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COMMISSION RECOMMENDATION

of XXX

on monitoring of the presence of bisphenol A, bisphenol S and other bisphenols in food with follow-up investigations for identifying the source of unintentional presence.

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on monitoring of the presence of bisphenol A, bisphenol S and other bisphenols in food with follow-up investigations for identifying the source of unintentional presence.

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

(1) The substance 4,4'-isopropylidenediphenol (CAS number 80-05-7) (FCM 151), commonly known as bisphenol A ('BPA'), is used in the manufacture of certain food contact materials and articles. Primarily it is used as a monomer or starting substance in the manufacture of epoxy resins that form the basis of varnishes and coatings, including those applied to the internal and external surfaces of metal food packaging, such as cans, tins and jar lids, as well as large tanks and vessels used in food production. It is also used in the manufacture of certain types of plastic food contact materials and articles, including those made from polycarbonate and polysulfone. Due to its diverse chemical properties, BPA may also be used in printing inks, adhesives and other materials that form part of finished food contact articles. BPA can migrate into food from the material or article with which such food is in contact, resulting in exposure to BPA for consumers of those foods.

(2) The European Food Safety Authority (EFSA) Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) adopted in 2023 a scientific opinion on the re-evaluation of the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs[1]. The CEP Panel established a tolerable daily intake (TDI) of 0.2 nanograms per kilogram (ng/kg) bodyweight for bispheol A.

(3) In light of the TDI established by the Authority in its 2023 opinion, even very small amounts of BPA that migrate from food contact materials and articles, several-fold below the current specific migration limit (SML) of 0.05 mg/kg for BPA, could lead to exposure above the established TDI. Therefore, in order to minimise BPA's presence and migration into food and subsequent consumers' dietary exposure as far as possible, its use, including that of its salts, in the manufacture of those food contact materials and articles of which it may be a component, including adhesives, rubbers, ion-exchange resins, plastics, printing inks, silicones and varnishes and coatings, has been prohibited by Commission Regulation (EU) …/… of ../12/2024[2].

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[1] EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids), Scientific Opinion on the re-evaluation of the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs. EFSA Journal 2023;21(4):6857, 392 pp. https://doi.org/10.2903/j.efsa.2023.6857

[2] Commission Regulation (EU) …/… of ../12/2024 on the use of bisphenol A (BPA) and other bisphenols and bisphenol derivatives with harmonised classification for specific hazardous properties in certain materials and articles intended to come into contact with food, amending Regulation (EU) No 10/2011 and repealing Regulation (EU) 2018/213. ELI

(4) As a consequence of similarities in their chemical structure and activity, certain other bisphenols or bisphenol derivatives may also present risks similar to BPA when they are used in food contact materials and articles and migrate into food. Some bisphenols have already been confirmed as having properties that are hazardous to human health due to their reproductive toxicity and have consequently been subject to harmonised classification and listed as such in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[3]. This includes 4,4'-sulphonyldiphenol (CAS number 80-09-1) (FCM 154), commonly known as bisphenol S ('BPS'), which is currently authorised for use in plastic food contact materials and articles.

(5) In addition to the intentional use of BPA in the manufacture of certain food contact materials and articles, its unintentional presence in other food contact materials and articles and subsequent migration into food may also occur at levels of relevance to human health. Principally, it may be present as a contaminant in the input waste stream used to produce recycled materials including paper and board. This contamination can persist despite the application of cleaning and decontamination processes and may eventually be present in the final food contact article, including single use packaging. Business operators do not intentionally use BPA in such manufacturing processes and such contamination cannot be fully controlled. In the light of ongoing efforts in the Union to promote a circular economy, it is neither practical nor proportionate to prohibit the unintentional presence of BPA in recycled materials. Furthermore, BPA can be present in food from sources other than food contact materials.

(6) It is important to perform a monitoring on the presence of BPA and BPS in food and in case of a finding above a threshold level to perform investigations on the source of contamination. The monitoring and outcome of the investigations will enable to establish the level of BPA that is to be considered as unavoidable presence from sources that cannot be controlled and that is not related to the intentional use of BPA.

(7) It is therefore appropriate to recommend the monitoring of BPA and BPS in food and to perform follow-up investigations on the source of contaminantion.

HAS ADOPTED THIS RECOMMENDATION:

(1) Member States should, with the active involvement of food business operators as well as manufacturers, processors and distributors of food contact materials and other interested parties, monitor the presence of bisphenol A (BPA), bisphenol S (BPS) and other bisphenols in food during 2025, 2026 and 2027. The monitoring should cover all kinds of food, but in particular target food packed in food contact materials from recycled materials including paper and board.

(2) Member States should perform food sampling in accordance with the provisions laid down in Commission Regulation (EC) No 333/2007[4]. The method of analysis used for the analysis of BPA and BPS in food and food contact material should have a limit of quantifcation of 1 µg/kg.

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[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] Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs, OJ L 88, 29.3.2007, p. 29. ELI: http://data.europa.eu/eli/reg/2007/333/oj

(3) In case of a finding of a level of 10 µg/kg of BPA or BPS in food, investigations should be performed to identfy the source of contamination, certainly in case of repetitive findings.

These investigations should include:

- Monitoring of the presence of BPA and BPS in the food contact material in which the sampled food was packed.
- Monitoring of the presence of BPA and BPS in food contact materials used in the supply chain, such as during storage or processing or other sources where there is a clear indication that these are contributing to the presence of BPA, and BPS in food.
- Where BPA and BPS are found in food which could not be related to the presence of BPA and BPS in the food packaging, further investigations should be performed in order to determine the possible source or sources.

(4) For all findings of BPA and BPS in food above the threshold of 0.01 mg/kg, a report on the outcome of investigations together with an assessment if the presence of BPA and BPS in food is

- related to intentional use of BPA or BPS in food contact material (authorised intentional use during transition period or unauthorised intentional use), or

- uintentional and unavoidable with information on the source of contamination and information why the presence of BPA or BPS is unavoidable, or

- unintentional but avoidable to a certain extent with information on the source of contamination and the preventive measures/good practies that could have been taken to minimize or avoid the presence of BPA or BPS in food.

By 30 June each year, the report on the findings of BPA or BPS above 10 µg/kg and the outcome of the investigations on the source of contamination should be provided to the Commission.

(5) Member States, food business operators, manufacturers, processors and distributors of food contact materials and other interested parties should provide to EFSA, by 30 June of each year, the data for the previous year for compilation into one database in line with the requirements of EFSA's Guidance on Standard Sample Description (SSD) for Food and Feed and EFSA's additional specific reporting requirements[5].

Done at Brussels,

Member of the Commission

[5] https://www.efsa.europa.eu/en/call/call-continuous-collection-chemical-contaminants-occurrence-data-0