Commission Directive (EU) 2018/725 of 16 May 2018 amending, for the purpose 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 chromium VI

COMMISSION DIRECTIVE (EU) 2018/725

of 16 May 2018

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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 sets a limit value for chromium VI in scraped-off toy material such as paints on toys, hard and soft polymers, wood, textiles, and others. The current limit value (0,2 mg/kg) is based on a virtually safe dose of 0,0053 μg of chromium VI per kg bodyweight per day proposed by the Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency[(2)].

(2) At the request of the European Commission, the Scientific Committee on Health and Environmental Risks (SCHER) assessed in 2015 the relevance of the oral cancer potency of chromium VI. In its opinion on 'Chromium VI in toys' adopted on 22 January 2015[(3)], SCHER reported to have reviewed, among others, the OEHHA technical support document for the Public Health Goal for chromium VI in drinking water[(4)] and a US-National Toxicology Program (NTP) study[(5)]. The SCHER considered 0,0002 μg of chromium VI per kg bodyweight per day, derived by the OEHHA as being associated with one additional cancer case in a million, as an appropriate virtually safe dose.

(3) Since children are also exposed to chromium VI through sources other than toys, only a certain percentage of the virtually safe dose should be taken as the basis when calculating the limit value for chromium VI. The maximum contribution from toys to the daily intake of chromium VI recommended by the Scientific Committee on Toxicity, Ecotoxicity and the Environment in its 2004 opinion[(6)] is 10 %. This percentage was confirmed twice by the Scientific Committee on Health and Environmental Risks in 2010[(7)(8)].

(4) In addition, for chromium VI and other chemical substances which are particularly toxic, Directive 2009/48/EC suggests in its recital 22 to set limit values at half of those

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considered safe by the relevant Scientific Committee, in order to ensure that only traces that are compatible with good manufacturing practice will be present.

(5) Applying 10 % of the virtually safe dose, multiplied by the average weight of a child under three years of age, estimated at 7,5 kg, divided by the daily quantity of scraped-off toy material ingested, estimated at 8 mg/day, and multiplied by

$\frac{1}{2}$

led the SCHER to propose, in its above-mentioned opinion on 'Chromium VI in toys', 0,0094 mg/kg as a revised limit value for chromium VI in scraped-off toy material.

(6) Compliance with the proposed limit value can, however, not be verified with the test method in European standard EN 71-3:2013+A1:2014, the reference of which has been published in the *Official Journal of the European Union*[9]. The proposed limit value is almost six times lower than the lowest concentration that can be reliably quantified with the test method in the standard, which is 0,053 mg/kg.

(7) In those circumstances, the subgroup 'Chemicals' of the Expert Group on Toys Safety established by the Commission[10] recommended at its meeting on 14 October 2016 to lower the limit value for chromium VI from the current 0,2 mg/kg to 0,053 mg/kg. The subgroup 'Chemicals' equally recommended to review available test methods for chromium VI every two years to possibly identify a test method that can reliably measure even lower concentrations, until the limit value proposed by SCHER has been reached.

(8) The European Committee for Standardisation (CEN) is currently reviewing the test method in standard EN 71-3 with regard to improving the detection of chromium VI. A revised test method is expected to be available soon allowing to reliably measure concentrations down to 0,0025 mg/kg. It would then be possible to strengthen further the limit value for chromium VI in scraped-off toy material.

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

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

In point 13 of Part III of Annex II to Directive 2009/48/EC, the entry for chromium VI is replaced by the following entry:

Element	**mg/kgin dry, brittle, powder-like or pliable toy material**	**mg/kgin liquid or sticky toy material**	**mg/kgin scraped-off toy material**
'Chromium (VI)	0,02	0,005	0,053'