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OPINION OF THE SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE) ON

"ASSESSMENT OF THE BIOAVAILABILITY OF CERTAIN ELEMENTS IN TOYS"

Adopted by the CSTEE by written procedure on 22nd June 2004

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BACKGROUND

The policy of the EU is to give a high priority to the protection of the health of children (EU White Paper on Environment and Health 2003). Ensuring the safety of toys used by children is an important component in achieving this aim. The Commission proposes to accomplish this aspect of its policy by setting standards for organic and inorganic substances in toys.

In the framework of the review of the Toy Directive, the Commission is to consider whether the essential safety requirements, in particular the limit values for the bioavailability of eight elements contained in toys, should be re-evaluated.

The CSTEE have been asked the following questions in respect of inorganic elements in children toys:

a) to advise whether the current limit values of bioavailability for the element listed in Annex II.II.3 under§ 2 of Directive 88/3/378/EEC of 3. May 1988 on the Safety of Toys should be revised according to more recent scientific knowledge in this area;

b) to advise whether the harmonised standard EN 71-3:1994, presenting test methods for limit values of bioavailability for referred elements, should be revised according to more recent scientific knowledge or to methodological advances in this area.

The Committee has considered in particular the following documents:

a) CEN report EN 71-3:1994 Safety of toys-Part 3: Migration of certain elements.

b) CEN report EN 71-3:1994/A1 on Safety of toys – Part 3: Migration of certain elements

c) Report EUR 12964 of the Scientific Advisory Committee, part III, "Chemical properties of toys (heavy metals).

d) Revision of the Toy directive-Danish Environmental Protection Agency

e) 88/378/EEC: Council Directive of 3 May 1988 on the approximation of the laws on the Member states concerning the safety of toys.

Question 1- Suitability of proposed limit values

The Directive appears to be based on the opinion of the Scientific Advisory Committee (1985). This needs to be updated to take into account revision of TDIs and ADIs since 1985. For example the Opinion of 1985 states that "there is no evidence of toxicity resulting from current intake of

cadmium from food and drink". This is no longer considered to be correct. A similar situation applies to lead.

Question (2) - Should the standard EN-3:1994 be updated.

Yes the standard does need to be updated to reflect advances in the science since 1994. The standard does not take mouthing into account. This is now accepted practice (CSTEE 1998).

GENERAL COMMENTS

1. **Choice of elements**. Standards have been determined for eight elements namely: As, Ba, Cd, Cr, Hg, Pb, Se and Sb. The reasons for choosing these elements and not others such as Ni, which is a strong sensitizer, are unclear. The CSTEE has already given its opinion on the risk assessment methodology that should be applied to identify substances of concern (CSTEE 2004)

2. **Basis for assumption on total daily intake from toys**. The requirements of the standard are based on the presumption that an average daily intake of 8 mg of toy material could be expected. It is more realistic to consider that children may ingest much more than 8 mg toy material in one day, for instance through ingestion of some liquid toy material. To ensure a high level of protection of young children the CSTEE considers that the maximum limits set for migration should be set at a lower value to ensure the maximum allowed daily intake of the selected 8 elements is achieved in practice.

3. **Consideration of bioavailability**. In Council Directive 88/378/EEC, it is stated that the levels of the bioavailability of 8 specific elements resulting from the use of toys must not, as an objective, exceed specified levels per day. The definition of bioavailability in the report is the soluble extract having toxicological significance. This is not in line with the general understanding of the term which is the amounts of each element in the toy which could be absorbed into the systemic circulation of a child.

4. **Criterion for setting the standard**. From a health perspective it is the total concentration of each metal that is absorbed which is the crucial factor in determining whether adverse effects may occur or not. In the case of metals the main source of exposure of children is via the diet. Ingestion of metals through chewing toys will be an additional source. Under these circumstances the CSTEE recommends that the current maximum tolerable intakes or limit values for food should be used and 10% allowed as a maximum contribution from toys. The CSTEE therefore agrees with the approach adopted by its former committee in 1985.

5. **Correction factors**. Correction factors are proposed to be used to account for variations in analytical results. The CSTEE does not support the use of such factors.

6. **Sampling**. The CSTEE does not accept that it is possible to take a single representative from many toys because of their heterogeneous nature.

SPECIFIC COMMENTS

1. Estimation of bioavailability.

Based on a daily intake of 8 mg and the maximum intake levels in Council Directive 88/378/EEC the maximum bioavailable concentration in toy materials will be:

Table 1 Maximum bioavailable concentrations in toy materials based on 8 mg of ingested toy material

As mg/kg	Ba mg/kg	Cd mg/kg	Cr mg/kg	Hg mg/kg	Pb mg/kg	Se mg/kg	Sb mg/kg
12.5	3125	75	37.5	62.5	87.5	625	25

In the standard the concentrations have been adjusted to the following values:

Table 2 Limits of element migration from toy material in EN 71-3

Element	As mg/kg	Ba Mg/kg	Cd mg/kg	Cr mg/kg	Hg mg/kg	Pb mg/kg	Se mg/kg	Sb mg/kg
Any toy except*)	25	1000	75	60	60	90	500	60
*) Modelling clay and finger paint	25	250	50	25	25	90	500	60

The CSTEE is uncertain what the scientific basis is for the differences between the two tables. It is unclear why the conversion factor appears to apply to some metals but not to others

2) The use of an analytical correction factor.

In respect of the test results, the standard prescribes the use of a correction factor. The correction factor is a percentage of the test results, 30-60 % depending of the element. The correction factor is subtracted from the results. The introduction of this factor corresponds to setting the "maximum limits of the migration" to a higher level. The reason for introducing this factor is the variation observed in the test results between different laboratories. However, using different instrumental techniques should give consistent results measuring concentration of elements in solutions when the instrument are operated and calibrated properly. Producing homogeneous test materials could, however, be a great challenge.

We suggest the correction factor should not be used in setting the standard. In any case the CSTEE judges that the safety factor may be too low to provide a high level of protection for young children.

3) The age of the child

In the note on this standard it is stated: "For the purposes of this standard, the following criteria are considered appropriate in the categorization of sucking, licking or swallowing: toys intended for children up to 6 years of age, i.e. all accessible parts and components where there is a probability that those parts or components may come into contact with the mouth." It is foreseeable however that children under 6 will have access to toys intended for children over 6. Thus these toys might also pose a risk for children under 6 and should therefore be tested.

4) Comparison with other standards

As the Danish EPA has pointed out, the standards for metals in textiles set lower limits for clothes to be worn by children than the EN 71-3 sets for textile toys meant for toddlers. This is not valid from a scientific viewpoint. It is noted that the age limit of six years is in contradiction with the Directive 88/378/EEC.

REFERENCES

CSTEE 1998 Opinion on Phthalate migration from soft PVC toys and child-care articles, CSTEE third plenary meeting, 24 April 1998

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out12_en.pdf

CSTEE 2004 Opinion on Assessment of the European Committee fro Standardization (CEN) on methods development CSTEE 43rd plenary meeting, 28 May 2004

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out232_en.pdf