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From:	European Commission
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To:	General Secretariat of the Council
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Subject:	COMMISSION DIRECTIVE (EU) .../... of XXX 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

Delegations will find attached document D054736/01.

Encl.: D054736/01



Brussels, **XXX**
[...](2017) **XXX** draft

COMMISSION DIRECTIVE (EU) .../...

of **XXX**

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

D054736/01

COMMISSION DIRECTIVE (EU) .../...

of **XXX**

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

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 toys¹, 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 Agency².
- (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 2015³, SCHER reported to have reviewed, among others, the OEHHA technical support document for the Public Health Goal for chromium VI in drinking water⁴ and a US-National Toxicology Program (NTP) study⁵. 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

¹ OJ L 170, 30.6.2009, p. 1.

² OEHHA (1999). Public health goal for chromium in drinking water. Pesticide and Environmental Toxicology Section, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. Dated February 1999. Cited in: Chemicals in Toys. A general methodology for assessment of chemical safety of toys with a focus on elements RIVM report 320003001/2008. National Institute for Public Health and the Environment (RIVM) of The Netherlands. p. 114, Table 8-1.

³ Scientific Committee on Health and Environmental Risks (SCHER), Opinion on "Chromium VI in toys". Adopted on 22 January 2015.
http://ec.europa.eu/health/sites/health/files/scientific_committees/environmental_risks/docs/scher_o_16_7.pdf

⁴ OEHHA (2011). Public health goals for chemicals in drinking water. Hexavalent chromium (Cr VI).
<http://oehha.ca.gov/water/phg/072911Cr6PHG.html>

⁵ National Toxicology Program (2008). Toxicology and Carcinogenesis Studies of Sodium Dichromate Dihydrate (CAS No. 7789-12-0) in F344/N Rats and B6C3F1 Mice (Drinking Water Studies). NTP TR 546, NIEHS, Research Triangle Park, NC. NIH Publication No. 08-5887.

Toxicity, Ecotoxicity and the Environment in its 2004 opinion⁶ 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 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 ½ 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 Commission¹⁰ 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 Standardization (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:

⁶ 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

⁷ Scientific Committee on Health and Environmental Risks (SCHER). Opinion on "Risk from organic CMR substances in toys". Adopted on 18 May 2010.

⁸ 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.

⁹ OJ C 378, 13.11.2015, p. 1.

¹⁰ 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>

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

Article 2

1. Member States shall adopt and publish, by *[18 months after publication in the OJ]* at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from *[18 months after publication in the OJ + 1 day]*.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

*For the Commission
The President
Jean-Claude Juncker*