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COMMISSION DIRECTIVE ../.../EU

of **XXX**

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

(Text with EEA relevance)

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amending, for the purpose of adopting specific limit values for chemicals used in toys, Appendix C to 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 toys¹, and in particular Article 46(2) thereof,

Whereas:

- (1) In order to ensure a high level of protection of children against risks caused by chemical substances in toys, Directive 2009/48/EC establishes certain requirements with regard to chemical substances such as those classified as carcinogenic, mutagenic or toxic for reproduction (CMR) under Regulation (EC) No 1272/2008 of the European Parliament and of the Council², allergenic fragrances and certain metals. In addition, Directive 2009/48/EC empowers the Commission to adopt specific limit values for chemicals used in toys which are intended for children under 36 months and in other toys intended to be placed in the mouth in order to ensure adequate protection in the case of toys involving a high degree of exposure. The adoption of such limit values takes the form of an inclusion in Appendix C to Annex II to Directive 2009/48/EC.
- (2) For a number of chemicals, currently applicable limit values are either too high in the light of available scientific evidence or do not exist. Specific limit values should therefore be adopted for them, taking into account the packaging requirements for food as well as the differences between toys and food contact materials.
- (3) In order to advise the European 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. The mission of its subgroup "Chemicals" is to provide such advice with regard to chemical substances which may be used in toys.
- (4) Phenol (CAS number 108-95-2) is used as a monomer for phenolic resins in the manufacture of plywood³ for toys. The degradation of phenolic antioxidants in polymers can be a further source of phenol in toys⁴. Phenol was identified in emissions

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 E. Edmonds (2013) Occurrence of Phenol and Formaldehyde in Toys. Report commissioned by Toy Industries of Europe, p. 4.

⁴ See footnote 3, pp. 5 and 8.

from game consoles⁵, in one of six analysed tents or tunnels for children⁶ and in packaging film⁷, it was tested in bath toys and other inflatable toys⁸, and it was considered to be present in polyvinyl chloride (PVC)⁹. Phenol could further be used as a preservative in water-based liquid toys such as bubble-blowing products, water-based liquid inks (e.g. felt-tipped marker pens)¹⁰ or finger paints¹¹.

- (5) In its deliberations on phenol the subgroup "Chemicals" took European standards EN 71-9:2005+A1:2007, EN 71-10:2005 and EN 71-11:2005 as the basis. Those standards refer to the presence of phenol in toy materials (EN 71-9) and provide specific methods of sample preparation (EN 71-10) and measurement (EN 71-11). EN 71-11 further sets limit values for phenol in toy materials, namely 15 mg/l (migration limit) for phenol as a monomer and 10 mg/kg (content limit) for phenol as a preservative in liquid toy materials.
- (6) The subgroup "Chemicals" also took account of the recommendation of the Scientific Committee on Health and Environmental Risks (SCHER) that the migration limit value of 15 mg/l for phenol set out in the existing European standard be lowered at least by a factor of 2 in order to reach a Margin of Exposure of 100 that could be considered sufficiently large¹².
- (7) Phenol is classified under Regulation (EC) No 1272/2008 as mutagenic category 2. According to point 5 of Part III of Annex II to Directive 2009/48/EC, mutagenic substances of category 2 such as phenol may be present in toys in concentrations equal to or smaller than the relevant concentration established for the classification of mixtures containing it, namely 1%, which equals 10 000 mg/kg (content limit). Directive 2009/48/EC does not currently provide for a migration limit for phenol.
- (8) In the light of the above, the subgroup "Chemicals" recommended at its meeting of 26 March 2014 that phenol be limited in toys to 5 mg/l (migration limit) when analysed as a monomer, and to a maximum concentration of 10 mg/kg (content limit) when analysed as a preservative. Analyses should be carried out in accordance with European standards EN 71-9:2005+A1:2007, EN 71-10:2005 and EN 71-11:2005.
- (9) While there is a generic migration limit for phenol as a monomer for use in certain food contact materials, the basic assumptions for deriving that migration limit are

⁵ Danish Environmental Protection Agency (EPA) (2003) Survey of chemical substances in consumer products Survey no. 32 – 2003. Emission and evaluation of chemical substances from selected electrical and electronic products, p. 47. <http://eng.mst.dk/media/mst/69115/32.pdf>

⁶ Danish EPA (2004) Mapping of Chemical Substances in Consumer Products nr. 46, 2004. Release of chemical substances from tents and tunnels for children. <http://eng.mst.dk/media/mst/69127/46.pdf>

⁷ Bundesinstitut für Risikobewertung (2009) Limit values for phenol in food-contact articles and toys are to be updated. Opinion No 038/2009, 18 August 2009. http://www.bfr.bund.de/cm/349/limit_values_for_phenol_in_food_contact_articles_and_toys_are_to_be_updated.pdf

⁸ Voedsel en Waren Autoriteit (2004) Market Surveillances on Toy Safety. Report nr. ND04o063/01. www.vwa.nl/txmpub/files/?p_file_id=10468

⁹ Suortti T (1990) Determination of phenol in poly(vinyl chloride). J Chromatogr. 1990 May 16; 507:417-20. <http://www.ncbi.nlm.nih.gov/pubmed/2380304>

¹⁰ CEN TC 52 (2002) Final report of the work of CEN/TC 52/WG 9 – Risk assessment. Contract BC/CEN/97/29.1.1. August 2002, p. 85.

¹¹ Activity report 1989 – 91 of the Scientific Advisory Committee to examine the toxicity and ecotoxicity of chemical compounds (EUR 13976). In Annex A to: CEN TC 52 (2002) Final report of the work of CEN/TC 52/WG 9 – Risk assessment. Contract BC/CEN/97/29.1.1. August 2002.

¹² Scientific Committee on Health and Environmental Risks (SCHER), Opinion on "CEN's response to the opinion of the CSTEE on the assessment of CEN report on the risk assessment of organic chemicals in toys", adopted on 29 May 2007, pp. 8 and 9.

different from those for the migration limit for phenol as a monomer in toys. The use of phenol as a preservative is not regulated for food contact materials.

- (10) Formamide (CAS number 75-12-7) is used, among others, in the plastics and polymers industry, particularly as a solvent, plasticiser or as a substance associated with a blowing agent used in the creation of foam¹³. In 2010 several Member States identified formamide in a range of foam toys, such as puzzle mats, which gave rise to concerns for the health of children through inhalation. Some Member States took or were considering taking regulatory action.
- (11) In its deliberations about formamide the subgroup "Chemicals" took the opinion of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) as a basis. The opinion recommended that emission into the air of formamide from puzzle mats be limited, so that it does not exceed 20 µg/m³ measured 28 days after unpacking and confinement in an outgassing chamber of new mats before their sale, following a test method¹⁴ in accordance with the ISO 16000-6 and 16000-9 standards and under suitable conditions for sampling within products and batches of products.
- (12) Formamide is classified under Regulation (EC) No 1272/2008 as toxic to reproduction category 1B. According to point 4 of Part III of Annex II to Directive 2009/48/EC, substances toxic to reproduction of category 1B such as formamide may be present in toys in concentrations equal to or smaller than the relevant concentration established for the classification of mixtures containing it, namely 0,5%, which equals 5 000 mg/kg (content limit), before 1 June 2015, and 0,3%, which equals 3 000 mg/kg (content limit) thereafter. Directive 2009/48/EC does not currently provide for an emission limit for formamide.
- (13) In the light of the above, the subgroup "Chemicals" recommended, at its meeting of 28 November 2013, that emissions of formamide from foam toy materials be limited in Appendix C to Annex II of the Directive to 20 µg/m³ after a maximum of 28 days from commencement of the emission testing. There are no known uses of formamide in food contact materials to be considered.
- (14) 1,2-Benzisothiazol-3(2H)-one (1,2-benzisothiazolin-3-one, BIT, CAS number 2634-33-5) is used as a preservative in toys¹⁵ including hobby paints and finger paints¹⁶, as shown by the results of a market survey involving economic operators and their trade associations, consumer representatives and allergy centres as well as through internet searches and shop visits¹⁷.
- (15) In its deliberations about BIT the subgroup "Chemicals" took as a basis the related opinion of the Scientific Committee on Consumer Safety (SCCS) noting that BIT is a well-documented contact allergen¹⁸. Although the opinion considers BIT as only a moderate sensitiser with a lower potency than other marketed cosmetic preservatives¹⁹,

¹³ French Agency for Food, Environmental and Occupational Health & Safety (ANSES), Opinion on the uses of formamide in consumer goods and health risks related to formamide in children's foam puzzle mats. ANSES Opinion, Request No. 2010-SA-0302, 4 July 2011, p. 4.

¹⁴ Emission test protocol with relative humidity of 50%, a temperature of 23°C, an air renewal rate of 0.5 volume.h⁻¹, a normal room size of 30 m³ and an emissive surface for the mat of 1.2 m².

¹⁵ Danish EPA (2014) Survey and health assessment of preservatives in toys. Survey of chemical substances in consumer products no. 124, 2014; table 24 on p. 56.

¹⁶ See footnote 15, pp. 38 – 39.

¹⁷ See footnote 15, p. 19 and following.

¹⁸ Scientific Committee on Consumer Safety (SCCS), Opinion on benzisothiazolinone (BIT). Opinion adopted on 26 – 27 June 2012, pp. 16 and 26.

¹⁹ See footnote 18, p. 16.

it concludes that isothiazolinones are important contact allergens for the consumer in Europe²⁰.

- (16) BIT is classified under Regulation (EC) No 1272/2008 as a skin sensitiser. Directive 2009/48/EC has currently no specific limit value for BIT, nor a general limit value for sensitisers.
- (17) In the light of the above, the subgroup "Chemicals" considered that BIT should not be used in toys. In accordance with European Standard EN 71-9, substances not to be used should be limited to the limit of quantification (LOQ) of an appropriate test method²¹. Accordingly the subgroup "Chemicals" recommended, at its meeting of 26 March 2014, that BIT in toys be limited to its LOQ, namely to a maximum concentration of 5 mg/kg. The use of BIT is not regulated for food contact materials.
- (18) 5-Chloro-2-methylisothiazolin-3(2H)-one (CMI) and 2-methyl-isothiazolin-3(2H)-one (MI) in a ratio of 3:1 (CAS number 55965-84-9)²² as well as its individual components CMI (CAS number 26172-55-4) and MI (CAS number 2682-20-4) are used as preservatives in toys²³ including hobby paints, finger paints, window/glass paints, glues and soap bubbles²⁴.
- (19) In its deliberations about CMI and MI in a ratio of 3:1 as well as the individual components CMI and MI the subgroup "Chemicals" took as a basis the related SCHER opinion noting that neither CMI and MI in a ratio of 3:1 nor the individual components CMI and MI are recommended for use in toys, due to contact allergic reactions observed with these substances in cosmetics²⁵. The subgroup "Chemicals" also took account of the related SCCS opinion which considers CMI and MI in a ratio of 3:1 an extreme contact allergen in humans as demonstrated by available data²⁶.
- (20) CMI and MI in a ratio of 3:1 is classified under Regulation (EC) No 1272/2008 as a skin sensitiser; CMI and MI individually are not classified under the Regulation. Directive 2009/48/EC has currently no specific limit value for CMI/MI 3:1, nor for CMI or MI individually, nor a general limit value for sensitisers.
- (21) In the light of the above the subgroup "Chemicals" recommended at its meeting of 15 February 2012 that CMI and MI in a ratio of 3:1 should not be used in toys.
- (22) According to the German Federal Institute for Risk Assessment (BfR, Bundesinstitut für Risikobewertung)²⁷ limit values for CMI and MI, which are strongly allergenic, should be set at a concentration considered protective for individuals who are already sensitised. This is the strictest way to limit allergens, since already sensitised individuals suffer from an allergy outbreak at even lowest allergen concentrations.

²⁰ See footnote 18, p. 26.

²¹ EN 71-9:2005+A1:2007, Annex A, section A.10.

²² Trade names are KathonTM CG, Microcare IT, Microcare ITL, Acticide 14, Acticide LG, according to the opinion of the Scientific Committee on Consumer Safety (SCCS) of 8 December 2009, p. 6.

²³ See footnote 15, table 24 on p. 56.

²⁴ See footnote 15, pp. 38 – 39.

²⁵ See footnote 12, p. 8 and table 1 on p. 9.

²⁶ Scientific Committee on Consumer Safety (SCCS), Opinion on the mixture of 5-chloro-2-methylisothiazolin-3(2H)-one and 2-methylisothiazolin-3(2H)-one. Opinion adopted on 8 December 2009, p. 35.

²⁷ Position paper of the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) of 24.9.2012, p. 4.

According to the abovementioned SCCS opinion such concentration is below 2 mg/kg²⁸.

- (23) According to the BfR, market surveillance is able to routinely quantify CMI down to 0,75 mg/kg and MI down to 0,25 mg/kg²⁹ (limits of quantification, LOQs).
- (24) In the light of the above, the Expert Group on Toys Safety recommended at its meeting of 23 May 2014 to also limit the uses of CMI and MI individually to their LOQs.
- (25) While there is a specific migration limit for MI individually as an additive for use in certain food contact materials, the basic assumptions for deriving that migration limit are different from those for the content limit for MI in toys. The uses of CMI and MI in a ratio of 3:1 and of CMI individually are not regulated for food contact materials.
- (26) A variety of preservatives other than BIT, CMI and MI in a ratio of 3:1 as well as CMI and MI individually are available, which could be used in toys instead. They most likely do not present any health risk³⁰ to children playing with toys, when such toys are preserved at concentrations usually applied in practice³¹.
- (27) In view of the above, Appendix C of Annex II to Directive 2009/48/EC should be amended to include a migration limit as well as a content limit for phenol, an emission limit for formamide, and content limits for BIT, for CMI and MI in a ratio of 3:1, as well as for CMI and MI individually, in toys.
- (28) The measures provided for in this Directive are in accordance with the opinion of the Toy Safety Committee,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Appendix C of Annex II to Directive 2009/48/EC is replaced by the following:

"Appendix C

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 adopted in accordance with Article 46(2)

Substance	CAS No	Limit value
TCEP	115-96-8	5 mg/kg (content limit)
T CPP	13674-84-5	5 mg/kg (content limit)
TDCP	13674-87-8	5 mg/kg (content limit)
Bisphenol A	80-05-7	0,1 mg/l (migration limit) in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005.

²⁸ See footnote 27, p. 33.

²⁹ See footnote 28, p. 4.

³⁰ Parabens, 2-phenoxyethanol, formaldehyde, bronopol. See footnote 15, p. 80 and following, p. 120 and following.

³¹ See footnote 15, p. 8.

Phenol	108-95-2	5 mg/l (migration limit) as a monomer 10 mg/kg (content limit) as a preservative Compliance with both limits is to be determined in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005.
Formamide	75-12-7	20 µg/m ³ (emission limit) after a maximum of 28 days from commencement of the emission testing of foam toy materials.
1,2-benzisothiazol-3(2H)-one	2634-33-5	5 mg/kg (content limit)
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9	1 mg/kg (content limit)
5-Chloro-2-methyl-isothiazol-3(2H)-one	26172-55-4	0,75 mg/kg (content limit)
2-methylisothiazol-3(2H)-one	2682-20-4	0,25 mg/kg (content limit)

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Article 2

- 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.
- 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*