Ban on bisphenols in Food Contact Materials - Regulation (EU) 2024/3190

TÜV Rheinland LGA Products - Information January 2025

The Commission has adopted a ban on the use of Bisphenol A (BPA) in food contact materials.

The ban means that BPA will not be allowed in products that come into contact with food or drink, such as the coating on metal cans, reusable plastic drink bottles, water distribution coolers and other kitchenware.

The ban follows a positive vote by EU Member States earlier in 2024, and a scrutiny period by the Council and the European Parliament, and takes into account the latest scientific assessment[1] from the European Food Safety Authority (EFSA). EFSA concluded in 2023 that BPA had potentially harmful effects on the immune system, and the proposed ban followed both a public consultation and extensive discussions with all Member States.

The legally binding version of Commission Regulation (EU) 2024/3190 of 19 December 2024 [2] was published in the Official Journal on 31.12.2024. Please find our overview for you.

ARTICLE 1 - SUBJECT MATTER AND SCOPE

The regulation applies to all FCMs, in particular with regard to the use of BPA and other critical bisphenols in the manufacture of FCMs:

- Plastics
- Varnishes and coatings
- Printing inks
- Silicones
- Adhesives
- Ion-exchange resins
- Rubbers

ARTICLE 3 - PROHIBITION OF THE USE OF BPA

- The use of BPA and its salts at any stage of the manufacture of the aforementioned materials and the placing on the market of food contact materials and articles made wholly or partly from these materials using BPA is prohibited.
- Exceptions to this prohibition are subject to certain restrictions, see information on Article 10.

[1] Bisphenol A in food is a health risk | EFSA
[2] Regulation - EU - 2024/3190 - EN - EUR-Lex

ARTICLE 4 - PROHIBITION OF THE PRESENCE OF BPA

- Materials and articles that come into contact with food and have been manufactured using another bisphenol or bisphenol derivative must not contain any residues of BPA.

ARTICLE 5 - PROHIBITION OF THE USE OF OTHER HAZARDOUS BISPHENOLS

- The use of other hazardous bisphenols at any stage of the manufacture of the aforementioned materials and the placing on the market of food contact materials and articles made wholly or partly from these materials using critical bisphenols is prohibited.
- This requirement does not apply to bisphenols that are otherwise authorized (e.g. in Regulation (EU) No. 10/2011).

ARTICLE 8 - WRITTEN DECLARATION OF COMPLIANCE

- - A declaration of compliance has to be issued for FCM falling under the exceptions in Annnex II.

ARTICLE 9 - VERIFICATION OF COMPLIANCE WITH THE REQUIREMENTS

The following rules apply for the selection of methods to check whether a food contact material or article contains BPA, other hazardous bisphenols or hazardous bisphenol derivatives or releases these substances to food above the specified detection limit.

- Where a method has been developed by the European Reference Laboratory for Food Contact Materials or a specific method is recommended, this method shall be chosen.
- The chosen method shall have a detection limit of 1 µg/kg, unless a different detection limit is specified or the method recommended in the first point has a different detection limit.

ARTICLE 10 - AMENDMENTS TO REGULATION (EU) NO 10/2011

- The entries in the Union list for bisphenol A and bisphenol S are deleted.
- BPA and hazardous bisphenols and bisphenol derivatives may only be used in accordance with Annex II of Regulation (EU) 2024/3190. In all cases migration of BPA must not be detectable with a detection limit of 1 µg/kg
    - 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
    - Plastics: for use as a monomer or starting substance in the manufacture of polysulfone filtration membrane assemblies.

ARTICLE 11 AND 12 - TRANSITIONAL PROVISIONS

- General transitional period for final food contact articles articles until 20 July 2026
- Longer periods for single use packaging used for fruits, vegetables and fishery products and articles on which varnish and coating using BPA is only applied to the outside: 20 January 2028
- Longer periods for repeat-use final food contact articles used as professional food production equipment (such as confectionary moulds, seals, pumps) using BPA: 20. January 2028

SUMMARY/ IMPORTANT ASPECTS

- The use of BPA and its salts in the manufacture of food contact materials and articles as above and the placing on the Union market of food contact materials and articles manufactured using BPA, is prohibited.
- Not only bisphenol A but also bisphenol S and other hazardous bisphenols and bisphenol derivatives are affected.
- Polymers in the production of which the above-mentioned substances are used will no longer be marketable, e.g. certain types of polycarbonates, epoxy resins, phenol-formaldehyde and related resins.

HINTS FOR ACTION

- It is recommended to get an overview of which materials will be affected by the expected ban on bisphenols and, if necessary, to examine and prepare alternatives.
- Currently there is no advice from the JRC available about the analytical methodology
- Using the existing methods and devices, we can provide you with the required detection limit of 1 µg/kg in migration tests; however, there is no guarantee that there might be higher detection limits in certain situations
- For tests on total content, the method details are not clear. We are investing lots of resources, but it might be impossible to reach such a low detection limit in an extraction test. In the current situation, we recommend to do migration testing with a detection limit of 1 µg/kg for the mentioned material types where the intentional use of BPA is probable.

MATERIALS THAT MAY CONTAIN BISPHENOLS, SOME EXAMPLES:

- Synthetic resins based on phenolic resins, in particular phenol-formaldehyde resins
- Synthetic resin, paint and adhesives based on epoxy resins
- Polycarbonates
- Polysulfones, polyether sulfones, PVC, thermoplastic elastomers (TPE) copolymers
- certain coatings or printings, used for paper or other materials

For further technical information, please contact:

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