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MANDATE TO CEN FOR STANDARDIZATION IN THE FIELD OF TOY SAFETY

ORGANIC CHEMICAL COMPOUNDS IN TOYS OTHER THAN CHEMICAL TOYS

I. GROUND

This standardization mandate is based on the Council Directive 88/378/EEC of 3 May 1988 concerning the approximation of legislation of the Member States concerning the safety of toys¹ amended by the Council Directive 93/68/EEC of 22 July 1993².

Annex II to Directive 88/378/EEC set out the essential safety requirements for toys. The Directive also provides that in order to facilitate proof of conformity harmonized standards must be laid down at European level.

In compliance with a Commission's mandate, the CEN has already prepared and examined the parts of standard EN 71 - Safety of toys concerning physical and mechanical properties (Part 1), flammability (Part 2) and the migration of certain elements (Part 3) viz. heavy metals whose maximum bioavailability is specified in the essential safety requirements in respect of chemical properties.

Chapter 3 of Annex II (Chemical Properties) also stipulates (Paragraphe 3) :

"Toys must not contain dangerous substances or preparations within the meaning of Directives 67/548/EEC and 88/379/EEC³ in amounts which may harm the health of children using them. At all events it is strictly forbidden to include, in a toy, dangerous substances or preparations if they are intended to be used as such while the toy is being used".

¹ OJEC N° L 187 of 16.07.88,p.1

² OJEC N° L 220 of 30.08.93, p. 1

³ OJEC N° L 196 of 16.08.67, p. 1 - OJEC N° L187 of 16.07.88, p. 14

However, where a limited number of substances or preparations are essential to the functioning of certain toys, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities they are permitted up to a maximum concentration level to be defined for each substance or preparation by mandate to the European Committee for Standardization (CEN) ..., provided the permitted substances and preparations comply with the Community classification rules in respect of labelling, without prejudice to point 4 of Annex IV" (warning and indications of precautions³).

In 1988, the Commission gave the mandate BC/01/88 to the CEN to prepare two parts of Standard EN 71 in regard to substances and preparations used for the manufacture of chemical toys, namely Part 4 for experimental sets for chemistry and Part 5 for chemical toys except for experimental sets for chemistry.

It is now necessary to prepare standards for the chemical substances and preparations which are normally used in all other types of toys. The Toxicology Section of the Scientific Advisory Committee examining toxicity and ecotoxicity was consulted in regard to the toxicity of certain organic compounds in toys. It delivered its opinion in report EUR 13976 of 1992, which mainly concerns solvents, preservatives, wood preservatives, plasticizers, flame retardants and monomers.

In its assessment, the Committee emphasises that a toxic effect may be compounded by the mutual interaction of several compounds and that the limits for the migration of all substances must be laid down at the lowest level in respect of toxicology safety, taking into consideration the greater sensitivity of children. In the event of certain difficulties in testing and/or analysis, it may sometimes be advisable in the context of this hazard-based approach to identify the total content of a dangerous substance rather than the dose committed to the child. However, this should only be done in exceptional cases and the evaluation should take into consideration a special risk analysis for special toys/group of toys and must be reasoned.

The Committee approves the use of standardized test procedures which are sufficiently sensitive for toxicological purposes to measure substance migration under relevant circumstances as well as bioavailability because the impact on humans may be caused by breathing, contact with the skin and mucous membranes or orally

II. TASK DESCRIPTION

The CEN is requested to prepare one or several European standards concerning the risks associated with the presence of organic chemical compounds in toys, bearing in mind Directive 88/378/EEC on the safety of toys and in particular the essential safety requirements defined in Annex II of the Directive.

The CEN will have to identify the substances that come within the remit of Directive 67/548/EEC, with the exception of those banned by Directive 76/769/EEC⁴, within the groups of organic chemical products recommended by the Toxicology Section of the Scientific Advisory Committee, as well as those of paints and colouring agents.

⁴ OJ No L 262, 27.9.76, p.201

However, the list is not exhaustive. Chemical toys are excluded from this mandate, because they are already dealt with in Parts 4 and 5 of harmonised standard EN 71 on the safety of toys.

The CEN is requested to provide data on the use of organic compounds in toys. It should prepare test procedures in order to assess migration potential and its toxicological effects for different uses of toys, bearing in mind the foreseeable behaviour of children (such as touching with the mouth, skin, mucous membranes, the eyes, by licking, biting, rubbing or splashing).

In these tasks, existing requirements concerning these organic chemical compounds and preparations shall be taken into consideration, such as those applying to materials which come into contact with foodstuffs and cosmetic products, or the possible risks of microbiological contamination of toys (e. g. fluid-containing toys, finger paints) related to high restrictions for use of preservatives which may cause infections to children.

III PERFORMANCE SCHEDULE

1. Within six months of accepting this mandate, the CEN will submit to the Commission a timetable comprising the deadlines for submitting the standards, taking into consideration the above-mentioned requirements.
2. The European standards must be adopted within the deadlines set out in the timetable. On this date the three language versions (German, English and French) must be available.
3. The "new approach" Directives make it mandatory for the Commission to publish the references to the harmonised standards in the Official Journal of the European Communities, hence conferring a presumption of conformity with the essential safety requirements of the national standards transposing the harmonised standards. With an eye to this publication, the CEN must, on adoption of the European standards, communicate the title of these standards in all official languages of the European Union.
4. The European standards must be transposed into national standards and the diverging standards of the Member States of the European Union must be withdrawn within six months of adoption of this amendment.
5. The standstill period for the purposes of Article 7 of Council Directive 83/189/EEC of 28 March 1983 shall begin to run on acceptance of this mandate by the CEN.⁵

⁵ OJ No L 189, 26.4.83