



Scientific Committee on Health and Environmental Risks

SCHER

## Evaluation of the Migration Limits for Chemical Elements in Toys



The SCHER adopted this opinion at its 8th plenary on 1 July 2010

## About the Scientific Committees

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 Safety (SCCS), 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 (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

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Opinions on risks related to pollutants in the environmental media and other biological and physical factors or changing physical conditions which may have a negative impact on health and the environment, for example in relation to air quality, waters, waste and soils, as well as on life cycle environmental assessment. It shall also address health and safety issues related to the toxicity and eco-toxicity of biocides.

It may also address questions relating to examination of the toxicity and eco-toxicity of chemical, biochemical and biological compounds whose use may have harmful consequences for human health and the environment. In addition, the Committee will address questions relating to methodological aspect of the assessment of health and environmental risks of chemicals, including mixtures of chemicals, as necessary for providing sound and consistent advice in its own areas of competence as well as in order to contribute to the relevant issues in close cooperation with other European agencies.

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### 1. BACKGROUND

The recently revised Toys Safety Directive (TSD) (Directive 2009/48/EC) established migration limits of 19 chemical elements from toys or components of toys. The migration limits shall not exceed the listed limits, depending on the toy material used. However, the chemical elements can be used if the toy or components of the toy exclude any exposure due to sucking, licking, swallowing or prolonged contact with the skin when used as intended or in a foreseeable way, bearing in mind the behaviour of children.

The migration limits are based on the RIVM study and opinions of the Scientific Committee. However, during legislative discussions with the European Parliament and Council, limit values for arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, and which should not be intentionally used in those part of the toys that are accessible to children, were set at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee. These levels aim at ensuring that only traces of these elements will be present which is in line with good manufacturing practice.

In the past, different Committees (SCCP, SCHER and CSTE) gave their opinion on questions related to chemical elements. However the Directorate-General for Enterprise and Industry (DG ENTR) would like to have an additional opinion on the evaluation of the migration limits of the chemical elements.

### 2. TERMS OF REFERENCE

DG Enterprise would like to know if the migration limits established in the TSD are a sound scientific basis for setting safe migration limits for 19 chemical elements.

DG Enterprise recognizes that in earlier opinions on safe limits for chemical elements in toys, the Committee favoured an approach based on migration testing and accepted the intake of 8 mg of toy material (EN71-3).

DG Enterprise would therefore like an opinion on the following questions:

- 1) Is the approach of the migration limits, followed in the TSD, scientifically sound and can they considered to be safe?
- 2) Is the Committee of the opinion that there are more recent scientific data on Tolerable Daily Intakes (TDIs) besides the new TDI for cadmium? If yes, could you indicate these TDIs and specify where the TSD will have to be improved?

### 3. OPINION

According to the TSD, toys placed on the market should not jeopardise the safety and health of children. The general and specific chemical requirement laid down by the Directive aim at protecting the health of children from certain substances in toys. Specific limits for elements have been established upon health-based limit values, tolerable daily intake (TDI) and assumed worst-case oral intake scenarios, i.e., scraped-off toy material (8 mg/day), dry, brittle, powder-like or pliable toy material (100 mg) and liquid or sticky toy material (400 mg). A certain percentage of the TDI is given to each of these three different exposure sources, scraped-off toy material (10%), powder-like or pliable toy material (10%) and liquid or sticky toy material (10%) for children below the age of three. As stated in the SCHER opinion on CMR in Toys (SCHER 2010a), the total contribution from toys should not exceed 10% of the TDI. However, the Directives set limit values for particularly toxic compounds, should they be used in those parts of the toys that are accessible to children, e.g. arsenic, cadmium, chromium(VI), lead, mercury and organic tin. These elements are to be used at levels that are half of those considered safe. Thus, in a worst-case scenario with a concomitant exposure from all three sources, the total oral exposure for the chemical elements is 30% and 15% of the TDI. However,

it is unlikely that exposure occurs through all three sources simultaneously. For children less than 3 years of age and for toys that are intended to be put into the mouth, oral exposure is the most relevant route of systemic exposure. But it has to be recognized that exposure to a chemical element from a toy can only occur when it is released from the toy matrix and becomes bioaccessible. Although the oral exposure is the most relevant route, contribution to total exposure from inhalation must be considered in case of chemical elements of high volatility (e.g. Se, Hg, and As), as well as inhalation of dust containing the chemical element. In addition, dermal exposure should be considered for parts of the toy that come into direct contact with the skin. SCHER is aware that the general term "migration" is nowadays used to describe both for the properly said migration, based on diffusion and partition phenomena, and for the release of metal ions, mostly derived from corrosion phenomena.

Currently, migration of 9 of the chemical elements is determined using the EN 71-3 established by the European Standards Organisation (CEN). Recently, this standard has been tested in an inter-laboratory exercise for 8 chemical elements, and revealed up to 10-fold inter-laboratory variation in the measurements (Baer et al. 2009), raising some concern about the reliability of the method and the suitability to still use the currently applied correction factors.

### 3.1. Question 1

**Is the approach of the migration limits, followed in the TSD, scientifically sound and can they be considered to be safe?**

The RIVM report 320003002/2008 on "a general methodology for assessment of chemical safety of toys with a focus on elements" is the basis for the particular safety requirements described in annex II to the TSD (Directive 2009/48/EC). It is important to note that the total amount of the chemical elements present in a toy *per se* does not necessarily represent a risk as most of the chemical elements will remain in the toy even after mouthing or swallowing parts of it. Therefore, the risk assessment should be based on examining the migration levels of the chemical elements.

The report recommends a risk-based methodology with three different options

- 1) Use of migration data – a child shall not be exposed to a certain element > X% of TDI;
- 2) Use of product (toy material) composition data –assuming 100% bioaccessibility, the level in toy should be less than X% TDI; and
- 3) Use of a quantitative risk based approach.

Thus, the basis for all approaches is a health-based limit value, e.g. TDI. The SCHER supports this approach as a starting point for risk assessment of chemical elements in toys and recommends the amount allocated to the toy to be limited to 10% (CSTEE 2004)

Toy-related exposures take place together with a background of exposure to the same chemical elements through other sources. Another important component in the health-based risk assessment is to demonstrate that the level of exposure of children to the chemical elements included in the TSD does not exceed relevant health-based values. The TDI is based on chronic exposure and children exposure may not occur continuously and does not cover the whole lifespan; thus, integration of the frequency of the use of the toy as well as length of exposure is important in the assessment of exposure.

SCHER agrees with the proposed default values for direct ingestion and the mouthing time and surface area in case of mouthing, and for skin contact. The assessment of exposure to chemical elements is focused on different relevant exposure scenarios: oral route encompassing direct ingestion and mouthing, inhalation via dust, and skin contact.

The relevant exposure scenarios for a particular toy should be determined on a case-by-case basis and SCHER agrees with the selection tree presented in the RIVM report (fig 1):

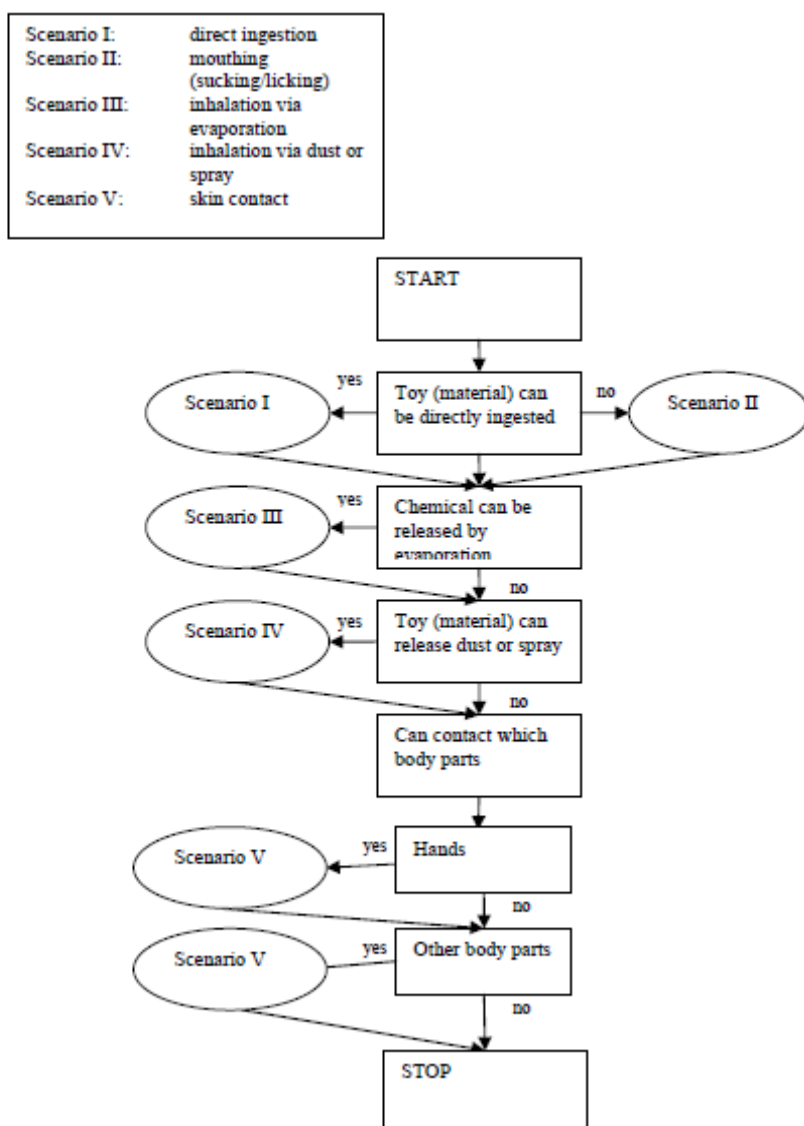


Figure 1: Exposure scenario selection tree

The exposure assessment requires information on migration of the chemical element from the toys, and can be translated into internal dose, if information on absorption is available. Exposure via the different routes can only be combined if the uptake i.e. contribution to the systemic dose, is available. The migration of the chemical elements is established by EN 71-3 using simulated gastric juice (0.07 M HCl, representing a pH of about 2). It should be noted that the pH of gastric juice in small children is higher than 2. Therefore, a lower pH in migration testing represents the worst-case scenario. However, in addition to oral exposure of 8 mg scraped particles, which will be ingested, children may also be exposed during sucking, licking and chewing of toys mediated by saliva. Thus, a combined exposure should be estimated by determining the migration of the chemical elements in the artificial saliva, in addition to simulated gastric juice. It has been observed that the bioavailability of some heavy metals is increased in the presence of certain biological molecules (e.g. lactate, citrate) due to complex formations (SCHER

2010b). Therefore, SCHER disagrees with the recommendation in the RIVM report that water can be used as extraction medium to simulate mouthing. Physiologically-based extraction tests should be applied for mouthing and dermal contacts, i.e., artificial saliva, simulated gastric juice, and artificial sweat. When toy materials are sampled for migration analysis, they should be representative of all accessible parts of the toy. The additional recommendations for an improved migration methodology to mimic children exposure through toys are described in the SCHER opinion on CMR in toys (SCHER 2010a).

SCHER agrees that the systemic dose of the chemical element depends on the fraction of the dose released from the matrix, the bioaccessible fraction, whereas the bioavailability represents the fraction of the administered dose (bioaccessible fraction) that reaches the systemic circulation.

SCHER agrees with the RIVM report that it is not recommended to extrapolate directly food contact material migration limits to toys, as already discussed in the CMR opinion (SCHER 2010a).

SCHER agrees also with the proposed general methodology for setting limit values for chemicals in toys and recommends option 3 of the RIVM report that uses risk-based data and routes of exposure.

A prerequisite for setting safe limit values for chemicals in toys is to decide what level of exposure is acceptable from a health-risk point of view. SCHER recommends that in addition to the oral route, all other routes of exposure should be taken into account, and should be the basis for risk assessment. Thus, a margin-of-safety approach is recommended which is in agreement with a previous SCHER opinion (SCHER 2007).

The migration limits used in the TSD are based upon the allocation of a certain percentage (5 or 10%) of the health-based limit values (TDI values). As mentioned previously, the 5% allocation for 6 chemical elements was decided during legislative discussions with the European Parliament and Council, in order to ensure that only trace amounts of these chemical elements will be present which is in line with good manufacturing practice. These allocation percentages are selected on the basis of the "toy-source" and seriousness of the adverse health effects used in the derivation of the TDI, but a scientific rationale for the selection of these values are not clear. Therefore, the SCHER does not support this differentiation and recommends the use of the 10% value of the TDI for all chemical elements.

### 3.2. Question 2

**Is the Committee of the opinion that there are more recent scientific data on TDIs (besides the new TDI for cadmium)? If yes, could you indicate these TDIs and specify where the TSD will have to be improved?**

The TDI for cadmium currently used in the TSD (0.5 µg/kg bw) was established by RIVM (2001), but recently a new TWI of 2.5 µg/kg bw was established for cadmium as a contaminant in food, corresponding to a daily intake of 0.36 µg/kg. This value is based on an association of urinary cadmium level and beta-2-microglobulin, a sensitive biomarker for kidney function (EFSA 2009a). Thus, SCHER considers that the new TDI of 0.36 µg/kg bw should be used in the context of the TSD.

The PTWI for lead of 25 µg/kg established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and endorsed by the EU Scientific Committee on Food (SCF), is no longer considered appropriate because there is no evidence for a threshold for the critical endpoints, e.g. developmental neurotoxicity. A benchmark dose level BMDL<sub>01</sub> value of 0.50 µg/kg bw/day for neurodevelopmental effects has been established (EFSA 2010). This concentration of 0.5 µg/kg bw/day is associated with a 1% risk level of IQ



decline by one point. The TDI cannot be derived on the basis of the non-threshold effect of lead. Therefore, SCHER recommends that a risk-based approach in contrast to a hazard-based-classification-limits approach is applied as described in the RIVM report (2008) and indicated in SCHER's opinion on CMR in Toys (2010).

The TDI for arsenic (1.0 µg/kg bw/day) used in the TSD was established by RIVM based on the Provisional Tolerable Weekly Intake (PTWI) established by JECFA. Since then, a range of adverse health effects has been reported at exposures lower than the PTWI. In a recent opinion (EFSA 2009b), the EFSA CONTAM scientific panel found that the use of the PTWI established by JECFA was no longer appropriate. The panel established a range of BMDL<sub>01</sub> value (0.3-0.8 µg/kg bw/day, with lung cancer as the most sensitive endpoint). However, SCHER notes that EFSA has not derived the TDI but used a risk-based value. In its recently delivered opinion on the Italian derogation for arsenic in drinking water (SCHER 2010c) the Committee concluded that arsenic shows a non-linear dose response regarding cancer. Using the present legal limit for drinking water (10 µg of As/L) and the food exposure defined by EFSA for average consumer, SCHER concludes that the daily human exposures to As are approximately 1 µg/kg bw/day and do not increase tumour incidence. Using this value of 1 µg/kg bw/day as a pragmatic TDI, exposure of children via toys should not exceed 0.1 µg/kg bw/day (10% of the pragmatic TDI).

### 3.3. Recommendations

1. Chemical elements classified as CMR categories 1A and 1B, according to the EU Classification, Labeling and Packaging regulation, should not be present in toys as intentionally added components.
2. Total contribution of chemical elements from toys should not exceed 10% of the TDI.
3. Relevant exposure scenarios for a particular toy should be determined on a case-by-case basis using the selection tree procedure.
4. SCHER reiterates its recommendation that toy safety should be based on migration limits. However, the method to measure the migration of chemical elements (EN 71-3) is not reliable as indicated by the recent inter-laboratory testing. Therefore, reliable methods should be developed and validated for all the chemical elements present in the TSD.
5. Valid and high-quality background exposure information from other sources is important for the evaluation of additional risk.
6. As information on children exposure is not available from most European countries, a certain percentage (50%) of adult human exposure is considered for children.

#### **4. LIST OF ABBREVIATIONS**

BMDL	Benchmark Dose Level
CEN	European Standardisation Organisation
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic and Reprotoxic
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
EFSA	European Food Safety Authority
FCM	Food Contact Material
PTWI	Provisional Tolerable Weekly Intake
RIVM	National Institute for Public Health and the Environment, The Netherlands
SCF	Scientific Committee for Food
TDI	Tolerable Daily Intake
TSD	Toy Safety Directives

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