



Commentary

Does the EU migration level of chromium VI in toys need to be lowered?

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1. Scientific Committee on Health and Environmental Risks published final opinion on chromium VI in toys

Recent studies have linked chromium VI in drinking water to gastro-intestinal cancer in experimental animals and indicated that public exposure to chromium VI in general may be higher than previously thought. Because of that, the European Commission asked its independent Scientific Committee on Health and Environmental Risks (SCHER) to review new scientific data, to assess whether the migration limit for chromium VI in toys should be altered in light of this new information, and if so, to propose new limits, providing scientific support. The resulting Opinion was published in January 2015.

The answers to these requests and the Scientific Committee's conclusions are summarised here, while links to the full Opinion and to a factsheet intended for the general public are provided at the end of the text.

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2. New data on chromium VI in drinking water shows link between oral exposure and cancer

The SCHER had published an Opinion on general aspects regarding the evaluation of migration limits for chemical elements in toys in 2010. New information has come to light since then, in particular a technical support document for the Public Health Goal for hexavalent chromium in drinking water, published by the United States Office of Environmental Health Hazard Assessment (OEHHA) in July 2011 based on a study by the US National Toxicology Program (NTP), which showed that oral exposure to chromium VI was carcinogenic in experimental animals. Due to the genotoxic mode of action, it cannot be ruled out that chromium VI would not also be carcinogenic for humans as well.

The European Commission therefore specifically requested the SCHER “to review the available scientific data and conclusions drawn for chromium VI in the light of the OEHHA technical support document for the Public Health Goal for hexavalent chromium in drinking water, of July 2011”.

In compliance with the request, the SCHER reviewed the OEHHA document as well as additional recently published scientific documents on the health effects of chromium VI and is of the opinion that the NTP study provides sound scientific evidence on the occurrence of gastro-intestinal cancer after oral uptake of chromium VI in rodents.

Although chromium VI is converted to less toxic chromium III in the gastro-intestinal tract, the SCHER is of the opinion that under certain circumstances the body may not be able to cope with the amount of chromium VI it may be exposed to and to convert it sufficiently in order to prevent genotoxic effects.

3. New data suggests need to lower migration limits for chromium VI in toys

In the second part of the mandate, the SCHER was specifically requested “to consider whether the migration limits for chromium VI in point 13 of Section 3 of Annex II of the Toy Safety Directive 2009/48/EC are still appropriate to ensure the safety of toys.”

The presence of chromium VI in toys sold in the EU is strictly limited by the Toy Safety Directive, which sets migration limits for

19 different elements. These standards are among the strictest in the world, but the limits do not apply if the toy or the toy components exclude any hazard due to sucking, licking, swallowing or prolonged skin contact when used as intended or in a foreseeable way, bearing in mind the young children's tendency to mouth objects.

Current migration limits were based on a 2008 report from the Netherlands National Institute for Public Health and the Environment (RIVM) and the 2010 SCHER Opinion on the evaluation of migration limits for chemical elements in toys, in which the SCHER supported the RIVM approach of using health-based limit values as starting point for the risk assessment of chemical elements in toys.

According to the 2008 RIVM report, the tolerable daily intake value (TDI) took into account non-carcinogenic effects by hexavalent chromium. For the carcinogenic effect, a highly uncertain Virtually Safe Dose (VSD) of 0.0053 $\mu\text{g}/\text{kg}$ bw/d had been proposed by OEHHA (1999). The TDI as well as the VSD were used by RIVM to propose migration limits for chromium VI. The 2008 report made reference to a "new drinking-water cancer bioassay with hexavalent chromium" that was being conducted by the US National Toxicology Program, which is indeed the one that prompted the reassessment of the current migration limits for chromium VI.

4. Revised migration limits for chromium VI should be based on new virtual safe dose value

If after examining new data and the current migration limits on chromium VI in toys the SCHER felt that existing limits were no longer appropriate, it was requested to propose "new limits, clearly indicating the data on which they would be based" as the third and final part of its mandate for this Opinion.

To fulfil its mandate, the SCHER made use of available studies that allow the quantification of the dose response relationship both for carcinogenic and non-carcinogenic endpoints. Current migration limits set in the Toy Safety Directive are based on the earlier and highly uncertain virtual safe dose of 0.0053 $\mu\text{g}/\text{kg}$ bw/d associated with one additional cancer case in a million, as suggested by OEHHA in 1999 before the new data on oral cancer potency came to light. But based on the 2008 NTP study, OEHHA derived a significantly lower daily dose of 0.0002 $\mu\text{g}/\text{kg}$ bw/d associated with one additional cancer case in a million, which is in the same range as a

DMEL the SCHER derived on the NTP data by using the "linearised" approach for the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

The SCHER is of the opinion that the general approach from OEHHA is appropriate to estimate additional cancer cases attributed to chromium VI exposure and is also of the opinion that current migration limits for chromium VI from toys should be revised and based on this new, lower value for a virtual safe dose.

Considering a virtual safe dose of 0.0002 $\mu\text{g}/\text{kg}$ bw/d based on data from the 2008 NTP study and using the current approach of the Toy Safety Directive, the SCHER proposes the following revised migration limits for chromium VI: 0.0094 mg/kg toy for scraped-off toy materials, 0.0008 mg/kg toy material for dry, (powder-like or pliable) toy materials and 0.0002 mg/kg toy material for liquid or sticky toy materials, respectively.

The SCHER acknowledges that new data for the amount of toy material ingested may be discussed and may lead to different migration limits in the future and also recognises that the proposed migration limits are conservative and may not be achieved for certain toy materials. In addition, detection methods for chromium VI migration have some limitations and may be insufficiently sensitive.

The newly finalised Opinion, published in January 2015 (after considering all comments from a public consultation on the preliminary Opinion held from 1 August to 28 September 2014), reflects the SCHER's view that children are particularly vulnerable in respect to exposure to chromium VI and need additional protection. Therefore, the SCHER Opinion on the migration limits for chromium VI in toys concludes that considering relevant background exposure, any additional exposure to chromium VI from toys should be limited to the lowest amount technologically possible.

Read the full opinion here: http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_167.pdf.

Read the easy to read fact-sheet available in four languages here: http://ec.europa.eu/health/scientific_committees/policy/opinions_plain_language/index_en.htm.

Transparency document

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