



Food Packaging Forum Foundation
Staffelstrasse 10
8045 Zürich
Switzerland
foodpackagingforum.org
info@fp-forum.org

European Food Safety Authority
Via Carlo Magno 1A
43126 Parma
Italy

May 7, 2026

PC-1873: Draft statement on data requirements for the safety assessment of hazardous bisphenols other than Bisphenol A (BPA) and their derivatives

Dear Madam or Sir,

We kindly thank EFSA for this opportunity to provide input on its draft scientific opinion regarding the safety assessment of hazardous bisphenols. The Food Packaging Forum Foundation (FPF) is a charitable, independent scientific organization. Our work supports protection of the public from hazardous chemicals in food contact materials and articles, by providing the scientific evidence base.

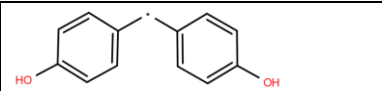
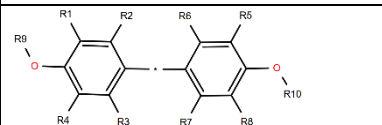
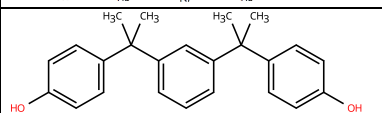
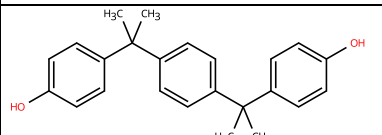
We welcome the publication of this draft statement as an important step towards implementing the ban on hazardous bisphenols and their derivatives, Regulation (EU) 2024/3190. We appreciate that the draft statement goes beyond genotoxicity testing and targets bisphenols and derivatives as a group by introducing data requirements for bisphenols to be newly authorized. However, while we recognise and support the directionality of these measures, we would like to highlight several important issues for ensuring an effective implementation:

The definition used for bisphenols and bisphenol derivatives is too narrow

The definition of bisphenols and bisphenol derivatives used in the draft statement and in Regulation (EU) 2024/3190 is narrow and does not cover all substances commonly understood as “bisphenols” (Table 1). In particular, the requirement that the two hydroxyphenyl groups be linked by merely a single bridging atom excludes relevant bisphenols such as bisphenol M (BPM, CAS 13595-25-0) and bisphenol P (BPP, CAS 2167-51-3), in which the phenyl rings are connected by more than one bridging atom. As a result, these substances do not fall within the scope of the hazardous bisphenol regulation and would not currently be subject to the testing requirements set out in this draft statement, despite being suitable for use in coatings, polycarbonate production, and other application areas where bisphenol A is or has been used. While we recognise

that the definition itself may not be amendable within the present draft statement document, we consider it essential that this limitation is clearly acknowledged, as it risks creating a regulatory gap that will lead to the continued exposure of Europe's citizens to hazardous bisphenols.

Table 1: Definition and structure of bisphenols and derivatives compared to two common bisphenols (Bisphenol P, Bisphenol M), that are not covered by that definition.

Bisphenol Regulatory definition		Note: * refers to any bridging group separating the two phenyl rings by one single atom, but the atom can have any substituent(s)
Bisphenol derivatives Regulatory definition		
Bisphenol M CAS 13595-25-0		The two hydroxyphenyl groups are linked by more than "one single atom", these substances are thus not covered by the regulatory definition.
Bisphenol P CAS 2167-51-3		

Carcinogens and endocrine disrupting chemicals do not have safety thresholds that can practically be enforced, and therefore their authorization for use in food contact materials is not recommended, considering the EU's high ambition to protect public health from hazardous chemical exposures.

Under the current draft, further testing can render 'hazardous bisphenols and bisphenol derivatives' eligible for authorisation in food contact materials after further testing. These substances are already classified as Category 1 'carcinogenic', 'mutagenic', 'toxic to reproduction', or 'endocrine disrupting for human health', and thus confirmed to be highly hazardous for human health regarding endpoints that do not have a safety threshold.

While we acknowledge that this approach is aligned with the current food contact material legislation, the premise that substances showing carcinogenicity or endocrine-disrupting effects are eligible for authorisation in food contact materials would strongly benefit from being reconsidered based on modern toxicological understanding as also aligned with the views of other policy-relevant perspectives ([EU parliament 2016 report](#), [EU Chemicals Strategy for Sustainability 2020](#), [EU Parliament 2026](#)).¹⁻³ What is more, even if such bisphenols would be authorised as monomer starting substances in food contact plastics, empirical evidence shows that monomers do migrate into food and food simulants and that polycarbonate plastics, such as those made with bisphenolic monomers, are highly prone to degradation over time and with alkaline or acidic conditions, leading to a release of the monomer.⁴⁻⁷ These findings are especially relevant for repeat use food contact articles, including those used in food processing.

For endocrine-active substances, there is broad scientific consensus that safe exposure thresholds cannot be derived with sufficient scientific certainty, due to non-monotonic dose-response relationships, low-dose effects, and increased vulnerability during sensitive life stages, or that identified safe exposure thresholds are well below levels that can be enforced – as the case of bisphenol A shows, where the TDI from exposure to the substance migrating from food contact materials is around 1000 times below the current regulatory enforcement level, set at 1 ppb.⁸⁻¹¹ Similarly, no safe threshold can be derived for most genotoxic carcinogens or thresholds cannot be enforced using today's available analytical methods.¹²⁻¹⁴ Hence, if the relevant statement would more clearly reflect current scientific understanding regarding endocrine disruptors and carcinogens, it would constitute strong grounds for not authorizing such substances and removing them from the positive list in EU 10/2011.

Related to this, we note that the currently required hazard data appears to be largely informed by known critical effects of BPA, such as reproductive or immune toxicity. Other critical endpoints documented for bisphenol alternatives – such as neurotoxicity, metabolic disruption, or diverse endocrine modes of action – may not be comprehensively covered in the current draft statement.^{15, 16} Greater clarity would help understand whether the proposed data requirements are sufficient to identify these effects and to provide adequate protection of European consumers.

Testing is not required for already authorized bisphenols and derivatives without harmonized hazard classification

The draft statement outlines data requirements for (1) authorized bisphenols and derivatives with harmonized hazard classifications showing clear evidence for hazard, and (2) for bisphenols and derivatives to be newly authorized. Already authorized bisphenols or derivatives lacking harmonized hazard classification or not showing evidence for CMR properties or endocrine disruption would not be subject to the same level of scrutiny. This gap risks perpetuating information gaps and may undermine the objective of preventing regrettable substitution within the bisphenol and bisphenol derivatives group.

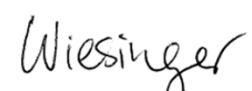
Hazardous bisphenols and derivatives are just one group among many hazardous chemicals and groups authorized for use in food contact materials and articles

We would like to emphasize that the draft statement is being developed within a regulatory framework that already operates with identified gaps regarding harmonized hazard data, testing of the final material and articles, and no risk assessment of migrating chemical mixtures.^{17, 18} While the ban of hazardous bisphenols and derivatives represents a significant advancement, bisphenols are only one group among many chemical groups, including several that are known to be of equal concern, in food contact materials. Overall, more than 190 known hazardous substances are currently authorized for use in plastic food contact materials and articles (Regulation (EU) 10/2011), and more than 420 lack harmonised hazard data, implying that they, too, may

be of high concern.¹⁹ Many of these known hazardous substances may have cumulative or even synergistic effects on human health, which are not taken into account in current approaches to risk assessment that assess individual chemicals but disregard the toxicity of the overall migrate.^{17, 20} This context reinforces the importance of a precautionary approach to the data requirements for hazardous bisphenols and confirms other stakeholders in highlighting the need for a comprehensive revision of the EU's food contact material legislation to ensure the protection of human health, by focusing on material inertness and the removal of known chemicals of concern from the authorized substances list.

In conclusion, we welcome the draft statement as an important step towards removing hazardous bisphenols and derivatives from authorization in food contact materials. However, to fully achieve this objective considering the latest scientific understanding, we encourage EFSA to clarify the scope of substances covered, to avoid threshold-based risk assessment for endocrine-disrupting and carcinogenic substances, and to ensure that empirical data are required for all authorized bisphenols and derivatives and all potentially critical endpoints due to the significant scientific uncertainty associated with the use of in silico data. Again, we thank EFSA for the opportunity to provide input on this important draft scientific opinion and remain available to provide further information within this process.

Yours sincerely,


Helene Wiesinger
Jane Muncke

References

- (1) European Parliament; Schaldemose, C. Implementation of the Food Contact Materials Regulation (EC) No 1935/2004 - 2015/2259(INI). *European Parliament - 2016* https://www.europarl.europa.eu/doceo/document/TA-8-2016-0384_EN.html (accessed 2026-05-07)
- (2) European Commission. Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment. *Brussels - European Commission*,, **2020** COM/2020/667. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2020:667:FIN> (accessed 2026-05-07)
- (3) European Parliamentary Research Services; Katsarova, I. *Food contact materials in the EU - State of play* European Union, 2026. [https://www.europarl.europa.eu/RegData/etudes/BRIE/2026/782669/EPRS_BRI\(2026\)782669_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2026/782669/EPRS_BRI(2026)782669_EN.pdf) (accessed 2026-05-07).

- (4) Huang, J.; He, C.; Li, X.; Pan, G.; Tong, H. Theoretical studies on thermal degradation reaction mechanism of model compound of bisphenol A polycarbonate *Waste Manag* **2018**, 71, 181–191. DOI: [10.1016/j.wasman.2017.10.016](https://doi.org/10.1016/j.wasman.2017.10.016).
- (5) Ghebremariam, D.; Desai, U.; Turan, M.; Cattaneo, G.; Mujovi, F.; Bonnet-Eymard, B.; Faes, A.; Ballif, C.; Sivula, K.; Abdullah, O. Impact of Acetic Acid on the Hydrolysis Kinetics of Polycarbonate *International Journal of Polymer Science* **2026**, 2026 (1). DOI: [10.1155/ijps/3765621](https://doi.org/10.1155/ijps/3765621).
- (6) Geueke, B.; Groh, K. J.; Maffini, M. V.; Martin, O. V.; Boucher, J. M.; Chiang, Y. T.; Gwosdz, F.; Jieh, P.; Kassotis, C. D.; Lanska, P.; et al. Systematic evidence on migrating and extractable food contact chemicals: Most chemicals detected in food contact materials are not listed for use *Critical Reviews in Food Science and Nutrition* **2023**, 63 (28), 9425–9435. DOI: [10.1080/10408398.2022.2067828](https://doi.org/10.1080/10408398.2022.2067828).
- (7) Food Packaging Forum (FPF). *FCCmigex database - A systematic evidence map to explore migrating and extractable food contact chemicals*. 2026. <https://foodpackagingforum.org/resources/databases/fccmigex> (accessed 2026-05-07).
- (8) Duh-Leong, C.; Maffini, M. V.; Kassotis, C. D.; Vandenberg, L. N.; Trasande, L. The regulation of endocrine-disrupting chemicals to minimize their impact on health *Nat Rev Endocrinol* **2023**, 19 (10), 600–614. DOI: [10.1038/s41574-023-00872-x](https://doi.org/10.1038/s41574-023-00872-x).
- (9) World Health Organization (WHO); United Nations Environment Programme (UNEP). *State of the science of endocrine disrupting chemicals 2012*; 2012. <https://www.who.int/publications/i/item/state-of-the-science-of-endocrine-disrupting-chemicals> (accessed 2026-05-07).
- (10) Endocrine Society. *Endocrine-Disrupting Chemicals - An Endocrine Society Position Statement*. Endocrine Society, 2025. <https://www.endocrine.org/advocacy/position-statements/endocrine-disrupting-chemicals> (accessed 2026-05-07).
- (11) Demeneix, B.; Vandenberg, L. N.; Ivell, R.; Zoeller, R. T. Thresholds and Endocrine Disruptors: An Endocrine Society Policy Perspective *J Endocr Soc* **2020**, 4 (10), bvaa085. DOI: [10.1210/jendso/bvaa085](https://doi.org/10.1210/jendso/bvaa085).
- (12) Crump, K. S.; Hoel, D. G.; Langley, C. H.; Peto, R. Fundamental carcinogenic processes and their implications for low dose risk assessment *Cancer Res* **1976**, 36 (9 pt.1), 2973–2979. https://aacrjournals.org/cancerres/article-pdf/36/9_Part_1/2973/2397820/cr0369p12973.pdf (accessed 2026-05-07).
- (13) Crump, K. S. Use of threshold and mode of action in risk assessment *Crit Rev Toxicol* **2011**, 41 (8), 637–650. DOI: [10.3109/10408444.2011.566258](https://doi.org/10.3109/10408444.2011.566258).
- (14) Felter, S. P.; Bhat, V. S.; Botham, P. A.; Bussard, D. A.; Casey, W.; Hayes, A. W.; Hilton, G. M.; Magurany, K. A.; Sauer, U. G.; Ohanian, E. V. Assessing chemical carcinogenicity: hazard identification, classification, and risk assessment. Insight from a Toxicology Forum state-of-the-science workshop *Crit Rev Toxicol* **2021**, 51 (8), 653–694. DOI: [10.1080/10408444.2021.2003295](https://doi.org/10.1080/10408444.2021.2003295).

- (15) Srebny, V.; Henneberger, L.; König, M.; Huchthausen, J.; Braasch, J.; Escher, B. I. Beyond Estrogenicity: A Comparative Assessment of Bisphenol A and Its Alternatives in In Vitro Assays Questions Safety of Replacements *Environmental Science & Technology* **2025**, 59 (33). DOI: [10.1021/acs.est.5c07018](https://doi.org/10.1021/acs.est.5c07018).
- (16) Boston College; Minderoo Foundation. *Plastic Health Aware*. 2025. <https://plastichealthaware.bc.edu/> (accessed 2026-05-07).
- (17) Muncke, J.; Andersson, A. M.; Backhaus, T.; Belcher, S. M.; Boucher, J. M.; Carney Almroth, B.; Collins, T. J.; Geueke, B.; Groh, K. J.; Heindel, J. J.; et al. A vision for safer food contact materials: Public health concerns as drivers for improved testing *Environment International* **2023**, 180, 108161. DOI: [10.1016/j.envint.2023.108161](https://doi.org/10.1016/j.envint.2023.108161).
- (18) Muncke, J.; Touvier, M.; Trasande, L.; Scheringer, M. Health impacts of exposure to synthetic chemicals in food *Nat Med* **2025**, 31 (5), 1431–1443. DOI: [10.1038/s41591-025-03697-5](https://doi.org/10.1038/s41591-025-03697-5).
- (19) Wiesinger, H.; Parkinson, L. V.; Geueke, B.; Boucher, J. M.; Cabane, E.; Zimmermann, L.; Muncke, J. *Food Contact Chemicals Priority (FCCprio) List*. Zenodo,, 2024. <https://zenodo.org/records/14881617> (accessed 2026-05-07).
- (20) Rudén, C.; Kortenkamp, A.; Backhaus, T.; Bornehag, C.-G.; Wagner, M.; Jahnke, A.; Syberg, K.; van den Brink, P.; Arp, H. P. H.; Scheringer, M.; et al. *Chemical mixtures pose a risk to ecosystems, biodiversity and human health. Addressing mixture toxicity in the REACH revision is therefore central to ensure adequate protection*. Stockholm University, 2025. <https://www.su.se/english/divisions/departments-of-environmental-science/news/articles/2025-06-25-european-researchers-unite-behind-call-for-stronger-chemical-mixture-regulation-in-reach> (accessed 2026-05-07).