



FCM

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EU Issues BPA Ban for Food Contact Materials

On December 31, 2024, the EU issued Regulation (EU) 2024/3190 to amend (EU) 10/2011 and repeal (EU) 2018/213, requiring that BPA be prohibited in food contact materials except for exemptions. From now on, food contact materials and articles sold to the EU will face more stringent requirements. The regulation will take effect on the 20th day after it is published in the EU Official Gazette. The details are as follows:

Scope:

This Regulation applies to food contact materials and articles falling within the scope of Article 1(2) of (EC) 1935/2004, including: adhesives, rubber, ion exchange resins, plastics, printing inks, silicones, varnishes and coatings.

Prohibited requirements:

1. It is prohibited to use BPA and its salts to manufacture food contact materials and articles. It is also prohibited to place food contact materials and articles made with BPA and its salts on the EU market, unless they meet the exemptions in Annex II of this Regulation. The exemptions are as follows:

FCM substance No	CAS No	Substance name	Material type	Specific application	Other restrictions
151	80-05-7	4,4'-isopropylidene diphenol (bisphenol A)	Varnishes and coatings	For use as a monomer or starting substance in the manufacture of liquid epoxy resins to be applied on self-supporting food contact materials or articles with a capacity greater than 1 000 litres	Migration into food shall not be detectable. Final food contact articles shall be cleaned and flushed prior to first being brought into contact with food
			Plastics	For use as a monomer or starting substance in the manufacture of polysulfone filtration membrane assemblies	Migration into food shall not be detectable. Final food contact articles shall be cleaned and flushed prior to first being brought into contact with food

2. Food contact materials and articles manufactured using other bisphenols or bisphenol derivatives





shall not contain any residual BPA;

3. The use of hazardous bisphenols or bisphenol derivatives other than BPA is prohibited unless the use has been authorized in accordance with Article 6 of this Regulation and is listed in Annex II. Hazardous bisphenols or bisphenol derivatives are bisphenols or bisphenol derivatives classified as category 1A or 1B "mutagenic", "carcinogenic", "reproductive toxicity" or category 1 "endocrine disruptor to human health" in Part 3 of Annex VI to CLP Regulation (EC) No. 1272/2008.

Declaration of compliance and supporting documentation

The business operator shall provide a written declaration of compliance, which shall include:

1. The identity and address as well as contact details including either a current telephone number or email address of the business operator issuing the declaration of compliance;
2. The identity and address as well as contact details including either a current telephone number or email address of the business operator which manufactures or imports the food contact material or article;
3. The identity of the food contact material or article, including both intermediate food contact materials and final food contact articles;
4. The date of the declaration;
5. A list of any bisphenols or bisphenol derivatives used in the manufacture of the food contact material or article;
6. A statement that the intermediate food contact material or article or final food contact article complies with this Regulation and the requirements set out in Articles 3, 15 and 17 of Regulation (EC) No 1935/2004.

Amendment to (EU) 10/2011

1. In Article 6, the following paragraph is added:

‘6. By way of derogation from Article 5, 2,2-bis(4-hydroxyphenyl)propane (“bisphenol A” or “BPA”) (CAS No 80-05-7) and other hazardous bisphenols or hazardous bisphenol derivatives as defined and falling within the scope of Regulation (EU) 2024/3190 may only be used in the manufacture of plastic materials and articles in accordance with that Regulation.’;

2. In Table 1 of Annex I, the entries concerning substance No 151 (2,2-bis(4-hydroxyphenyl)propane) and substance No 154 (4,4'-dihydroxydiphenyl sulphone) are deleted.

Transitional provisions





Single-use final food contact articles

1. Products that comply with the applicable provisions before the date of entry into force of this Regulation but do not comply with this Regulation may be placed on the market before July 20, 2026;
2. As an exemption from Article 1, the following products that comply with the applicable provisions before the date of entry into force of this Regulation but do not comply with this Regulation may be placed on the market before January 20, 2028:
 - (1) Articles used to preserve fruits or vegetables, fishery products,
 - (2) Single-use final food contact articles on which a varnish or coating manufactured using BPA has only been applied to the exterior metal surface;
3. Single-use final food contact articles placed on the market in accordance with paragraphs 1 and 2 may be filled with food and sealed during the 12 months following the expiry of the applicable transitional period. The resulting packaged food may be placed on the market until exhaustion of stocks.

Repeat-use final food contact articles

1. Repeat-use final food contact articles manufactured using BPA and complying with the rules as applicable before the date of entry into force of this Regulation, which do not comply with the rules in this Regulation, may be first placed on the market until 20 July 2026.
2. By way of derogation from paragraph 1, repeat-use final food contact articles used as professional food production equipment, complying with the rules as applicable before the date of entry into force of this Regulation, which do not comply with the rules in this Regulation, may be first placed on the market until 20 January 2028.
3. Repeat-use final food contact articles that were first placed on the market in accordance with paragraphs 1 and 2 may remain on the market until 20 January 2029 at the latest.

Original link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202403190

HCT SOLUTION:

After the release of this regulation, the EU has greatly tightened the requirements for bisphenol A in food contact materials. HCT recommends that companies involved in food contact materials and products promptly check whether the materials they use contain BPA, especially PC, epoxy resin and other materials, and eliminate BPA-containing materials as soon as possible to meet the requirements of this regulation.

