Commission Directive (EU) 2017/774 of 3 May 2017 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, as regards phenol (Text with EEA relevance)

COMMISSION DIRECTIVE (EU) 2017/774

of 3 May 2017

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, as regards phenol

(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(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 Council[(2)], allergenic fragrances and certain elements. 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 resin-bonded wood[(3)] for toys. The degradation of phenolic antioxidants in polymers can be a further source of phenol in toys[(4)]. Phenol was identified in emissions from game consoles[(5)], in one of six analysed tents or tunnels for children[(6)]

and in packaging film[7], it was tested in bath toys and other inflatable toys[8], 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 or water-based liquid inks (e.g. felt-tipped marker pens)[10].

(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 71-9:2005+A1:2007) and provide specific methods of sample preparation (EN 71-10:2005) and measurement (EN 71-11:2005). EN 71-11:2005 repeats and details the limit values for phenol in toy materials set in EN 71-9:2005+A1:2007, 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 large[11].

(7) The subgroup 'Chemicals' furthermore took account of the opinion of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) at the European Food Safety Authority (EFSA), which reduced the tolerable daily intake (TDI) of phenol from 1,5 mg/kg body weight per day to 0,5 mg/kg body weight per day[12].

(8) 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.

(9) In the light of the above, the subgroup 'Chemicals' recommended at its meetings of 26 March 2014 and 18 February 2015 that phenol be limited in toys to 5 mg/l (migration limit) when analysed in polymeric materials, and to a maximum concentration of 10 mg/kg (content limit) when analysed as a preservative, it being understood that 10 mg/kg (content limit) are a *de facto* use ban. Analyses should be carried out in accordance with European standards EN 71-10:2005 and EN 71-11:2005.

(10) 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 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.

(11) In view of the above, Appendix C to Annex II to Directive 2009/48/EC should be amended to include a migration limit as well as a content limit for phenol in toys.

(12) The measures provided for in this Directive are in accordance with the opinion of the Committee established in 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 shall be added:

Substance	**CAS No**	**Limit value**
'Phenol	108-95-2	5 mg/l (migration limit) in polymeric materials in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005. 10 mg/kg (content limit) as a preservative in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005.'

Article 2

1 Member States shall adopt and publish, by 4 November 2018 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 4 November 2018.

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, 3 May 2017.

For the Commission

The President

Jean-Claude JUNCKER

(**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.

(**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. https://www.nvwa.nl/binaries/nvwa/documenten/communicatie/inspectieresultaten/consument/2016m/market-surveillances-on-toy-safety/ND04o063-01_speelgoed.pdf

(**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**) 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.

(**12**) European Food Safety Authority (EFSA), Scientific Opinion on the toxicological evaluation of phenol, *EFSA Journal* 2013;11(4):3189 [44 pp]. http://www.efsa.europa.eu/en/efsajournal/pub/3189.htm