

Scientific Committee on Health and Environmental Risks (SCHER)

Request for an opinion on estimates of the amount of toy materials ingested by children

1. Background

The Toy Safety Directive 2009/48/EC¹ establishes migration limits for 19 elements in toys or components of toys, depending on the type of toy material used: dry, brittle, powder-like or pliable toy material; liquid or sticky toy material; and scraped-off toy material. These migration limits, listed in point 13 of Part III of Annex II of the Toy Safety Directive, may not be exceeded.

The migration limits were based on a 2008 Report² which assumed that a child would ingest 100 mg/day of dry, brittle, powder-like or pliable toy material, 400 mg/day of liquid or sticky toy material, and 8 mg/day of scraped-off toy material.³ With these assumptions the Report derived tentative limits⁴ on which the migration limits of the Toy Safety Directive were based.

However, in another section, the Report also noted that the ingestion of 100 mg of dry, brittle, powder-like or pliable toy material and 400 mg of liquid or sticky toy material, although reasonable, may not occur daily, but only once a week,⁵ adding that this was a rough estimate which needed further research.

An "Erratum"⁶ was added to the Report in January 2015, which used the assumption of weekly ingestion of the amounts to re-calculate the derived limits, thus increasing them 7-fold.

2. Terms of reference

Taking this new development 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.

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009L0048-20140721&rid=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 RIVM advisory report of 2008 (see footnote above), section 8.5.1.

⁴ RIVM advisory report of 2008 (see footnote above), section 8.6.

⁵ RIVM advisory report of 2008 (see footnote above), section 3.5.2.

⁶

http://www.rivm.nl/Documenten_en_publicaties/Wetenschappelijk/Rapporten/2009/april/Chemicals_in_toys_A_general_methodology_for_assessment_of_chemical_safety_of_toys_with_a_focus_on_elements?sp=Y3RsMT1yZXBvcnQ7SU5MSUJSQVJZPXRYdWU7U0IURUxBTkVQUdFPW5sO3NIYXJjaGJhc2U9MDtzZWYyY2hyYW5nZT01MDtzZWYyY2hleHByZXNzaW9uPShjdGwxKSBBTkQgSU5MSUJSQVJZIEFORCBTSVRFTEFOR1VBR0U7c29ydGZpZWxkPXB1Ymxpc2hkYXRIO3NvcnRyZXZlcnNIZD10cnVlOw==&query=&pagenr=1&result=rivmp%3A12983< /font>

- To review the available data on the ingestion of all three types of toy materials provided for in the Toy Safety Directive 2009/48/EC (dry, brittle, powder-like or pliable toy material; liquid or sticky toy material; and scraped-off toy material) by children;
- To consider, in the light of the review, whether the estimated ingestion amounts (100 mg/day of dry, brittle, powder-like or pliable, 400 mg/day of liquid or sticky and 8 mg/day of scraped-off toy material), which formed the basis for the limits in the Toy Safety Directive, are still appropriate;
- To propose, if the estimated ingestion amounts are no longer considered appropriate, new amounts which would be more appropriate, clearly indicating the data on which they are based.

In this work SCHER should take account of the Guidance on consumer exposure estimation of the European Chemicals Agency (ECHA), in particular section R.15.2.5.⁷

⁷ http://echa.europa.eu/documents/10162/13632/information_requirements_r15_en.pdf