



EUROPEAN
COMMISSION

Brussels, XXX
[...] (2026) XXX draft

COMMISSION DIRECTIVE (EU) .../...

of XXX

amending Annex II to Directive 2009/48/EC of the European Parliament and of the Council as regards allergenic fragrances in toys, bisphenol A, phenol and benzisothiazolinone

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION DIRECTIVE (EU) .../...

of **XXX**

amending Annex II to Directive 2009/48/EC of the European Parliament and of the Council as regards allergenic fragrances in toys, bisphenol A, phenol and benzisothiazolinone

(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(1), first paragraph, point (b), and Article 46(2) thereof,

- (1) Directive 2009/48/EC lays down a general prohibition of 58 allergenic fragrances in toys in order to protect children from allergies that those fragrances can cause when used in toys. Those allergenic fragrances are listed in the table in Part II, point 11, first paragraph, of Annex II to that Directive.
- (2) Directive 2009/48/EC also lays down a general obligation to list on the toy, on an affixed label, on the packaging or in an accompanying leaflet, the names of any of 72 allergenic fragrances if they are added to a toy where the concentrations of those fragrances exceed 100 mg/kg in the toy or components thereof. Those allergenic fragrances are listed in Part III, point 11, third paragraph, the table, of Annex II to that Directive.
- (3) The allergenic fragrance listed in Part III, point 11, third paragraph, the table, point 7, of Annex II to Directive 2009/48/EC under the name *Lilial* (2-(4-tert-butylbenzyl) propionaldehyde, CAS number 80-54-6), was classified by Commission Delegated Regulation (EU) 2020/1182² as toxic for reproduction category 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council³. In view of this classification, which became applicable on 1 March 2022, this substance should not be allowed in toys. Therefore, it should be removed from the list of allergenic fragrances that can be used in toys subject to labelling and should be included in the list of prohibited allergenic fragrances set out in Part III, point 11, first paragraph, the table, of Annex II to that Directive.

¹ OJ L 170, 30.6.2009, p. 1, ELI: <http://data.europa.eu/eli/dir/2009/48/oj>.

² Commission Delegated Regulation (EU) 2020/1182 of 19 May 2020 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 261, 11.8.2020, p. 2, ELI: http://data.europa.eu/eli/reg_del/2020/1182/oj).

³ 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, ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>).

- (4) Appendix C to Annex II to Directive 2009/48/EC lays down specific limit values for chemicals in toys intended for children under 36 months or in other toys intended to be placed in the mouth. In particular, Appendix C sets out limit values for bisphenol A, phenol, and 1,2-benzisothiazol-3(2H)-one (BIT), and requires that toys are tested for these substances in accordance with the methods laid down in European standards EN-71-10 and EN - 71-11⁴.
- (5) The European Committee for Standardisation (CEN) adopted in 2025 European Standards EN 71-17:2025 – Safety of toys: Certain isothiazolinones (MIT, CIT, BIT) in aqueous toy materials, EN 71-18:2025 – Safety of toys: Phenol in aqueous (content) and polymeric (migration) toy materials and EN 71-19:2025 – Safety of toys: Migration of bisphenol A from toy materials. These three standards provide for specific testing methods for BIT, phenol and bisphenol A in toys, respectively, in accordance with the limit values set out in Appendix C to Annex II to Directive 2009/48/EC. As a result, European Standards EN 71-10 and EN 71-11 no longer represent the state of the art as regards the testing methods for BIT, phenol and bisphenol A. Appendix C to Annex II to that Directive should, therefore, be amended to delete the obligation to analyse the presence of BIT, phenol and bisphenol A in toys in accordance with the methods laid down in European Standards EN 71-10 and EN 71-11. Following the deletion of the reference to European Standards EN 71-10 and EN 71-11 from Appendix C to Annex II of that Directive, European Standards EN 71-17:2025, EN 71-18:2025 and EN 71-19:2025, which provide relevant testing methods to demonstrate compliance of toys with the limit values for specific substances set out in Appendix C to Annex II to that Directive, may be assessed and, where appropriate, referenced in the *Official Journal of the European Union* in order to provide a presumption of conformity with those limit values.
- (6) Appendix C to Annex II to Directive 2009/48/EC sets out a limit value for bisphenol A in toys intended for children under 36 months or to be put in the mouth of 0,04 mg/l (migration limit). This limit value was based on the 2015 European Food Safety Authority (EFSA) scientific opinion on a ‘temporary’ tolerable daily intake (TDI) for bisphenol A, which was set at 4 microgram per kilogram body weight per day⁵. Based on that TDI, the bisphenol A migration limit of 0,04 mg/l in toys was set assuming a child's body weight of 10 kg, a daily mouthing time of three hours, a mouthed toy surface of 10 cm² and an allocation of 10 % of the temporary TDI to the exposure of a child to bisphenol A from toys.
- (7) EFSA published an updated opinion on bisphenol A in 2023⁶, taking into account the results of new studies and scientific data to address remaining uncertainties. In this opinion, EFSA concluded that bisphenol A exerts a number of adverse effects, including on the immune system, which it considered the most sensitive to effects from bisphenol A. On that basis, EFSA established a TDI of 0,2 nanograms per kilogram (ng/kg) bodyweight, which is 20 000 times lower than the temporary TDI of 4 micrograms per kilogram (µg/kg) (or 4 000 ng/kg) bodyweight it established in its 2015 opinion. EFSA noted that a dose range similar to that which led to effects on the

⁴ European standard EN – 71- 10 concerns sample preparation and extraction of organic chemical compounds, and European Standard EN 71-11 concerns methods of analysis of organic chemical compounds.

⁵ EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) (2015) Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs: Executive summary. *EFSA Journal* 2015; 13 (1):3978, 23 pp. doi:[10.2903/j.efsa.2015.3978](https://doi.org/10.2903/j.efsa.2015.3978).

⁶ *EFSA Journal* 2023; 21(4):6857, 392 pp. <https://doi.org/10.2903/j.efsa.2023.6857>.

immune system also caused adverse metabolic effects as well as adverse effects on the reproductive and developmental systems. A comparison between the TDI of 0,2 ng/kg bodyweight and the dietary exposure estimates from EFSA's 2015 opinion indicates that the exposure for all age groups exceeds the TDI by two to three orders of magnitude. EFSA therefore concluded that there is a health concern from dietary bisphenol A exposure for all population groups. In view of EFSA's updated opinion in 2023, the limit value set out in Appendix C to Annex II of Directive 2009/48/EC is too high and should, therefore, be revised.

- (8) European Standard *EN 71-19: Migration of bisphenol A from toy materials* developed specific testing methods for bisphenol A in toys and established a new limit of quantification for bisphenol A at 0,005 mg/l. In order to ensure adequate protection of children from bisphenol A in toys, the limit value for bisphenol A in Appendix C to Annex II to Directive 2009/48/EC should be reduced to the lowest achievable value with existing testing methods developed by toy industry, that is, to 0,005 mg/l.
- (9) The Expert Group on Toy Safety, as well as the subgroup "Chemicals" of that Expert Group have expressed their support for these amendments.
- (10) 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 Committee established by Article 47 of Directive 2009/48/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex II to Directive 2009/48/EC is amended as follows:

- (1) in Part III, point 11 is amended as follows:
 - (a) in the first paragraph, in the table, the following entry is added:

'No.	Name of the allergenic fragrance	CAS number
(59)	2-(4-tert-butylbenzyl) propionaldehyde	80-54-6'

;

- (b) in the third paragraph, the table, entry (7) is deleted;
- (2) in Appendix C, the table, the entries for 'bisphenol A', '1,2-benzisothiazol-3(2H)-one' and 'phenol' are replaced by the following:

'Bisphenol A	80-05-7	0,005 mg/l (migration limit)'
'1,2-benzisothiazol-3(2H)-one	2634-33-5	5 mg/kg (content limit) in aqueous toy materials'
'Phenol	108-95-2	5 mg/l (migration limit) in polymeric materials.

	10 mg/kg (content limit) as a preservative.’.
--	---

Article 2

1. Member States shall adopt and publish, by *[Insert here the date 12 months after the date of 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 *[Insert here the date 12 months after date of publication in the OJ]*.

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
Ursula von der Leyen