

Proposal from ANEC for

The coverage of organic CMR substances in toys for children below 36 months of age and for mouth actuated toys

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1. Background

Article 46 of the revised Toy Safety Directive (2009/48/EC) provides for the option to “*adopt specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth, taking into account the packaging requirements for food as laid down in Regulation (EC) No 1935/2004 and the related specific measures for particular materials, as well as the differences between toys and materials which come into contact with food*”, i.e. to establish specific requirements for some toy categories superseding the requirements applicable for toys in general. The reference to food contact material legislation gives clear guidance concerning the level of safety to be achieved and calls for an adaptation of its provisions to toys. This is a clear mandate.

In its comments on the SCHER opinion “Risk from organic CMR substances in toys (May 2010)” ANEC expressed the following position¹:

“A case by case risk assessment of CMR substances in toys is – whilst desirable from a scientific perspective – impossible to carry out in a reasonable time frame and may take decades. This is absolutely unacceptable from a consumer protection perspective. Insofar the approach taken in the Toy Safety Directive to ban CMR substances in a generic fashion (under certain conditions) is in principle more useful and constitutes a step forward in regulating chemicals in products. However, the limits based on thresholds used for the classification of mixtures cannot be considered as safe values (we agree on this point with SCHER). Moreover, from a consumer perspective the release of the substances is more relevant than the content.

In its expert opinion 051/2009 on Polycyclic aromatic hydrocarbons (PAHs) in toys (October 2009), the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) has shown the way forward. The

¹ ANEC position on SCHER opinion : “Risk from organic CMR substances in toys”, ANEC-CHILD-2010-G-092, November 2010

institute recommends to use a migration limit of 0,01 ppm for all CMR substances and all kinds of toys following the ALARA principle.

"BfR recommends that, in general, regulations for CMR substances in toys should not apply to the content but instead to the migration since only this is relevant to exposure. The regulation of CMR substances in food contact materials requires that the release of CMR substances is not detectable (<0.01 mg/kg). This is technologically feasible and already best practice. It should be adopted for all toy materials without age limit in order to minimise the exposure of children to CMR substances".

ANEC applauds to this position which is largely in line with its own views. This BfR statement should be the basis for the revision of the Toy Safety Directive with respect to the coverage of CMR substances. At the very minimum these principles should be used in a first step for toys intended to be used by children up to 3 years or to be mouthed. However, ANEC insists that a revision of the TSD is necessary. ANEC had repeatedly called for using the Comitology procedure to introduce or modify limits for all kinds of hazardous substances to avoid lengthy procedures required for changing the directive. As this was rejected there is, unfortunately, no other route to adequately protect children".

2. CMR-relevant aspects of food contact materials (FCM) legislation

Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food provides a framework for establishing specific measures (authorisation) for materials and articles listed in Annex I or combinations thereof.

One of the specific measures is the Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs. Article 7a (introduced by amendment 2007/19/EC) provides that non-authorised substances may be used in layers of multi-layer materials or articles separated from food by a functional barrier provided a maximum migration level of 0,01 mg/kg food or simulant (10 ppb) is kept. Substances that are mutagenic, carcinogenic or toxic to reproduction (all categories), however, are exempted from this permission, i.e. they must not be (deliberately) used at all in food contact materials or articles without previous authorisation and are therefore not be covered by the functional barrier concept. This means a general exclusion of non-authorised substances at the 10 ppb level (considered as detection limit) which can, of course, also be used as practical enforcement limit to confirm absence of CMR substances.

Commission Directive 2002/72/EC establishes some CMR limits. For instance, Plastic materials and articles shall not release primary aromatic amines in a detectable quantity (DL = 0,01 mg/kg of food or food simulant). Again, the 10 ppb level is used as limit. Another example is Directive 78/142/EEC relating to

materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs.

It should be noted that FCM regulations address only the oral contact route.

3. CMR limits for toys for children below 36 months of age and mouth actuated toys

3.1 Contact route mouthing

The approach used for food contact materials could be used for toys intended for use by children under 36 months or in other toys intended to be placed in the mouth. The release of CMR substances from toys during mouthing should not be detectable.

It would seem reasonable to apply this limit of detection to saliva simulant reflecting the release from a solid toy as a result of licking and sucking per day using a dynamic migration method as given in EN 71-10 "Safety of toys - Part 10: Organic chemical compounds - Sample preparation and extraction". This standard uses a toy sample of 10 cm² and a "head-over-heel" method (rotating bottles of 250 ml, 15 cm from rotation axis, at (60 ± 5) r/min for (60 ± 5) min, 100 ml deionized water as simulant, at (20 ± 2) °C). The aqueous migrate is further analysed.

Notwithstanding the need to adopt some of the parameters to the contact conditions of toys (e.g. temperature – 36° seem more appropriate than 20°, the extraction time is 1 hour whilst the assumed exposure time for small children by RIVM and CSTEE was 3 hours) the method seems to be a suitable basis for excluding CMRs from toys.

The requirement for solid toy materials would be: CMR ≤ 0,01 mg/l saliva simulant in accordance with EN 71-10 or, related to the amount of simulant actually used in the standard test: ≤ 0,001 mg/100 ml saliva simulant.

This approach, however, does not seem to be useful for powder-like toys as in this case it is the ingestion which is relevant rather than licking and sucking. The test procedure given in EN 71-3 "Safety of toys Part 3: Migration of certain elements" using hydrochloric acid to simulate worst case conditions is not appropriate either for organic substances:

The RIVM report on "Chemicals in toys" (2006) points out:

"The research with the in vitro digestion models by RIVM has shown that the amount extracted in the acid environment of the stomach does not represent a worst case situation for the bioavailable amount of an organic substance (Oomen, 2000). For, most organic compounds are not as susceptible for the low pH environment of the stomach as the elements considered in EN 71-3. Furthermore, the research by RIVM has shown that for many substances the release from a matrix in the intestine is highest when fed conditions are

simulated in the in vitro digestion model (Oomen, 2000). The complexing capacities of the extraction juices of an in vitro digestion model are higher when fed conditions are simulated as food constituents are present, and more complexing agents such as bile and enzymes are present in digestive juices secreted during fed conditions. Therefore, the methodology of EN 71-3 to determine the bioavailable amount of elements is suitable as a worst case bioavailable amount for elements, whereas it is not applicable for organic compounds".

Given that a method simulating the worst case migration of organic substances from ingested toy materials is not available the only solution is to base the limit on content rather than on migration. Hence, the CMR content for powder-like toy materials should be not detectable (limit of detection < 0,01 mg/kg toy material). Powder-like toys would have to be extracted using appropriate organic solvents.

A similar approach could be used for liquid toys. The CMR content for liquid toy materials should be not detectable (limit of detection < 0,01 mg/kg toy material)

In principle the same screening tools used in the enforcement of food contact legislation for the detection of not approved substances can be used. It would, however, be useful to develop standards for screening of toys.

The establishment of a generic CMR exclusion which may be released from toys as a result of mouthing should be considered as a first priority!

3.2 Contact route inhalation

For volatile organic compounds a different method must be chosen.

EN 71-10 uses a tiered approach for the assessment of inhalation exposure to volatile organic solvents:

1. The total amount of solvent present in a toy sample (tier 1).
2. The (initial) evaporation rate of a solvent from a toy sample (tier 2).

It should be noted that both methods are not normative as they could not be validated by CEN TC 52.

Given that the purpose of the exercise is to exclude the use of CMR chemicals (rather than establishing limit values) the first method using a high evaporation temperature seems to be entirely sufficient.

Bearing in mind the data indicated in Table A.4 – "Limit of detection, limit of quantification and emission limit" it appears that the LODs are in the range 0,01 µg – 0,06 µg absolute (e.g. for benzene 0,03 µg) relating to a 10 mg sample. These values could be taken as a starting point for a limit for volatile CMR substances (such as benzene) in toys - not only for solvents as in the CEN

standard but also for other volatile substances. The method needs to be validated.

3.3 Contact route skin contact

This issue needs further consideration and discussion. To some extent the approaches suggested above for mouthing will also cover skin contact (migration into a saliva simulant using a dynamic extraction procedure, content limit for liquid toys).

It can be anticipated that for lipophilic organic compounds from solid toy materials with intensive skin contact additional measures might be needed. One option may be to use instead of the aqueous simulant for the dynamic migration test of solid toy materials a simulant with a certain percentage of an organic solvent (e.g. 15% ethanol – current simulant C in FCM legislation), which should be tested.

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About ANEC

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