

DIRECTIVES

COMMISSION DIRECTIVE 2014/79/EU

of 20 June 2014

amending Appendix C of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards TCEP, TCPP and TDCP

(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) The substance tris(2-chloroethyl) phosphate (TCEP), CAS No 115-96-8, is a phosphate ester used as a flame-retardant plasticiser in polymers. The main industrial branches in which TCEP has been used are the building industry, the furniture and the textile industry. TCEP is classified under 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 ⁽²⁾ as carcinogenic category 2 and toxic for reproduction category 1B.
- (2) Directive 2009/48/EC establishes general requirements for substances which are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) under Regulation (EC) No 1272/2008. Such substances may not be used in toys, in components of toys or in micro-structurally distinct parts of toys, except if inaccessible to children, permitted by a Commission decision or contained in individual concentrations equal to or smaller than the relevant concentrations established for the classification of mixtures containing them as CMRs. In the absence of any specific requirements, TCEP can thus be contained in toys in concentrations equal to or smaller than the relevant concentration established for the classification of mixtures containing it as CMRs, namely 0,5 % as from 20 July 2013 and 0,3 % as from 1 June 2015 respectively.
- (3) TCEP was comprehensively evaluated in 2009 under Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances ⁽³⁾. The risk assessment report, entitled 'European Union Risk assessment on TCEP', shows that TCEP easily migrates, and, when ingested, results in toxicity in the kidney, liver and brain, causing health damages and potentially cancer.
- (4) The risk assessment report also shows that since 2001 there is no EU TCEP production. Its use in the EU had also declined, TCEP being replaced progressively by other flame retardants. Nevertheless, the presence of TCEP in toys cannot be excluded, as most toys available on the EU market are imported, thus manufactured outside the EU.
- (5) To assess the health effects of TCEP in toys and the appropriateness of Directive 2009/48/EC's generic limits for TCEP as a CMR substance, the Commission sent a request for an opinion to the Scientific Committee on Health and Environmental Risks (SCHER). In its opinion, adopted on 22 March 2012 and entitled 'Opinion on tris (2-chloroethyl) phosphate (TCEP) in toys', SCHER notes that health effects (in particular kidney effects) have been observed after repeated exposure to 12 mg of TCEP/kg body weight per day. SCHER also notes that the TCEP content found by the Danish Environmental Protection Agency (Danish EPA) in toys (0,5-0,6 %), as reported in the Danish EPA's 'Survey and risk assessment of perfume and flavours in toys and childcare articles. Survey of chemical substances in consumer products', corresponds to a risk for children, even without considering other exposures. When considering TCEP exposure from other sources than toys (e.g. air, dust), SCHER concludes that

⁽¹⁾ OJ L 170, 30.6.2009, p. 1.

⁽²⁾ OJ L 353, 31.12.2008, p. 1.

⁽³⁾ OJ L 84, 5.4.1993, p. 1.

no additional exposure from toys can be considered as safe, and recommends setting the limit for TCEP in toys at the detection limit of a sufficiently sensitive analytical method.

- (6) In the light of the above, the generic limit values of 0,5 % and 0,3 % referred to by Directive 2009/48/EC appear to be inappropriate for protecting children's health. Following a stakeholder consultation, the 'detection limit of a sufficiently sensitive analytical method' for TCEP was set at 5 mg/kg. As this limit refers to a detection level, it is not based on a toxicological approach.
- (7) In addition to TCEP, SCHER also assessed TCEP's halogenated alternatives, namely tris[2-chloro-1-(chloromethyl) ethyl] phosphate (TDCP), CAS No 13674-87-8, and tris(2-chloro-1-methylethyl) phosphate (TCPP), CAS No 13674-84-5, in the above-mentioned opinion of 22 March 2012. These alternatives were assessed in 2008 under Regulation (EEC) No 793/93.
- (8) In its opinion SCHER agrees with the conclusion of the alternatives' risk assessments that there is sufficient information from the structures, physical-chemical properties, toxicokinetics and mutagenic profiles of TCEP, TDCP and TCPP to support a qualitative read-across, indicating a potential concern for carcinogenicity for TCPP by a non-genotoxic mechanism. The read-across implies, according to SCHER, that considerations given for TCEP could be applied to its halogenated alternatives as well, if used in toy manufacturing.
- (9) TDCP is classified under Regulation (EC) No 1272/2008 as carcinogenic category 2, and for TCPP, although not classified, SCHER identified a potential concern for carcinogenicity. In line with the above considerations for TCEP and the SCHER opinion, limit values for TDCP and TCPP should therefore also be set at 5 mg/kg.
- (10) Directive 2009/48/EC foresees that, to further protect children's health, specific limit values for chemicals can be set out, when appropriate, for toys intended for use by children under three years old or other toys intended to be placed in the mouth.
- (11) Directive 2009/48/EC should therefore be amended accordingly.
- (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

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)
TCPP	13674-84-5	5 mg/kg (content limit)
TDCP	13674-87-8	5 mg/kg (content limit)

Article 2

1. Member States shall adopt and publish, by 21 December 2015 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 21 December 2015.

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, 20 June 2014.

For the Commission
The President
José Manuel BARROSO
