, failing that, include an indication as to which of the requirements are not satisfied;
- Ø Ensure that the standards intended to support the Directive 2009/48/EC include an annex providing information with regard to the relationship between its clauses and the essential safety requirements of the Directive in order to allow the users of the standard to establish to what extent the standard provides for a presumption of conformity with the essential safety requirements in accordance with the agreement on this subject between the Commission and the European Standardisation Organisations;
- Ø Ensure that the harmonised standards intended to support the Directive include an informative annex with the background and justification for the requirements.

4. EXECUTION OF THE MANDATE

- Ø CEN and CENELEC are requested to communicate to the Commission, within three months of the acceptance of the mandate, a work plan for the execution of

the abovementioned standardisation tasks, indicating the new standards that need to be developed, the standards requiring revision or amendment.

- Ø CEN and CENELEC are requested to communicate to the Commission within twelve months of the acceptance of the mandate, an interim report on the progress of the tasks set out in this mandate, indicating any possible difficulties encountered.
- Ø CEN and CENELEC will revise standards which need adaptation to Directive 2009/48/EC within two years from accepting the mandate for all requirements excluding the chemical requirements and within four years from accepting the mandate for the chemical requirements. CEN and CENELEC are also requested to communicate to the Commission, within one year from accepting the mandate a list of harmonised standards supporting the implementation of Directive 2009/48/EC. The list shall include the titles of the standards in all of the official languages of the EU.
- Ø CEN and CENELEC will develop the new standards within 2 years for all requirements excluding the chemical and noise requirements and within four years from accepting the mandate for the chemical and noise requirements.
- Ø CEN and CENELEC are requested to draw up the work plan and execute the above mentioned tasks in close cooperation in order to ensure consistency and avoid overlapping standards.
- Ø When executing the standardisation tasks covered by this mandate, CEN and CENELEC are requested to take due account of feedback from the stakeholders. Wherever possible, when the abovementioned tasks involve the development of new standards or the revision of existing standards, the tasks should be executed within the framework of the Vienna and Dresden Agreements with a view to preparing international standards that satisfy the relevant essential safety requirements of Directives 2009/48/EC.
- Ø Acceptance by CEN of this mandate starts the standstill period referred to in Article 7 of Directive 98/34/EC of 22 June 1998 (OJ N° L 204/37 of 21 July 1998).

5. BODIES TO BE ASSOCIATED

As appropriate, CEN and CENELEC will invite the representative organisations of consumers' interests (ANEC¹), environmental protection (ECOS²), workers (ETUI-REHS³) and small and medium-size enterprises (NORMAPME⁴) to take part in the development of the standards.

1 European Association for the Co-ordination of Consumer Representation in Standardisation

2 European Environmental Citizens Organisations for Standardisation

3 European Trade Union Institute - Research, Education, Health and Safety

4 European Office of Crafts, Trades and Small and Medium- Sized Enterprises for Standardisation