Commission Directive (EU) 2019/1922 of 18 November 2019 amending, for the purposes of adaptation to technical and scientific developments, point 13 of part III of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards aluminium (Text with EEA relevance)

COMMISSION DIRECTIVE (EU) 2019/1922

of 18 November 2019

amending, for the purposes of adaptation to technical and scientific developments, point 13 of part III of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards aluminium

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys[(1)], and in particular Article 46(1)(b) thereof,

Whereas:

(1) Directive 2009/48/EC lays down migration limits for aluminium from toys or components of toys. Currently, the limits for aluminium are 5 625 mg/kg for dry, brittle, powder-like or pliable toy material, 1 406 mg/kg for liquid or sticky toy material and 70 000 mg/kg for scraped-off toy material.

(2) The Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) has reviewed the available data on the toxicity of aluminium, taking into account the different tolerable intake levels for aluminium established by the European Food Safety Authority in 2008[(2)] and by the Joint FAO/WHO Expert Committee on Food Additives in 2011[(3)]. The SCHEER considered, in its 'Final opinion on tolerable intake of aluminium with regard to adapting the migration limits for aluminium in toys', adopted on 28 September 2017, a tolerable daily intake (TDI) of 0,3 mg/kg body weight per day as an appropriate base for revising the migration limits for aluminium from toys.

(3) Since children are exposed to aluminium also through sources other than toys, only a certain percentage of the TDI should be allocated to the exposure from toys when calculating the limits. The maximum contribution from toys to the daily intake recommended by the Scientific Committee on Toxicity, Ecotoxicity and the Environment in its 2004 opinion[(4)] is 10 %. In 2010, this percentage was confirmed by the Scientific Committee on Health and Environmental Risks in its opinion on 'Risk from organic CMR substances in toys'[(5)] and in its opinion on 'Evaluation of the migration limits for chemical elements in toys'[(6)].

(4) The SCHEER applied 10 % of the TDI, multiplied by the average weight of a child under three years of age (estimated at 7,5 kg) and divided by the daily quantity of toy

material ingested. That quantity was estimated at 100 mg/day for dry, brittle, powder-like or pliable toy material, 400 mg/day for liquid or sticky toy material and 8 mg/day for scraped-off toy material. On the basis of that calculation, the SCHEER proposed revised migration limits for aluminium from toys of 2 250 mg/kg for dry, brittle, powder-like or pliable toy material, 560 mg/kg for liquid or sticky toy material and 28 130 mg/kg for scraped-off toy material ('the proposed migration limits').

(5) Compliance with the proposed migration limits can be verified with the test method set out in European standard EN 71-3:2013+A3:2018, the reference of which has been published in the *Official Journal of the European Union*[(7)]. The proposed migration limits can be easily enforced, since they are several thousand times higher than the lowest concentration that can be reliably quantified with the test method set out in the standard[(8)].

(6) In order to advise the Commission in the preparation of legislative proposals and policy initiatives in the area of toy safety, the Commission established the Expert Group on Toys Safety[(9)]. The mission of its subgroup Working Group on chemicals in toys (subgroup Chemicals) is to provide advice to the Expert Group on Toys Safety with regard to chemical substances that may be used in toys.

(7) The subgroup Chemicals considered, at its meeting on 26 September 2017, that the migration limits proposed by SCHEER were appropriate.

(8) Market surveillance data on aluminium in toys[(10)(11)(12)(13)] from approximately 5 800 tests has showed compliance with the proposed migration limits in almost all cases. Data from writing instrument manufacturers on approximately 250 samples[(14)] has suggested that a substantial part of the writing materials are already compliant with those limits.

(9) The Expert Group on Toys Safety agreed, at its meeting on 19 December 2017, that the migration limits for aluminium should be amended as proposed.

(10) In light of the available scientific evidence, the opinion of the SCHEER, the data provided by the Member States and the writing materials industry and the recommendations from the Expert Group on Toys Safety and its subgroup chemicals, it is necessary to adapt the current migration limits for aluminium from toys or components of toys to technical and scientific developments by replacing them with the proposed migration limits.

(11) Directive 2009/48/EC should therefore be amended accordingly.

(12) The measures provided for in this Directive are in accordance with the opinion of the Toy Safety Committee,

HAS ADOPTED THIS DIRECTIVE:

(**1**) OJ L 170, 30.6.2009, p. 1.

(**2**) European Food Safety Authority (EFSA), Safety of aluminium from dietary intake — Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC). Opinion adopted on 22 May 2008. *EFSA Journa*l (2008) 754, p. 1-34. http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/754.pdf

(**3**) 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

(**4**) Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE). Opinion on 'Assessment of the bioavailability of certain elements in toys'. Adopted on 22 June 2004. http://ec.europa.eu/health/archive/ph_risk/committees/sct/documents/out235_en.pdf

(**5**) Scientific Committee on Health and Environmental Risks (SCHER). Opinion on 'Risk from organic CMR substances in toys'. Adopted on 18 May 2010.

(**6**) Scientific Committee on Health and Environmental Risks (SCHER). Opinion on 'Evaluation of the migration limits for chemical elements in Toys'. Adopted on 1 July 2010.

(**7**) OJ C 282, 10.8.2018, p. 3.

(**8**) See table E.5 in EN 71-3:2013+A3:2018.

(**9**) See Register of Commission Expert Groups, Expert Group on Toys Safety (E01360). http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=1360

(**10**) Nederlandse Voedsel- en Warenautoriteit, Geverfd houten speelgoed 2016. (Dutch Food and Product Authority, Painted wooden toys 2016). https://www.inspectieresultaten.nvwa.nl/productonderzoek/geverfd-houten-speelgoed-0

(**11**) Finnish Customs Laboratory, Market surveillance data from Finland for aluminium. Submission to the subgroup 'Chemicals' as EXP/WG/2017/039 in the follow-up to the meeting on 26 September 2017.

(**12**) Results of market surveillance in France. Submission to the subgroup 'Chemicals' as a follow-up to the meeting on 26 September 2017.

(**13**) Results of market surveillance in Austria. Submission to the subgroup 'Chemicals' as a follow-up to the meeting on 26 September 2017.

(**14**) Data provided by the European Writing Manufacturers Association (EWIMA). Submission to the subgroup 'Chemicals' as a follow-up to the meeting on 26 September 2017.