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Occupational exposure limits - Call for comments and evidence on bisphenols

Dear Madam or Sir,

We kindly thank ECHA for the opportunity to provide input on its process for setting occupational exposure limits for selected 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. Drawing from our various systematically compiled databases, we provide comments here as to the scope of included bisphenols.

The selected bisphenols represent only a small subset of the many hazardous chemicals and chemical groups to which Europeans are exposed

Exposure typically occurs to mixtures rather than individual substances. Current regulatory frameworks already include recognized gaps, such as limited harmonized hazard data and the lack of approaches addressing mixture toxicity.^{1,2} While setting occupational exposure limits for certain bisphenols is an important step, these chemicals constitute only a fraction of all bisphenols,³ which themselves are just one of many chemical groups of concern. Co-exposures to multiple hazardous substances may lead to cumulative or synergistic effects that are not captured by substance-by-substance risk assessments.^{1,2} This context highlights that hazardous bisphenols should not be assessed in isolation but considered as part of combined chemical exposures.

There are many more hazardous bisphenols in addition to BPS, PBF, and BPAF

Bisphenol S (BPS), bisphenol F (BPF), and bisphenol AF (BPAF) represent only a small fraction of the many bisphenols and related compounds in use.³ Evidence indicates that numerous additional bisphenols are likely to have similar hazardous properties.^{4,5}

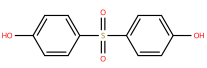
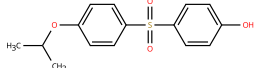
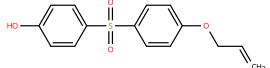
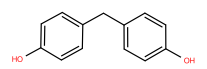
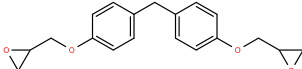
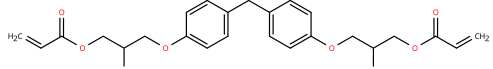
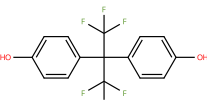
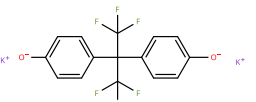
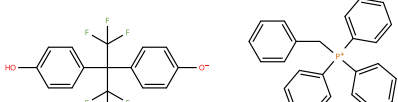
Regarding the use and presence of bisphenols in food contact materials, we queried three of our publicly available databases to provide evidence-based information:

- The FCCdb is a curated peer-reviewed database of chemicals that are intentionally used in the manufacture of food contact materials, compiled from publicly available regulatory lists and industry sources, which links chemicals to their potential use in the manufacture of specific materials.^{6,7} The database is publicly available for download at <https://foodpackagingforum.org/fccdb>
- The FCCmigex database is a systematic evidence map of chemicals that have been detected in migrates or extracts of food contact materials, based on primary scientific literature, thereby providing evidence for chemical presence in materials with the potential for human exposure.^{8,9} The database is publicly available as a dashboard at <https://foodpackagingforum.org/fccmigex>
- The FCChumon is a database capturing evidence of food contact chemicals monitored in human samples (e.g., biomonitoring and exposome studies), thus providing information on real-world human exposure to these substances.^{10,11} The database is publicly available as a dashboard at <https://foodpackagingforum.org/fcchumon>

A total of 179 bisphenols and derivatives have been identified as food contact chemicals (see **Attachment**), and thus are particularly relevant for broad consumer exposure and exposure to workers during production of food contact materials. Among the 179 food contact relevant bisphenols:

- 134 are listed for use in the production of food contact materials in the FCCdb.^{6,7}
- 74 have been detected in food contact materials in the FCCmigex database.^{8,9}
- 43 have been detected in human samples in the FCChumon database.^{10,11}

Table 1: BPS, BPF, BPAF, and analogues known to be used as food contact chemicals

BISPHENOL S	4-[[4-(1-Methylethoxy)phenyl]sulfonyl] phenol	4-[[4-(2-Propen-1-yloxy)phenyl]sulfonyl] phenol
		
CASRN 80-09-1	CASRN 95235-30-6	CASRN 97042-18-7
BISPHENOL F	Bis(4-glycidyloxyphenyl) methane	1,1'-[Methylenebis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]] di-2-propenoate
		
CASRN 620-92-8	CASRN 2095-03-6	CASRN 64448-68-6
BISPHENOL AF	Phenol, 4,4'-[2,2,2-trifluoro-1-(trifluoro-methyl)ethylidene]bis-, potassium salt (1:2)	Phosphonium, triphenyl(phenylmethyl)-, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoro-methyl)ethylidene]bis[phenol] (1:1)
		
CASRN 1478-61-1	CASRN 25088-69-1	CASRN 75768-65-9

Particularly salts and simple derivatives of BPS, BPF, and BPAF may be important to the setting of appropriate exposure limits. Among known food contact chemicals, six bisphenols are structurally equivalent or closely related to BPS, BPF, or BPAF (**Table 1**).

Evidence for exposure from food contact materials for BPS, BPF, and BPAF

All three of these bisphenols - BPS, BPF, and BPAF - are listed for use in the production of food contact materials in the FCCdb,^{6,7} have been analytically detected in food contact materials according to the FCCmigex database,^{8,9} and have been identified in human biomonitoring samples according to the FCChumon database.^{10,11} An overview of the available evidence is provided in the attachment.

Regarding detection in European food contact materials, recent studies report the presence of BPS in food contact plastics, paper and board, metal coatings, and multi-materials,¹²⁻¹⁴ while BPF has been detected in plastics,¹⁵⁻¹⁷ and BPAF in plastics and metal coatings.^{17,18} Additional evidence and details are publicly available through the [FCCmigex dashboard](#) and the [FCChumon dashboard](#), or we are glad to provide these to ECHA upon request. All references showing the detection of BPS, BPF, and BPAF in food contact materials are provided in the attachment.

The evidence for food contact materials indicates that workers involved in the production or handling of food contact materials may be exposed to BPS, BPF, and BPAF. In addition, exposure of both workers and the general population can occur via migration of these substances into food. Occupational exposure limits should therefore be considered in the context of this existing background exposure.

Evidence for human exposure and health impacts of the selected bisphenols

Additionally, we would like to highlight recent scientific studies providing evidence for exposure and health impacts of bisphenols:

- The systematic evidence map by Seewoo et al. highlights widespread human exposure to bisphenols, including BPS, BPF, and BPAF, with indications of increasing use and exposure over time.¹⁹
- The [Plastic Health Aware dashboard](#) systematically collects evidence on health impacts observed in epidemiological studies. For bisphenols, the available evidence suggests potential effects across multiple endpoints, including neurodevelopment, reproductive toxicity, metabolic disruption, and immunotoxicity, as summarized in the Plastic Health Evidence Grid.⁴
- A recent in-vitro study indicates that the selected bisphenols, as well as other bisphenols, exhibit biological activity profiles comparable to bisphenol A, raising concerns about mixture toxicity of these substances.⁵

In conclusion, we welcome the setting of occupational exposure limits for the selected hazardous bisphenols. To ensure that these efforts are aligned with current scientific understanding, we encourage ECHA to consider simultaneous exposure to the broader range of bisphenols and other chemicals in use to account for combined exposures. We thank ECHA for the opportunity to provide input and data and remain available to support this process.

Yours sincerely,


Helene Wiesinger
Jane Muncke
Albert Anguera Sempere

Attachments

- Overview of Bisphenols in food contact materials
- References for BPS, BPF, BPAF detected in food contact materials

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