EUROPEAN
COMMISSION

Brussels, XXX
[…](2014) XXX draft

COMMISSION DIRECTIVE ../…/EU

of XXX

amending, for the purpose of adapting to technical progress, Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys

(Text with EEA relevance)

COMMISSION DIRECTIVE ../…/EU

of XXX

amending, for the purpose of adapting to technical progress, Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys

(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 toys or components of toys, for a range of elements, including lead, in dry, liquid and scraped-off toy material. The limits for lead are 13,5 mg/kg, 3,4 mg/kg and 160 mg/kg in each toy material, respectively.

(2) Those limits were based on the recommendations of the Dutch National Institute for Public Health and the Environment (RIVM) made in the 2008 report entitled 'Chemicals in Toys. A general methodology for assessment of chemical safety of toys with a focus on elements'.[2] The RIVM recommendations were based on the conclusion that exposure of children to elements such as lead may not exceed a certain level, called 'tolerable daily intake'. In the report, a tolerable daily intake of 3,6 microgram per kilogram body weight per day was determined for lead as the toxicological reference value.

(3) Since children are exposed to elements, such as lead, also via other sources than toys, only a certain percentage of the toxicological reference value should be allocated to toys. The Scientific Committee on Toxicity, Ecotoxicity and Environment (CSTEE) recommended that 10% of the maximum tolerable intake of certain elements such as lead should be allowed as the maximum contribution from toys[3]. The Scientific Committee for Health and Environmental Risks (SCHER) concurred with the approach that the uptake of elements such as lead from toys should not exceed 10% of a toxicology-based reference value[4]. Furthermore, since lead is considered particularly toxic, its limits in Directive 2009/48/EC were set at levels half of those considered safe according to the criteria of the relevant Scientific Committee, in order to ensure that only traces that are compatible with good manufacturing practice will be present.

---

1 OJ L 170, 30.6.2009, p. 1.

2 J.G.M. Van Engelen, et al. (2008) RIVM report 320003001/2008. http://www.rivm.nl/bibliotheek/rapporten/320003001.pdf

3 Scientific Committee on Toxicity, Ecotoxicity and Environment (CSTEE), Opinion on the "Assessment of the bioavailability of certain elements in toys", adopted on 22 June 2004, p. 3.

4 Scientific Committee on Health and Environmental Risks (SCHER), Opinion on the "Evaluation of the Migration Limits for Chemical Elements in Toys", adopted on 1 July 2010, p. 5.

Accordingly, the limits for lead were set at 5% of the tolerable daily intake, determined as migration from lead in toys.

(4) The European Food Safety Agency (EFSA) concluded that for lead, as a toxic metal, there is no threshold below which the exposure to lead has no critical health effects. Even low-level exposure to lead is susceptible to cause neurotoxicity (i.e. damage to the nervous system and brain), in particular learning deficits. Therefore, according to the new scientific knowledge published by EFSA, the tolerable daily intake should no longer be used as the toxicological reference value[5].

(5) According to EFSA, the new toxicological reference value to be used for establishing lead limits is the $BMDL_{01}$ (benchmark dose limit) relating to neuro-developmental effects. The $BMDL_{01}$ is the lower confidence limit (95% percentile) of the benchmark dose of a 1% extra risk of intellectual deficits in children measured by the Full Scale IQ score, i.e. a decrease in IQ by 1 point on that scale[6]. The $BMDL_{01}$ is equivalent to a lead intake of 0,5 microgram per kilogram body weight per day.

(6) The Committee for Risk Assessment (RAC) established under the European Chemicals Agency (ECHA) agreed with EFSA that the $BMDL_{01}$ is the highest tolerable exposure for lead[7]. Since the current average blood lead levels in European children are up to 4 times higher than this highest tolerable exposure level, and since no threshold for the neuro-developmental effects can be established, any additional exposure must be avoided as far as possible[8].

(7) Applying the latest scientific developments to the methodology in the above-mentioned RIVM report to calculate safe limits for elements in toys, and applying the approach of Directive 2009/48/EC to managing the risks of particularly toxic elements such as lead, the limits for lead in toys laid down in Directive 2009/48/EC should be reviewed, and should be set at a 5% allocation of the $BMDL_{01}$ for the protection of children's health.

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

(9) 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 the table under point 13 of part III of Annex II the entry for lead is replaced by the following:

---

5 EFSA CONTAM Panel (2013), Scientific Opinion on Lead in Food. (See footnote above) p. 5. Applied in: SCHER (2011), Opinion on a Lead Standard in Drinking Water, adopted on 11 January 2011.

6 EFSA CONTAM Panel (2013), Scientific Opinion on Lead in Food. (See footnote above.) p. 5, p. 98.

7 ECHA (RAC) (2013), Opinion on an Annex XV dossier proposing restrictions on lead and its compounds in articles intended for consumer use, adopted on 10 December 2013, ECHA/RAC/RES-O-0000003487-67-04/F, p. 5.

8 ECHA RAC (2013), Opinion on an Annex XV dossier proposing restrictions on lead and its compounds in articles intended for consumer use (see footnote 6, p. 5.

Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material	mg/kg in scrapped-off toy material
‘Lead	2,0	0,5	23’

Article 2

1. Member States shall adopt and publish, by […*(Fill in date falling 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 […*Fill in same date as in previous subparagraph)*].

   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