

**Scientific Committee on Health, Environmental and Emerging Risks
(SCHEER)**

**Request for a scientific opinion on the tolerable intake of aluminium with regards to
adapting the migration limits for aluminium in toys**

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 Section III of Annex II of the Directive, must not be exceeded.

The migration limits were based on a 2008 Report² listing available Tolerable Daily Intake (TDI) data for each of the 19 elements.³ For aluminium, the TDI was given as 0,75 mg/kg bw/day, derived from data of the Office of Environmental Health Hazard Assessment (OEHHA) with own considerations added.⁴ This TDI corresponds to 5,25 mg/kg bw/week.

The migration limits in Directive 2009/48/EC were calculated by taking 10 % of the TDI (in order to take account of the exposure to aluminium from sources other than toys), multiplied by the bodyweight of a child (7,5 kg for a child below 3 years of age) and divided by the quantity of toy material ingested per day: 100 mg for dry, brittle, powder-like or pliable toy material, 400 mg for liquid or sticky toy material, and 8 mg for scraped-off toy material. These daily ingestion amounts were recently confirmed by SCHER.⁵ The current migration limits for aluminium in Directive 2009/48/EC are thus: 5625 mg/kg in dry, brittle, powder-like or pliable toy material, 1406 mg/kg in liquid or sticky material, and 70000 mg/kg in scraped-off toy material.

The European Food Safety Authority (EFSA) established in 2008 a Tolerable Weekly Intake (TWI) of 1 mg aluminium/kg bw/week, based on the combined evidence from several studies in mice, rats and dogs that used dietary administration of aluminium

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), Table 2-2 on p. 26, Table 8-1 on p. 114.

⁴ OEHHA (2000) Public health goal for aluminium in drinking water. Pesticide and Environmental Toxicology Section Office of Environmental Health Hazard Assessment California Environmental Protection Agency. DRAFT dated February 2000. Referred to in the RIVM advisory report of 2008 (see footnote above), section II.1.6, p. 145.

⁵ Scientific Committee on Health and Environmental Risks (SCHER) Opinion on Estimates of the amount of toy materials ingested by children. Adopted on 8 April 2016.

compounds.⁶ In view of the cumulative nature of aluminium in the organism after dietary exposure, EFSA considered it more appropriate to establish a TWI rather than a TDI.

To note that under Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, a new aluminium limit has recently been established,⁷ based on the above EFSA TDI. Due to the high dietary exposure of a significant part of the European Union's population to aluminium (see EFSA opinion in footnote 6), the contribution from exposure by food contact materials to the overall exposure was calculated by applying an allocation factor of 10 % to the conventionally derived migration limit.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated available data for aluminium in 2011.⁸ The Committee concluded that a No Observed Adverse Effect Level (NOAEL) of 30 mg/kg bw/day was appropriate for establishing a Provisional Tolerable Weekly Intake (PTWI) for aluminium compounds. Because long-term studies on the relevant toxicological endpoints had become available, there was no longer the need for an additional uncertainty factor for deficiencies in the database. The Committee therefore established a PTWI of 2 mg/kg bw/week from the NOAEL of 30 mg/kg bw/day by applying an uncertainty factor of 100 for interspecies and intraspecies differences.

Thus, both EFSA and JECFA established tolerable intake levels for aluminium that are notably lower than the level that was the basis for the migration limits for aluminium in the Toy Safety Directive 2009/48/EC. This suggests the migration limits be adapted.

2. Terms of reference

SCHEER is asked:

1. To review the available data on the toxicity of aluminium that are currently available, taking into account the different tolerable intake levels for aluminium established by EFSA in 2008 and JECFA in 2011;
2. To advise on a tolerable intake level for aluminium based on most recent data that could be used to adapt the migration limits for aluminium in the Toy Safety Directive 2009/48/EC, taking account of the exposure to aluminium from sources other than toys.

3. Timeline:

Preliminary opinion – May 2017

Final opinion – autumn 2017

⁶ European Food Safety Authority (EFSA) Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC) (2008) Scientific Opinion on Safety of aluminium from dietary intake. The EFSA Journal (2008) 754, 1-34. <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2008.754/pdf>

⁷ Commission Regulation (EU) 2016/1416. OJ L 203, 25.8.2016, p. 22. <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R1416&from=EN>

⁸ WHO (2011) Technical Report 966 – Evaluation of certain food additives and contaminants. 74th report of the Joint FAO/WHO Expert Committee on Food Additives. P. 16. http://apps.who.int/iris/bitstream/10665/44788/1/WHO_TRS_966_eng.pdf