ANEC position on SCHER opinion:

Risk from organic CMR substances in toys (May 2010)

2010-11-23

Introduction

Many statements in the SCHER opinion on organic CMR substances are very much appreciated as they broadly coincide with positions held by ANEC for a long time. This includes in particular:

- the (questionable) use of limits established for the classification of mixtures for the purpose of setting thresholds of chemicals in products such as toys
- the adequacy of food contact regulations for the purpose of regulating chemicals in toys

However, ANEC believes that the positions taken by SCHER concerning an alternative approach are somewhat unclear, inconsistent or even contradictory.

Handling of CMR substances

The most rigorous position on the acceptability is expressed in 3.5 concerning question 4 (page 14, item III):

"Action limits for CMR and very toxic compounds are not acceptable as these compounds should not be present in toys. Thus, they should be determined directly in the toy using appropriate extraction procedures and sensitive chemical-analytical procedures".

This position seems to promote a limit of detection approach for all CMR substances (and other very toxic compounds) based on an extraction (rather than migration) procedure ("directly in the toy").

Conversely, in 3.2 relating to question 1 (page 9, first and last paragraph) we can read:

"The SCHER recommends the identification of exposure levels through appropriate migration tests (see below").

And:

"It is recommended that a risk-based approach, as described in the RIVM report (2008), as opposed to a hazard-based classification limits approach, should be applied".

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Here SCHER follows a traditional substance by substance risk assessment approach based on migration testing (for all CMR chemicals).

Yet another line of argument can be found in the first part of 3.2 (pages 7 and 8):

"In accordance with previous opinions by CSTEE, CMR categories 1 and 2 (now categories 1A, 1B according to the CLP regulation) non-thresholded carcinogens should not be present in toys as intentionally added components. Indeed, the acceptance for those chemicals of a non-threshold mechanism makes the definition of a safe level virtually impossible".

And:

"It is the SCHER opinion that the presence of CMR category 3 (or category 2 according to CLP regulation), when characterized by a threshold mechanism, can be accepted, pending a case-by-case evaluation. This evaluation should be based on available toxicological data (to derive a TDI) compared with exposure data, in order to identify possible risks".

This seems to imply that the risk assessment approach should be used for CMR category 3 chemicals with a threshold mechanism only whilst CMR substances of category 1 and 2 should be generally excluded.

Food contact material (FCM) regulations

SCHER points to significant limitations of the possibilities to use FCM provisions for toys (e.g. coverage of a limited number of materials, static migration testing, food specific test conditions using different simulants, contact times and temperatures, coverage of oral route of exposure only, etc.) and concluded "that FCM legislation cannot be generally used to assess the risk to children from exposures to CMR in toys, but a case by case adaptation would be necessary". However, SCHER also states that "the toxicological evaluations that are behind the SML could be used to evaluate the safety of the chemicals of concern". It should be also noted that SCHER has not investigated all relevant aspects of FCM (see below).

Other issues

SCHER claims that it is unlikely that water is a good simulant for saliva (page 6, list point 3 and page 12, list point 4). SCHER also claims that in particular for lipophilic compounds water is not suitable. However, no evidence is provided that any other simulant is better suited and yields results which are more in line with what can be achieved with real saliva.

Further SCHER regrets that the extraction method (head-over-heels) included in EN 71-10 is not adequately described (page 7, list point 4, page 14, list point 6). However, EN 71-10 uses the same equipment and rotation speed as it was used

in the “Validation of methodologies for the release of diisononylphthalate (DINP) in saliva simulant from toys” co-ordinated by JRC Ispra.

ANEC opinion

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 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 sub-stances 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.

The SCHER statement lacks clarity and consistency regarding the way forward with respect to CMR substances and needs to be revised.

The use of **Food contact material (FCM) regulations** (in particular, Directive 2002/72/EC on plastics materials) requires a more in-depth discussion. It is undoubtedly true – and in line with positions expressed by ANEC in the past – that a material which is in compliance with FCM regulations is not necessarily

safe for use in a toy context. This is not only a question of test conditions (simulant, temperature, time, static versus dynamic migration testing) but also related to the fact that e.g. SMLs are based on TDI values (rather than a fraction of it) and related to adults of 60 kg rather than children (in fact, SMLs are just TDIs x 60 where a TDI exists). Nevertheless the provisions of the FCM regulation and its specific measures (in particular the one on plastics materials) are a suitable starting point for developing a set of criteria applicable for toys for children under 36 months and toys intended to be placed in the mouth – at least for plastics materials. Some of the key points are:

- The principle of authorisation – only approved materials are allowed to be used
- Not approved materials may be used only under restrictive conditions (functional barriers, no CMRs) and only if the migration into food simulant does not exceed 0,01 mg/kg (10 ppb)
- An overall migration limit of 60 mg/kg is defined to ensure the inertness of plastics material

One could envisage a set of toy criteria for the (most important) oral contact route (mouthing) allowing only substances approved as FCM, recalculating limits on the basis of a 5% or 10% allocation of the TDI, based on toy specific parameters (7,5 kg body weight, 3 hours exposure, 10 cm^2 contact area) and using a dynamic migration test similar to EN 71-10 with perhaps slightly other parameters (e.g. higher temperature of 36°, three extractions instead of just one). This could be complemented by a test ensuring that non-approved substances are below the level of 0,01 mg/kg and the overall (also based on dynamic migration). In addition, the dermal contact route needs to be addressed.

ANEC proposes:

- CMR substances (all categories) should be eliminated from (accessible parts of) toys following the ALARA (as low as reasonably achievable) and precautionary principles;
- the release of (non-volatile) CMR substances should be determined based on a dynamic migration test (head-over-heels) such as the one contained in EN 71-10 (modified);
- CMR substances (all categories) should generally not be detectable at a limit of 0,01 mg/kg (10 ppb);
- equivalent approaches should be used for volatile CMR substances and the dermal contact route;

- exemptions may be granted only on the basis of a full risk assessment and a positive opinion by SCHER;
- suitable screening methods need to be developed;
- the use of legislation for food contact materials – in particular for plastics materials – should be further discussed taking into consideration the points raised above.

END.

About ANEC

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