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

“ASSESSMENT OF THE EUROPEAN COMMITTEE FOR STANDARDISATION (CEN) REPORT ON METHODS DEVELOPMENT”

REPORT VERSION:

**Final Report of the work of CEN/TC 52/WG 9/TG 2 – May 2003
(Contract BC/CEN/97/29.3.1)**

**Adopted by the CSTEE during the 43rd plenary meeting
of 28 May 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. The CEN was charged with advising on these standards and on the analytical procedures necessary to ensure that they are achieved. The CSTEE has already given its opinion on the risk assessment component of the work carried out by the CEN ([CSTEE, 2003](#)) This opinion relates to the proposals by the CEN in their Report on the analytical methods to be adopted (Method Development, Final Report CEN/TC 52/WG 9/TG 2, May 2003).

The CSTEE have been asked the following questions in respect of organic chemicals in children toys:

- (1) assess the overall scientific quality of the report on method development taking into account the interdependence between this and the report on risk assessment now under examination by the SCTEE.
- (2) Comment on whether the methods of analysis that are presented in the report are appropriate for detecting organic chemical compounds in toys that pose a risk to children's health.

In order to review the whole process from sampling to the analytical output the CSTEE has also examined the documents Draft prEN 71-9 and Draft prEN 71-10 that describe the requirements and sample preparation, respectively, and Draft prEN 71-11 dealing with the analytical techniques.

General Comments

The CSTEE is generally happy with the report on development of methods (CEN/TC 52 N 865 REV 2) to measure the concentrations of chemicals in the extraction medium. It is scientifically sound and the use of lead and review laboratories are shown to be effective in generating produce useful methods. For most analyses good quantification limits, precisions and recoveries have been obtained.

The Committee has, however, a number of comments on the overall process:

1. Standards appear to be set on the basis of individual toy types that young children may play with. This is understandable in order to enforce quality control measures. However from a child health perspective it must be emphasised that the total exposure from all toys **and all other sources, of**

each substance, must be identified in order to identify the risk and to set an appropriate standard for each toy type. ([CSTEE, 2003](#)).

2. The CEN report is inconsistent in the way solvent extraction is applied to support the standard it is unclear whether the aim is to extract:

- i) the total extractable chemical from the available surface of each toy or
- ii) the bioavailable component only or
- iii) a reproducible extraction percentage

The relationship between total extractable material and exposure needs to be identified.

3. Many toys are complex structures, For example different polymers and dyes may be present in different areas of the toy. The report does not properly address the issue of how to take a sample for such toys.

4. The term simulant is used in the text presumably to imply a simulant for saliva. The prEN 71-10 (p19 B7) states that water was as good a simulant as others (which would include simulated saliva). The CSTEE would welcome the evidence to support this contention since it is at variance with other data it has seen for phthalates and related chemicals.

For parts of toys, including particles that are swallowed, it is gastric juice that needs to be simulated. It is unlikely that water is a good simulant. Evidence is also required to support the statement (p19 B7) that water could be used to assess all contact routes other than inhalation. This statement would include water as a suitable simulant for sweat.

5. The basis for the selection of extraction solvents proposed for different groups of chemicals needs to be justified in the report.

6. If the Report is to be revised it should be produced in a format that ensures ease of understanding and lack of ambiguities for the user laboratories.

7. The CSTEE will consider two further aspects of standards for toys in a subsequent opinion:

- i) Inorganic compounds
- ii) Limit values for bioavailability of certain elements.

Specific Comments

1. The documentation is difficult to follow. Draft prEN 71-9 and Draft prEN-10 are not fully consistent with one another in various aspects. More cross referencing is needed.
2. The use of a devise to ensure adequate mixing of sample with extraction fluid is mentioned in several places. The definition of the devise varies in Draft prEN 71-9 and Draft prEN 71-10 for consistency it should be described as head over heels extraction. The details of this procedure need to be described in the text.
3. Procedure need to be specified to ensure that sampling is representative of a particular toy. There is particular concern when a specific toy is produced in more than one factory and in more than one country.
4. A reference is made in Draft prEN 71-9 (§9, Section A11, p15) to exposure models specifically designed for the purpose of this standard. It is unclear how this model is applied elsewhere in the report.
5. In respect of inhalation in particular there is an issue of the combined releases from all the toys around a child, not just a single toy.

6. In Draft prEN 71-9 (p 16) the statement is made that it may be appropriate to rely on data generated from testing for food contact purposes. The CSTEE has already identified that in the case of phthalates this is an incorrect assumption ([CSTEE, 2001](#))
7. Also in Draft prEN 71-9 (p16) reference is made to components intended to mimic cosmetics. Comparison against the compositional requirements for real cosmetics is recommended. However in the case of young children there is a high likelihood of oral consumption. This is not the case for most adult cosmetics.
8. The sample handling for the head-space analysis of solvents and monomers is still missing in prEN 71-11.
9. For the determination of flame retardants in textiles a total extraction technique is recommended. The single extraction with acetonitrile may not extract all of these substances, especially such lipophilic compounds eg decabromodiphenyl ether.
10. In the methods where the use of a kieselguhr column is recommended, the dimensions of that column have to be specified.
11. For the analyses of preservatives in wood, drilling is recommended if the wooden part is thicker than 1 cm. To get an effective extraction the same technique is also recommended for thinner parts.
12. Dichloromethane and trichloroethane should if possible be included in the HS-GC-MS method as the present recommendations will depend on two different instrumental configurations.
13. In the determination of monomers and solvents with the static head-space technique it seems to be assumed that the total amount present in the solid test material is evaporated. This need to be supported.
14. In most cases where a specific brand is mentioned in prEN 71-11, it is qualified by “or equivalent”. This is not the case for the equipment named for the dynamic head-space.
15. The distinction between the need for regulations to control exposure to organics in toys designed for children under six but not for toys designed for children over six assumes that children under six will not access toys designed for children over six. The CSTEE does not believe that this can be achieved in practice.
16. The influence of detergents on the migration of chemicals from toys is not covered.

References

CSTEE, 2001, Opinion on Chapters 6 and 8 (on risk issues) of the RPA ETD/99/502498 Final Report – July 2000 - The Availability of Substitutes for Soft PVC Containing Phthalates in Certain Toys and Childcare Articles. Opinion expressed at the 22nd CSTEE plenary meeting, 6/7 March 2001,

http://europa.eu.int/comm/health/ph_risk/committees/sct/docshtml/sct_out92_en.htm.

CSTEE, 2003, Opinion on assessment of the European Committee for Standardisation (CEN) report on the risk assessment of organic chemicals in toys Report version: final report of the work of CEN/TC 52/WG 9 - January 2003 (Contract BC/CEN/97/29.1.1). Opinion expressed at the 40th plenary meeting, 12 November 2003

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