

Scientific Committee on Health and Environmental Risks (SCHER)

Request for an opinion on chromium VI in toys

1. Background

The Toy Safety Directive¹ establishes migration limits for 19 elements in toys or components of toys, depending on the toy material used. The migration limits may not be exceeded. However, they do not apply if the toy or the components of the toy clearly exclude any hazard 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 a 2008 RIVM report² and opinions of the Scientific Committee. In the 2010 SCHER opinion on the evaluation of migration limits for chemical elements in toys³, SCHER supports the RIVM approach as a starting point for risk assessment of chemical elements in toys, namely that the basis for all approaches presented in the report is the tolerable daily intake (TDI) as a health-based limit value. In accordance with an earlier CSTE opinion⁴ SCHER also recommended the amount allocated to exposure from toys to be limited to a maximum of 10%.

In section 2.3.5 of the 2008 RIVM report it is stated that the TDI value for chromium VI “only takes into account non-carcinogenic effects by hexavalent chromium; for the carcinogenic effect by hexavalent chromium a highly uncertain Virtually Safe Dose of 0.0053 µg/kg bw/day has been proposed by OEHHA (1999). A new drinking-water cancer bioassay with hexavalent chromium is being conducted within the US-NTP” (Note "a" to Table 2-2).

Based on recent findings of the US-NTP⁵, a level of 0.02 ppb in drinking water was proposed by OEHHA⁶ in December 2010⁷. A final technical support document for the Public Health Goal for hexavalent chromium in drinking water was published in July 2011⁸.

2. Terms of reference

Taking this new information into consideration, SCHER is asked:

¹ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys. OJ L 170, 30.06.2009, p. 1.

² RIVM advisory report of 2008, Chemicals in toys. A general methodology for assessment of chemical safety of toys with a focus on elements. <http://www.rivm.nl/bibliotheek/rapporten/320003001.pdf>

³ http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_126.pdf

⁴ Opinion of the Scientific Committee on Toxicity, Ecotoxicity, and the Environment on "Assessment of the bioavailability of Certain Elements in Toys", 22 June 2004.

http://ec.europa.eu/health/archive/ph_risk/committees/sct/documents/out235_en.pdf

⁵ NTP ... National Toxicology Programme

⁶ Office of Environmental Health Hazard Assessment, California

⁷ <http://oehha.ca.gov/water/phg/chrom123110.html>

⁸ <http://oehha.ca.gov/water/phg/pdf/Cr6PHG072911.pdf>

- 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;
- to consider whether the migration limits for chromium VI in point 13 of section III of Annex II of the Toy Safety Directive 2009/48/EC are still appropriate to ensure the safety of toys;
- to propose, if the current limits are no longer appropriate, new limits, clearly indicating the data on which they would be based.