

ANEC position on SCHER opinion:

Evaluation of the migration limits for chemical elements in toys (July 2010)

2010-11-23

Allocation of 10% of the respective TDI value

SCHER holds the view that the limits for chemicals in toys should be set on the basis of an allocation of 10% of the respective TDI values and deplores that the migration limits for certain elements (arsenic, cadmium, chromium VI, lead, mercury and organic tin) were set at a lower level (5% of the TDI values) in the political process. This raises a question of more fundamental nature – who is responsible for limit setting which is a value choice (rather than a scientific undertaking)?

Limits for cadmium, lead and arsenic

Further, SCHER elaborates on TDI values for cadmium, lead and arsenic in 3.2 concerning question 2 (page 8).

A slightly lower TDI for **cadmium** is proposed (0,36 µg/kg bw/day instead of 0,5 µg/kg bw/day) based on an opinion of the EFSA Panel on Contaminants in the Food Chain (CONTAM, January 2009).

As regards **lead** SCHER refers to a recent EFSA opinion (on lead in food, March 2010) which considered the PTWI for lead of 25 µg/kg bw established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and endorsed by the EU Scientific Committee on Food (SCF) no longer appropriate because there is no evidence for a threshold for the critical endpoints, e.g. developmental neurotoxicity. Hence, a TWI or a TDI cannot be set.

"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)".

This is difficult to understand as the limit proposed by RIVM is based on the PTWI mentioned above (so based on a value declared invalid by EFSA). It has nothing to do with a hazard based approach. Further it remains unclear what the SCHER proposal precisely is.

Finally, SCHER considers a value of 1 µg /kg bw/day as a "pragmatic" TDI for **arsenic** - contrary to EFSA (opinion on arsenic in food, October 2009), which considers the TDI of 1 µg /kg bw/day no longer appropriate - on the grounds

that arsenic shows a non-linear dose response curve regarding cancer and that *"the daily human exposures to As are approximately 1 µg/kg bw/day and do not increase tumour incidence"*.

ANEC opinion

Scientific committees should facilitate policy making by providing the appropriate tools and methods but should not replace it. It is not the role of science or scientists to take value choices on behalf of the society. What the acceptable risk is to be answered by the society and the relevant interest groups – not by scientific bodies. In particular, it is a political decision to determine the fraction of the TDI which is acceptable. This holds true for toys and any other product. The RIVM report made it quite clear: "In our proposed methodology, only a fraction of the TDI should be allocated to exposure from toys. What this fraction would be is in principle a decision that should be made by policy makers. However, some recommendations with respect to elements can be given" (Chemicals in toys, August 2006, pages 111/112). ANEC strongly supports this perspective. There is no scientific basis for a 10% allocation anyway.

ANEC agrees with the SCHER proposal regarding the use of a lower TDI (0,36 µg/kg) for **cadmium**. However, it must be borne in mind that the EFSA CONTAM Panel noted that *"the mean dietary exposures in European countries are close to or slightly exceeding the TWI of 2.5 µg/kg b.w."* and that *"subgroups such as vegetarians, children, smokers and people living in highly contaminated areas may exceed the TWI by about 2-fold. Although adverse effects on kidney function are unlikely to occur for an individual exposed at this level, the CONTAM Panel concluded that exposure to Cd at the population level should be reduced"*. Hence, ANEC strongly disagrees with SCHER that a 10% (rather than 5%) allocation of the TDI value should be used which would mean e.g. to increase the cadmium limit in the TDS from 23 mg/kg in scraped-off toy material to 33 mg/kg (using the new TDI). On the contrary, ANEC calls for a reduction of the current level to at least 17 mg/kg (using a 5% allocation of the TDI) and to adjust the other limits accordingly. In addition, ANEC considers that a child might play with all 3 categories of toys for which limits have been set and that therefore a further lowering of the limits is needed. This position is shared by the German BfR (opinion on lead and cadmium, Nr. 048/2009). Cadmium limits should be reduced as far as technically feasible following the ALARA principle.

EFSA CONTAM has made it quite clear in its opinion on **lead** in food that the PTWI for lead is inappropriate:

"The CONTAM Panel concluded that the current PTWI of 25 µg/kg b.w. is no longer appropriate as there is no evidence for a threshold for critical lead-induced effects. In adults, children and infants the margins of exposures were such that the possibility of an effect from lead in some consumers, particularly in children from 1-7 years of age, cannot be excluded. Protection of children against the

potential risk of neurodevelopmental effects would be protective for all other adverse effects of lead, in all populations.” (page 1).

“Estimated exposure in children up to age seven exceeds the BMDL₀₁ intake level of 0.50 µg/kg b.w. per day for neurodevelopmental effects. The MOE in average 1 to 3 year old child consumers ranged from 0.16 to 0.45, and was only slightly higher in 4 to 7 year old children. Therefore, the MOE is such that the possibility of an effect in some children cannot be excluded. It was not possible to estimate the potential numbers of children who might be affected, as even in average consumers the MOE was <1” (page 5).

And these MOE figures are only for average 1-3 year old consumers. For “high consumers” the MOEs ranged from 0.09 - 0.29! For children aged 1 to 3 years mean lead dietary exposure estimates range from 1.10 to 3.10 µg/kg b.w. per day, for high consumers, lead exposure estimates range from 1.71 to 5.51 µg/kg b.w. per day. For children aged 4 to 7 years mean lead dietary exposure estimates range from 0.80 to 2.61 µg/kg b.w. per day, for high consumers, lead exposure estimates range from 1.30 to 4.83 µg/kg b.w. per day.

This means that the actual lead exposure of children (the most sensitive population) is considerably above the BMDL₀₁ of 0,5 µg/kg bw/day which corresponds to a 1% risk of a decline of the IQ by 1 point (the IQ is the critical endpoint for neurodevelopmental effects). And non-dietary sources of exposure are not even included!

ANEC welcomes the main conclusion of EFSA that “work should continue to reduce exposure to lead, from both dietary and non-dietary sources”. The increase of lead limits as a result of the revision of the TSD was a step in the wrong direction. The new TSD allows e.g. the migration of 160 mg/kg in scraped-off toy material (based 5% of the TDI value) whilst the existing CEN standards based on the maximum bioavailability defined in the previous directive of 0,7 µg for lead and an assumed ingestion of 8 mg set the migration limit at 90 mg/kg toy material. If the limit had been set using a 10% allocation of the TDI the limit would have been even further increased to 320 mg/kg. ANEC thinks on the basis of the EFSA opinion that even a further reduction of the lead levels compared to the former limits (i.e. lower than 90 mg/kg) is warranted and calls for a reduction of the current level to at least 22 mg/kg (using the BMDL₀₁ intake level of 0.50 µg/kg b.w. per day and a 5% allocation) and to adjust the other limits accordingly. In addition, ANEC considers that a child might play with all 3 categories of toys for which limits have been set and that therefore a further lowering of the limits is needed. Lead limits should be reduced as far as technically feasible following the ALARA principle.

Similar considerations apply to **arsenic**. As in case of lead EFSA considers the existing PTWI of 15 µg/kg established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) inappropriate as “*new data had established that*

inorganic arsenic causes cancer of the lung and urinary tract in addition to skin, and that a range of adverse effects had been reported at exposures lower than those reviewed by the JECFA". The EFSA CONTAM panel indicated an overall range of BMDL₀₁ values of 0.3-8 µg/kg b.w. per day. The lowest BMDL₀₁ values were for lung cancer (0.34-0.69 µg/kg b.w. per day).

Children under three years of age are the most exposed to inorganic arsenic - their estimated inorganic dietary arsenic intake ranges from 0.50 to 2.66 µg/kg b.w. per day. The estimated national dietary exposures to inorganic arsenic for average (0.13-0.56 µg/kg b.w. per day) and high level adult consumers (0.37-1.22 µg/kg b.w. per day) in Europe.

And EFSA CONTAM concludes:

"The estimated dietary exposures to inorganic arsenic for average and high level consumers in Europe are within the range of the BMDL₀₁ values identified by the CONTAM Panel, and therefore there is little or no MOE and the possibility of a risk to some consumers cannot be excluded".

SCHER claims that arsenic shows a non-linear dose response relation regarding cancer. However, EFSA follows a more precautionary approach:

"The CONTAM Panel noted that inorganic arsenic is not directly DNA-reactive and there are a number of proposed mechanisms of carcinogenicity such as oxidative damage, epigenetic effects and interference with DNA damage repair, for each of which a threshold mechanism could be postulated. However, taking into account the uncertainty with respect to the shape of the dose-response relationships, it was not considered appropriate to identify from the human data a dose of inorganic arsenic with no appreciable health risk, i.e. a tolerable daily or weekly intake. Therefore an assessment should be made of the margins of exposure (MOEs) between the identified reference points from the human data and the estimated dietary exposure to inorganic arsenic in the EU population".

And finally the conclusion of EFSA is that dietary exposure should be reduced.

SCHER advocates a "pragmatic" TDI of 1 µg/kg bw/day and to allocate 10% of the value to toys. Again this would mean an increase of the value compared to the limit in the current TSD. This is not acceptable.

The new TSD allows e.g. the migration of 47 mg/kg in scraped-off toy material (based 5% of the TDI value) whilst the existing CEN standards based on the maximum bioavailability defined in the previous directive of 0,1 µg for arsenic and an assumed ingestion of 8 mg set the migration limit at 25 mg/kg toy material. If the limit had been set using a 10% allocation of the TDI the limit would have been even further increased to 94 mg/kg. This is what SCHER seems to support and we strongly disagree with it. On the contrary, ANEC thinks on the basis of the EFSA opinion that a reduction of the current arsenic limits at least to 24 mg/kg using an average BMDL₀₁ intake level of 0.50 µg/kg b.w. per day for

lung cancer and a 5% allocation) is more appropriate. The other limits need to be adjusted accordingly. Finally, ANEC considers that arsenic limits should be reduced as far as technically feasible following the ALARA principle. In addition, ANEC considers that a child might play with all 3 categories of toys for which limits have been set and that therefore a further lowering of the limits is needed.

ANEC proposes:

- Cd levels should be reduced at least by a factor 0,36/0,5 (new TDI/old TDI) using a 5% allocation, i.e. in scraped-off toy material from 23 mg/kg to 17 mg/kg;
- Pb levels should be reduced at least by a factor 0,5/3,6 (new BMDL₀₁/old TDI) using a 5% allocation, i.e. in scraped-off toy material from 160 mg/kg to 22 mg/kg;
- As levels should be reduced at least by a factor 0,5/1 (new BMDL₀₁/old TDI) using a 5% allocation, i.e. in scraped-off toy material from 47 mg/kg to 24 mg/kg;

END

About ANEC

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