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[...] (2018) **XXX** draft

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

of **XXX**

amending Appendix C to Annex II to Directive 2009/48/EC of the European Parliament and of the Council for the purpose of adopting specific limit values for chemicals used in certain toys, as regards formaldehyde

(Text with EEA relevance)

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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 toys¹, and in particular Article 46(2) thereof,

Whereas:

- (1) Directive 2009/48/EC establishes certain requirements for chemical substances that are classified as carcinogenic, mutagenic or toxic for reproduction under Regulation (EC) No 1272/2008 of the European Parliament and of the Council². Appendix C to Annex II to the Directive lays down specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth.
- (2) Formaldehyde (CAS number 50-00-0) is currently not listed in Appendix C to Annex II to Directive 2009/48/EC. It is classified as carcinogenic category 1B under Regulation (EC) No 1272/2008. Pursuant to point 4(a) of Part III of Annex II to Directive 2009/48/EC, formaldehyde may be used up to a concentration of 0,1 %, which corresponds to 1000 mg/kg (content limit).
- (3) In order to advise the Commission in the preparation of legislative proposals and policy initiatives in the area of toy safety, the Commission has established the Expert Group on Toys Safety³. 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 which may be used in toys.
- (4) Formaldehyde is used as a monomer in the manufacture of polymeric materials. Polymeric materials are often used in toys. Children may therefore ingest formaldehyde when mouthing toys containing polymeric materials. The tolerable daily intake (TDI) for formaldehyde was set by the World Health Organisation (WHO)⁴ and has been confirmed by the Scientific Panel on Food Additives, Flavourings,

¹ OJ L 170, 30.6.2009, p. 1.

² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

³ Register of Commission Expert Groups, Expert Group on Toys Safety (E01360).

⁴ <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=1360>

WHO (1993) Guidelines for drinking-water quality. Second Edition. World Health Organisation. Geneva. p. 98.

Processing Aids and Materials in Contact with Food (AFC) of the European Food Safety Authority⁵. The TDI is 0,15 mg/kg bodyweight per day. With an allocation of 10 % of the TDI to the intake of formaldehyde from toys⁶, a child with a bodyweight of 10 kg should therefore not take in more than 0,15 mg formaldehyde per day. Assuming a daily ingestion of 100 ml of mouthing saliva, the subgroup Chemicals recommended, at its meeting on 26 September 2017⁷, a formaldehyde migration limit of 1,5 mg/l in polymeric materials when the migration of formaldehyde is determined in accordance with the test method in standards EN 71-10:2005⁸ and EN 71-11:2005⁹.

- (5) Formaldehyde is also used in the manufacture of resin-bonded wood products such as particle board, oriented-strand board (OSB), high-density fibre board (HDF), medium density fibre board (MDF) and plywood. Formaldehyde resins include phenol-formaldehyde (PF), urea-formaldehyde (UF), melamine-formaldehyde (MF) and polyacetal (polyoxymethylene - POM) resins. POM tends to be used only for small internal components and not in whole toys. The subgroup Chemicals recommended, at its meeting on 26 September 2017, a formaldehyde emission limit of 0,1 ml/m³ when the emission of formaldehyde is determined in such materials in accordance with the test chamber method in standard EN 717-1:2004¹⁰. That limit corresponds to the indoor air limit value that the WHO has established to prevent sensory irritation in the general population and to prevent cancer¹¹.
- (6) Formaldehyde may also be present in textile toy material due to its use during the manufacture of textiles. According to a report from the Organisation for Economic Cooperation and Development (OECD) published in 2002, the lowest threshold concentration for allergic contact dermatitis from formaldehyde is 30 mg/kg¹². On that basis and in order to protect also the most sensitised individuals, the subgroup Chemicals recommended, at its meeting on 26 September 2017, a formaldehyde content limit of 30 mg/kg when the content of formaldehyde is determined in accordance with the water extraction method in standard EN ISO 14184-1:2011¹³.
- (7) Formaldehyde may be present in leather toy material due to its use during the manufacture of leather. Since leather toy material may lead to an exposure similar to textile toy material the subgroup Chemicals recommended, at its meeting on

⁵ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2007.415>. Referred to in the position paper of the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) for the subgroup Chemicals EXP/WG/2016/041.

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

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

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 Register of Commission Expert Groups, Expert Group on Toys Safety (E01360), tab 'Meetings'. http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail_groupMeeting&meetingId=4151.

The limit value was included in meeting document EXP/WG/2017/023.

⁸ Safety of toys - Part 10: Organic chemical compounds – Sample preparation and extraction.

⁹ Safety of toys - Part 11: Organic chemical compounds – Methods of analysis.

¹⁰ Wood-based panels - Determination of formaldehyde release - Part 1: Formaldehyde emission by the chamber method.

¹¹ World Health Organisation (WHO) 2010, WHO guidelines for indoor air quality: selected pollutants. P. 140-142. http://www.euro.who.int/_data/assets/pdf_file/0009/128169/e94535.pdf
EXP/WG/2016/058.

¹³ Textiles - Determination of formaldehyde - Part 1: Free and hydrolysed formaldehyde (water extraction method) (ISO 14184-1:2011).

26 September 2017, a formaldehyde content limit of 30 mg/kg when the content of formaldehyde is determined in accordance with standard EN ISO 17226-1:2008¹⁴.

- (8) Formaldehyde in paper toy material should have a content limit of 30 mg/kg according to the recommendation of the subgroup Chemicals at its meeting on 26 September 2017, when determined in accordance with the water extraction method in standard EN 645:1993¹⁵ and with standard EN 1541:2001¹⁶. That conclusion was based on the consideration that paper toy material may lead to an exposure similar to textile and leather toy material.
- (9) Formaldehyde may be present in water-based toy material due to its function as a preservative. It could be used in water-based toy materials such as soap bubbles or inks in felt-tip pens, and also in dry materials intended to be mixed with water prior to use. In light of the opinion of the Scientific Committee on Health and Environmental Risks (SCHER) that CMR compounds should not be present in toys¹⁷, the subgroup Chemicals recommended, at its meeting on 3 May 2018¹⁸, a formaldehyde limit of 10 mg/kg in water-based toy material when the content of formaldehyde is determined according to the test method published by the European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (the EDQM method) on the Determination of free formaldehyde in cosmetic products¹⁹. The recommended limit is close to the lowest value that can be reliably determined by the EDQM method and takes account of traces of formaldehyde that certain other preservatives may release.
- (10) The Expert Group on Toys Safety took note, at its meeting on 19 December 2017²⁰, of the recommendations of its subgroup Chemicals regarding the limits for formaldehyde in different toy materials. It expressed support and suggested a number of improvements for the Commission to consider.
- (11) Pursuant to Article 46(2) of Directive 2009/48/EC, the packaging requirements for food as laid down in Regulation (EC) No 1935/2004 are to be taken into account when adopting specific limit values for chemicals in Appendix C to that Directive. The basic assumptions behind the specific migration limit for formaldehyde as a monomer in plastic food contact material²¹ are, however, different from the basic assumptions behind the recommended migration limit for formaldehyde as a monomer in toys. Therefore, it is not possible to take account of the packaging requirements for food when setting a limit for formaldehyde as a monomer in toys..
- (12) In light of the available scientific evidence and the recommendations of the Expert Group on Toys Safety and its subgroup Chemicals, it is necessary to set the recommended limits for formaldehyde in different toy materials.

¹⁴ Leather - Chemical determination of formaldehyde content – Part 1: Method using high performance liquid chromatography (ISO 17226-1:2008).

¹⁵ Paper and board intended to come into contact with foodstuffs - Preparation of a cold water extract.

¹⁶ Paper and board intended to come into contact with foodstuffs - Determination of formaldehyde in an aqueous extract.

¹⁷ Scientific Committee on Health and Environmental Risks (SCHER). CEN's response to the opinion of the CSTE on the assessment of CEN report on the risk assessment of organic chemicals in toys. Adopted on 29.5.2007.

¹⁸ http://ec.europa.eu/health/archive/ph_risk/committees/04_scher/docs/scher_o_056.pdf

¹⁹ Register of Commission Expert Groups, Expert Group on Toys Safety (E01360), tab 'Meetings'. <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeeting&meetingId=6870>.

²⁰ <https://www.edqm.eu/en/cosmetics-testing>

²¹ Register of Commission Expert Groups, Expert Group on Toys Safety (E01360), tab 'Meetings'. <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeeting&meetingId=1485>

²¹ Entry 15 in Table 2 of Annex I of Regulation (EU) No 10/2011. OJ L12, 15.1.2011, p. 1.

- (13) Appendix C to Annex II to Directive 2009/48/EC should therefore be amended accordingly.
- (14) The measures provided for in this Directive are in accordance with the opinion of the Toy Safety Committee established under Article 47 of Directive 2009/48/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

In Appendix C to Annex II to Directive 2009/48/EC, the following entry is added:

Substance	CAS No	Limit value
Formaldehyde	50-00-0	1,5 mg/l (migration limit) in polymeric toy material 0,1 ml/m ³ (emission limit) in resin-bonded wood toy material 30 mg/kg (content limit) in textile toy material 30 mg/kg (content limit) in leather toy material 30 mg/kg (content limit) in paper toy material 10 mg/kg (content limit) in water-based toy material.'

Article 2

- Member States shall adopt and publish, by [*Insert here the date that is 18 months after the 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 [*Insert here the date that is 18 months + 1 day after the publication in the OJ*].

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.
- 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