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From: European Commission
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To: Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union

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Subject: Commission Directive .../.../EU of XXX 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 bisphenol A

Delegations will find attached document D029355/04.

Encl.: D029355/04



Brussels, **XXX**
[...] (2014) **XXX** draft

COMMISSION DIRECTIVE ../.../EU

of **XXX**

**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 bisphenol A**

(Text with EEA relevance)

D029355/04

COMMISSION DIRECTIVE ../.../EU

of **XXX**

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 bisphenol A

(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) 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 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 1907/2006². 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. To further protect children's health, specific limit values for such substances 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.
- (2) The substance bisphenol A is a high volume chemical that is widely used in the production of a large variety of consumer products. Bisphenol A is used as a monomer in the manufacture of polycarbonate plastics. Polycarbonate plastics are used, amongst others, in the manufacture of toys. Moreover, bisphenol A has been found in certain toys.
- (3) Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys³ governed the essential safety requirements for chemical properties of toys until 19 July 2013. European standard EN

¹ OJ L 170, 30.6.2009, p. 1.

² OJ L 353, 31.12.2008, p. 1.

³ OJ L 187, 16.7.1988, p. 1.

71-9:2005+A1:2007 provides a migration limit of 0.1 mg/l for bisphenol A. European standards EN 71-10:2005 and EN 71-11:2005 provide the relevant test methods. The limits and methods for bisphenol A set out in EN 71-9:2005+A1:2007, EN 71-10:2005 and EN 71-11:2005 are used by the toy industry as a reference to ensure that there is no unsafe exposure from bisphenol A in toys. Yet, those standards do not constitute harmonised standards.

- (4) Bisphenol A is classified under Regulation (EC) No 1272/2008 as toxic for reproduction category 2. In the absence of any specific requirements, bisphenol A can 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 5% as from 20 July 2013 and 3% as from 1 June 2015 respectively. It cannot be excluded that that concentration may lead to increased exposure of small children to bisphenol A, compared to the migration limit of 0.1 mg/l for bisphenol A set by European standards EN 71-9:2005+A1:2007, EN 71-10:2005 and EN 71-11:2005.
- (5) Bisphenol A was comprehensively evaluated in 2003 and 2008 under Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances⁴. The final risk assessment report, entitled "Updated European Union Risk Assessment Report 4,4'-isopropylidenediphenol (bisphenol-A)", found, among other things, that bisphenol A has endocrine modulating activity in a number of *in vitro* and *in vivo* screening assays and concluded that further research was needed to resolve the uncertainties surrounding the potential for bisphenol A to produce adverse effects on development at low doses. Nevertheless, a high level of protection of children against risks caused by chemical substances in toys, in the light of the particular needs of children, who are a vulnerable group of consumers, warrants incorporating the migration limit of 0.1 mg/l for bisphenol A into Directive 2009/48/EC.
- (6) The effects of bisphenol A are under evaluation in scientific fora including the European Food Safety Authority. The migration limit laid down by this Directive should be reviewed if relevant new scientific information becomes available in the future.
- (7) Directive 2009/48/EC should therefore be amended accordingly.
- (8) The measures provided for in this Directive are in accordance with the opinion of the Committee,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

"Appendix C

⁴ OJ L 84, 5.4.1993, p. 1.

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)
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

"

Article 2

1. Member States shall adopt and publish, by [... *(Fill in same date as in Article 2 of the Commission Directive on TCEP, TCPP and TDCP)*] 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
José Manuel BARROSO