Commission Directive (EU) 2017/898 of 24 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 bisphenol A (Text with EEA relevance)

COMMISSION DIRECTIVE (EU) 2017/898

of 24 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 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 toys[(1)], and in particular Article 46(2) thereof,

Whereas:

(1) Directive 2009/48/EC establishes certain requirements for chemical substances which are classified as carcinogenic, mutagenic or toxic for reproduction under Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(2)]. Appendix C to Annex II to Directive 2009/48/EC 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) The specific limit value for bisphenol A (CAS number 80-05-7) is 0,1 mg/l (migration limit). European standards EN 71-10:2005 (sample preparation) and EN 71-11:2005 (measurement) provide the relevant test methods.

(3) EN 71-10:2005 requires that 10 cm^2 of a toy material be extracted with 100 ml of water during one hour. Compliance with the specific limit value of 0,1 mg/l thus means that during this extraction a maximum of 0,01 mg bisphenol A may migrate out of the toy material.

(4) In order to provide it with advice 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. The subgroup ‘Chemicals’ of the Expert Group on Toys Safety considered at its meeting on 1 October 2015 that applying the specific limit value and the test methods set out above leads to an exposure of 3 microgram per kilogram body weight per day in a child of 10 kg body weight mouthing a toy during 3 hours daily.

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(5) New data on bisphenol A and refined methodologies led the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) of the European Food Safety Authority (EFSA) to set a 'temporary' tolerable daily intake (TDI) for bisphenol A at 4 microgram per kilogram body weight per day[(3)]. The CEF Panel designated the TDI as temporary, pending the outcome of the long-term study in rats involving prenatal as well as postnatal exposure to bisphenol A, currently being undertaken by National Toxicology Programme of the United States Food and Drug Administration.

(6) In the light of the above, the subgroup 'Chemicals' of the Expert Group on Toys Safety recommended at its meeting of 1 October 2015 that bisphenol A be limited in toys to 0,04 mg/l (migration limit) when tested in accordance with EN 71-10:2005 and EN 71-11:2005, assuming a child's body weight of 10 kg, a daily mouthing time of three hours, a mouthed toy surface of 10 cm^2 and an allocation of 10 % of the temporary TDI to the exposure of a child to bisphenol A from toys. The Expert Group on Toys Safety supported this recommendation at its meeting of 14 January 2016.

(7) While Commission Regulation (EU) No 10/2011[(4)] sets down a specific migration limit for bisphenol A as a monomer for use in certain food contact materials, as well as a prohibition to use bisphenol A for the manufacture of polycarbonate infant feeding bottles, the basic assumptions for deriving that migration limit and laying down the prohibition are different from those for the migration limit for bisphenol A in toys.

(8) In the light of available scientific evidence and considering the differences between toys and materials which come into contact with food, the currently applicable specific limit value for bisphenol A in toys is too high and should be revised.

(9) The effects of bisphenol A are under review in scientific fora. While it may be necessary to review the migration limit if relevant new scientific information becomes available in the future, the limit reflecting current scientific knowledge should be laid down in order to ensure adequate protection of children.

(10) Appendix C to Annex II to Directive 2009/48/EC should therefore be amended accordingly.

(11) 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, in the table, the entry for bisphenol A is replaced by the following:

Bisphenol A	80-05-7	0,04 mg/l (migration limit) in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005.