EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Health and Environmental Risks

SCHER

CEN's response to the opinion of the CSTEE on the assessment of CEN report on the risk assessment of organic chemicals in toys

Scientific Committees
on consumer products
on emerging and newly identified health risks
on health and environmental risk

The SCHER adopted this opinion at its 17th plenary on 29 May 2007

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Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCHER
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In particular, the Committee addresses questions related to new and existing chemicals, the restriction and marketing of dangerous substances, biocides, waste, environmental contaminants, plastic and other materials used for water pipe work (e.g. new organics substances), drinking water, indoor and ambient air quality. It addresses questions relating to human exposure to mixtures of chemicals, sensitisation and identification of endocrine disrupters.

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http://ec.europa.eu/health/ph_risk/risk_en.htm

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1. BACKGROUND

On March 2003, DG ENTR consulted the Scientific Committee for Toxicity, Ecotoxicity and Environment (CSTEE) on the European Committee for Standardisation (CEN) report on the risk assessment of organic chemicals in toys. The CSTEE was, in particular, requested to assess the overall scientific quality of the report, to elaborate any reasons for divergence of opinion and to make suggestions on how to improve the risk assessment of organic compounds.

In its opinion of 12 November 2003, the CSTEE concluded that there were numerous inconsistencies and errors in the report, e.g. the report focuses on hazards and not on risk assessment, it does not make a clear distinction between risk assessment and risk management, it does not follow the European Chemicals Bureau approach and there are deficiencies in the outcome of the implementation of the ranking system. Therefore, the approach followed does not provide a suitable basis for setting standards.

In addition, DG ENTR consulted the CSTEE, on CEN report on methods development for organic chemicals. The CSTEE was, in particular requested to assess the overall scientific quality of the report and whether the methods of analysis presented in the report are appropriate for detecting organic chemical compounds in toys that pose a risk to children's health.

In its opinion of 28 May 2004, the CSTEE stated that it was generally happy with the report which was scientifically sound according to its opinion. The CSTEE made, however, a number of specific comments on the Report.

By a letter of 21 December 2004, CEN provided details of its technical response to the opinion on the risk assessment report. In its letter, CEN furthermore informed the Commission services that the topics in question would also be taken into account in the forthcoming CEN technical Report with a provisional title "Rational and assessment of hazard, exposure and potential risk to children from organic chemicals in toys" which is still under preparation. However, CEN has later informed the Commission that they have given up work on this report.

On the 19th of January 2006, CEN sent the Commission services a request to publish in the Official Journal the reference numbers of the three standards on organic chemicals that have been approved by CEN members, that is EN 71:9 (Organic chemical compounds – Requirements), EN 71:10 (Organic chemical compounds – Sample preparation and extraction) and EN 71:11 (Organic chemical compounds – Methods of Analysis), in order for them to give presumption of conformity to the essential safety requirements of the Directive 88/378/EEC.

2. TERMS OF REFERENCE

On the basis of the above, the Scientific Committee on Health and Environmental risks is requested to give its opinion on whether

1) the CEN response is sufficient to reassure the Scientific Committee about the concerns raised in the opinion of the CSTEE as regards the inconsistencies and errors in the report on risk assessment and as a consequence about the general scientific quality of the report;

2) if the response to the first question is positive, can the report as completed by the CEN response, therefore, be a sound basis for setting the standards on organic chemicals?

3. OPINION

3.1 General comments

The WG has re-evaluated the CEN report, the CEN response of 21 December 2004 to the opinions of CSTEE and the three standards on organic chemicals: EN 71:9 (organic chemical compounds – requirements), EN 71:10 (Organic chemical compounds – sample preparation and extraction), and EN 71:11 (Organic chemical compounds – Methods for analysis).

In its responses to the CSTEE opinions CEN has responded to all points that CSTEE had addressed and describes the actions to be taken. After carefully evaluating each of the responses, SCHER appreciates that CEN generally agreed with the comments and proposals of CSTEE. However, the responses are rather non-specific and in most cases it is stated: "Will be considered when drafting the CEN TR". However, the SCHER notes that the original CEN report has not been amended and that there is no intention for future amendment.

The Standard EN 71-9 provides Action Limits and limit values per litre or kg, of which the action limits represent analytical detection limits as described in EN 71-11. The SCHER considers the CEN-approach to the chemical-analytical methods for the different compounds and their detection limits acceptable. Limit values are defined as maximal allowable concentrations in the hydrophobic or hydrophilic extraction fluid as described in EN 71-10. However, the representatives of CEN explained that the extraction has been performed in a hydrophilic extraction fluid. The SCHER questions the appropriateness of using an aqueous medium as a simulant. This may be appropriate for water-soluble compounds but not for lipophilic compounds.

The SCHER has carefully considered the written CEN response to the CSTEE opinion and has had the opportunity for further up discussions with CEN representatives. The SCHER has reached the conclusion, that there is still insufficient information to justify the health significance of the limit values listed in EN 71-9. Furthermore the criteria for the selection of the compounds listed in 71-9 remains unclear, and by this it is not understood why limit values for other compounds such as alternatives to phthalate esters or organotin compounds have not been given.

For clarification the SCHER formulated a number of questions to which CEN responded.

From the responses and the information previously given by CEN representatives SCHER concludes that

- The migration studies have only been performed with plastic foils using an aqueous extraction medium. No toys or toys materials have been investigated, because the aim of the project was to develop methods, not to investigate toys.
- The variation of the data obtained from the different studies by the different participating laboratories cannot be estimated. This does not permit evaluation of the uncertainties of the limit values and action limits. Although there are estimates of RSD of the analytical results for the different analytes given in EN 71:11, the uncertainties of the limit values are a function of the whole process and difficult to estimate.
- The lists of compounds presented in EN 71-9 are not complete. They include substances that have been officially classified as dangerous in the Dangerous Substances Directive (67/548/EEC) and compounds that have been proposed by interested parties (member states, industry, regulators and consumer organizations). No systematic search for compounds used in toys has been performed.

- For dangerous compounds (67/548/EEC) action limits have been established. Limit values given in EN 71-9 are based on migration data without sufficient description to what extent exposure and toxicological data such as NOEL have been considered.

3.2 Questions 1

The CEN response is sufficient to reassure the Scientific Committee about the concerns raised in the opinion of the CSTEE as regards the inconsistencies and errors in the report on risk assessment and as a consequence about the general scientific quality of the report

Response

The major critique of CSTEE to the CEN report was that no rationale for deriving the proposed standards has been provided. CEN responded to the different comments made by CSTEE in that they will consider them when amending the original report. However, the report has not been amended and the CEN responses of 21 December 2004 are too vague and general and do not provide the essential information requested by CSTEE. The three EN documents EN 71-9, 71-19 and 71-11 do not provide this information nor does the CEN response to the different questions raised by the SCHER. Consequently the SCHER like the CSTEE is not in a position to evaluate whether the standards on organic chemicals proposed by CEN have been set on a scientifically defendable basis.

3.3 Question 2

If the response to the first question is positive, can the report as completed by the CEN response, therefore, be a sound basis for setting the standards on organic chemicals?

Response

It follows from the answer to question 1 that it cannot be decided whether the proposed standards for organic chemicals in toys have been set on a scientifically sound basis.

4. CONCLUSIONS and RECOMMENDATIONS

I. Since the limit values are not based on toxicological criteria each standard needs further evaluation by considering:
   - Concentration in the simulant
   - Migration rates over time
   - Exposure of children
   - NOELs or ADI
   - Difference between NOEL and exposure (MOE)

II. For the migration studies an aqueous extraction medium has been used because pilot studies revealed negligible differences between hydrophilic and lipophilic media. However, the SCHER questions the justification of using the aqueous medium because no information is given whether compounds with large differences in their log P_{OW} have been investigated. The SCHER concludes that migration data of compounds with log P_{OW} beyond 3 may be acceptable by using a correction factor for example 5.

III. Since there is uncertainty about the accuracy of the chemical-analytical data the migration data determined require correction

IV. The SCHER does not accept the procedure to define action limits for MCR and very toxic compounds. Such compounds should not be present in toys and need to be determined directly in the toys using appropriate extraction procedures and suitably sensitive chemical - analytic methods

V. Since the selection of the compounds listed in EN 71-9 is not complete the SCHER recommends establishing a comprehensive list of chemicals currently used in toys. On the basis of this information, migration data, exposure assessment toxicological information including NOEL, the margin of exposure can be established.

VI. To evaluate whether the limit values listed in the EN 71-9 constitute a risk to children mouthing the toys the SCHER has determined the Margin of Exposure between the exposures resulting from saliva containing the chemicals at limit value concentrations as compared to the NOELs. The result is given in table 1. Assuming that during the day the toy comes into contact with 20 ml of saliva, into which a chemical is leached up to the concentration of its limit value, and assuming 100% absorption, an 8 kg infant is exposed to 1/50 of the limit value resulting in a daily exposure of 1/400 of the limit value per kg body weight. This value is given under Expo (µg/kg). The MOE is based on the NOEL from an oral repeated dose study.

The MOE values indicate that even considering uncertainties in chemical-analytical measurements, of the extraction procedure and the validity of actual use patterns of the toys the exposure is considerably less than levels, which are considered of health concern.

An exception is phenol. Its limit value has to be lowered at least by a factor of 2, based on a MOE of 100 being considered to be sufficiently large.

Moreover, the use of Kathone or its 2 components in toys is not recommended. Contact allergic reactions to the mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazoline-3-one are most frequently associated with intolerance to cosmetics. Morren et al (1992) described that such reactions, particularly on the face, can have unusual clinical presentations that are very similar to seborrheic eczema, lupus erythematosus, lymphocytic infiltrate or photo-dermatitis. Presently the SCCP is evaluating, that the preservative mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3- one in a ratio of 3:1 is safe for the consumers, when used as a preservative up to a maximum authorised concentration of 0.015 % in cosmetic products.

VII. In case of structurally related compounds a combined limit value should be used for the group. For calculation of the MOE the lowest NOEL for an individual member of the group should be used.

VIII. The SCHER does not see the need to categorize the chemicals in 10 different groups. Instead all chemicals present in toys require risk assessment as outlined in the table.

Table 1: Calculation of the MOE based on the limit values given in EN 71-9:

Substance	Limit Value (mg/l)	Expo (μg/kg)	NOEL (mg/kg)	MOE
Bisphenol A	0.1	0.25	5[1]	20,000
Formaldehyde	2.5	6.25	15[2]	2,400
Phenol	15	37.5	1.8[3]	48
Styrene	0.75	1.9	200[4]	100,000
Dichloromethane	0.06	0.15	2[5]	13,300
2-Methoxyethyl acetate 2-Ethoxyethanol 2-Ethoxyethylacetate Bis(2-methoxyethyl) ether 2-Methoxypropyl acetate	Total 0.5	1.25	125[6] 109[7] 500[8] 31[9] 150[10]	100,000 87,200 400,000 24,800 120.000
Methanol	5	12.5	40[11]	3,200
Cyclohexanone	46	0.12	100 iv[12]	80,000
3,5,5-Trimethyl-2-cyclo-hexene-1-one	3	7.5	102[13]	13.600
Toluene	2	5	625[14]	125,000
Ethylbenzene	1	2.5	136[15]	54,000
Xylene (all isomers)	2	5	100[16]	20,000
2-Methyl-4-isothiazolin-3-one	10	25	19[17]	Not recommended
5-Chloro-2-methyl-4-isothiazolin-3-one	10	25	No data[18]	Not recommended
5-Chloro-2-methyl-4-isothiazolin-3-one + 2-Methyl-4-isothiazolin-3-one 3:1 (Kathone)	15	37.5	72[19]	Not recommended

[1] EFSA (2006)

[2] Til et al (1989)

[3] Hsieh et al (1992)

[4] Quast et al (1979)

[5] US-EPA (1985)

[6] Nagano et al (1979)

[7] NTP (1993)

[8] Nagano et al (1979)

[9] No NOEL. Analogy to 2-methoxyethanol: ECETOC (1995)

[10] No NOEL. Analogy to 2-ethoxyethanol: Hurtt and Zenick (1986)

[11] Greim 1999, IRIS databank (EPA-1988)

[12] Greener et al (1982)

[13] Rohm and Haas (1972)

[14] SIDS initial assessment profile

[15] Wolf et al (1956)

[16] IRIS databank (EPA-2003); Condie et al (1988); SIDS initial assessment profile

[17] SCCNFP (2004)

[18] see [19]

[19] IUCLID Dataset (2000)

5. LIST OF ABBREVIATIONS

ADI	Acceptable daily intake
CEN	European Committee for Standardisation
CMR	Carcinogen, Mutagen, Reproductive toxic
CSTEE	Scientific Committee on Toxicology, Ecotoxicology and the Environment
NOEL	No Observed Effect Levels
MOE	Margin of Exposure

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