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Responsible for Directorates  
E, F and G  
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European Commission  
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## **FoodDrinkEurope additional considerations on BPA and industrial applications**

Dear Ms Bury,

On behalf of FoodDrinkEurope we would like to follow-up on our previous exchanges on Bisphenol A (BPA) in food contact materials.

After EFSA published its opinion on BPA on 19 April 2023, the European Commission (DG SANTE) announced on 19 May its initiative to ban the use of BPA in food contact materials, including plastics and coated packaging.

As part of its risk management approach<sup>1</sup>, the Commission proposes to:

- remove BPA from Annex I to Regulation (EU) 10/2011 as “*an authorized monomer and propose to ban its use in the manufacture of all other synthetic organic materials for which it may be used*”; and
- consider applications from business operators providing justifications for longer transition periods than 18 months.

FoodDrinkEurope supports introducing a restriction on the intended use of BPA in food contact materials. However, we would like to take the opportunity to express some concerns regarding the above proposed approach. With the following suggestions, our aim is to minimise impact on technologies and industrial applications that are essential for food processing.

### **1. Incidental presence of BPA in food**

We are encouraged that the Commission recognises the incidental presence of BPA in food and clarifies its intention to focus on its intentional use. However the Commission has paid little consideration so far to the background-level BPA in food which was extensively discussed in the 2015 EFSA opinion<sup>2</sup>. This leaves food business operators with uncertainty as to how to distinguish between intentionally used and incidentally present BPA in food.

Clear provisions on how compliance will be demonstrated and how monitoring will be performed are needed.

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<sup>1</sup> Webinar on an EU ban on the use of bisphenol A (BPA) in food contact materials (FCMs) of 18 July 2023– [Presentation](#) and [Q&A](#)

<sup>2</sup> Cf. EFSA's Scientific Opinion on BPA, Part 1 – Exposure Assessment (2015), section 4.3.2. For non-canned food categories, the middle-bound BPA levels reported in Table 4 are as follows (in µg/kg): drinking water, 0.2; non-alcoholic beverages, 0.2; milk and milk products, 0.3; fruit and vegetable juices, 0.7; egg and egg products, 0.9; grain and grain-based products, 1.0; fish and other seafood, 7.4; meat and met products, 9.4.

**Suggestion 1: Clarifying the distinction between incidental and intentionally added BPA.**

- **detection of BPA in food should not automatically lead to the assumption of the use of BPA-based packaging;**
- compliance to food contact materials regulation will be based upon supplier **statements of non-intended use of BPA;**
- an appropriate analytical method including minimum performance requirements (limit of quantification) is to be established;
- further monitoring of BPA levels in foods and beverages will be needed and to be performed through a **Commission recommendation;** including appropriate method minimum performance (limit of quantification), and
- a clearly defined **indicative level** for analytically determined levels of BPA in food, considering that limits of detection will inevitably be higher than a theoretical **Specific Migration Limit (SML)** derived from the new TDI.

**2. Delisting of BPA from Annex I of Regulation (EU) 10/2011**

The Commission has been clear on its intention to delist BPA as a starting substance. This despite the fact that no impact assessment has been conducted and that possibly not all food contact applications essential to food safety and food security have been considered.

Delisting would de facto ban *any* use of BPA in food contact applications, including critical applications in food manufacturing and processing used to ensure the supply of high quality and safe food to European consumers.

The consequence of delisting extends not only to epoxy coatings and polycarbonate but also to polyetherimide (made of bisphenol A dianhydride), and to polysulfone<sup>3</sup> (made of disodium salt of bisphenol A with 4,4-dichlorodiphenyl sulfone), and possibly others.

In the above-mentioned applications, that are currently impossible to replace, articles are in contact with food, but with orders-of-magnitude lower surface-to-volume ratio than the default factor of 6 dm<sup>2</sup> to 1 kg of food.

**Suggestion 2: Using restrictions to impose a ban**

Rather than delisting BPA from Annex I of the Plastics Regulation, the Commission could instead **keep the BPA listing in Annex I and impose restrictions on applications that are known to contribute to BPA exposure.** This approach is similar to the proposed action by the Commission to continue permitting BPA in BADGE in coating applications. The specific proposal is laid out in **Appendix I.**

<sup>3</sup> By way of example, polysulfone is used as a separation membrane or as a support material for reverse osmosis and nanofiltration. Polysulfone membranes enable the critical preparation of safe food and safe food ingredients including, among others, dairy processing, clarification and concentration of fruit juices, de-alcoholisation of wine and beer, and purification of sugar. Dairy ingredients produced from milk and whey, which rely on the use of these membranes in their production offer essential nutrients such as amino acids and minerals that exist in forms easy to adsorb by the body and are used in infant formulas, clinical and sports nutrition products, and other food formulations. No alternative has been found - or is thought to be able to be found within the foreseeable future - that can provide the necessary mechanical strength and chemical stability.

### **3. Impact on unintended consequences**

Banning the use of BPA across the board is highly likely to cause unknown and unintended consequences, e.g., there may be other applications potentially not notified to the Commission. This concern must be addressed for two reasons:

1. the Commission is not undertaking an impact assessment to ascertain the proportionality of the forthcoming measure, and
2. EFSA's most recent exposure assessment on BPA in 2015 did not include any references to food processing<sup>4</sup>, presumably because of its extremely low migration.

**Suggestion 3: Permitting applications essential to food safety and food security via a Specific Migration Limit (SML).**

Rather than deciding on derogations on food manufacturing and processing applications from stakeholders one by one, **the Commission could consider setting a specific migration limit (SML) based on the TDI of 0.2 ng/kg-bw/day.** This theoretical SML would allow the essential uses of BPA (e.g. filtration membrane) to be permitted on the basis of their very low exposure. **And even though a revised SML based on the new TDI would be too low for analytical verification,** it is perfectly suitable for demonstrating compliance within the existing FCM regulations by using approved worst-case migration calculation and mathematical migration modelling<sup>5</sup>.

We thank you in advance for considering the above recommendations and look forward to a constructive dialogue with the European Commission and relevant sectors of the value chain to identify the best way to implement these important changes within the industry.

Sincerely,

Rebeca Fernandez

Director Food Safety, Research & Innovation  
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CC:

Mr Klaus BEREND

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<sup>4</sup> Cf. EFSA's Scientific Opinion on BPA, Part 1 – Exposure Assessment (2015), section 4.3.1.

<sup>5</sup> Demonstration of compliance via screening approaches is permitted under Annex V of Regulation (EU) No 10/2011. Recently, Commission has proposed to use the residual content (QM) with 100% worst-case calculation for styrene monomer. Furthermore, mathematical modelling has been used since 2011 by EFSA to demonstrate that the maximum migration level for infant exposure is 0.017 µg/kg food for chemicals with structural alerts raising concern for potential genotoxicity, below which the risk to human health would be negligible. (doi:10.2903/j.efsa.2011.2184)

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## Appendix I

As noted in the Commission's Q&A, Regulation (EU) 2018/213 lays down the prohibition of BPA in FCMs specifically for infants and young children.

We suggest using Regulation (EU) 2018/213 as a base, but extending the intended prohibition to food packaging **for all ages** as follows:

Regulation (EU) No 2018/213	Current Text	Proposed Text	FoodDrinkEurope Suggestion
Article 2(1)	The migration into or onto food of 2,2-bis(4-hydroxyphenyl)propane ('BPA') (CAS No 0000080-05-7) from varnishes or coatings applied to materials and articles shall not exceed a specific migration limit of 0,05 mg of BPA per kg of food (mg/kg).	The migration into or onto food of 2,2-bis(4-hydroxyphenyl)propane ('BPA') (CAS No 0000080-05-7) from varnishes or coatings applied to materials and articles shall not exceed a <b>specific migration limit (SML)</b> _____ of mg of BPA per kg of food (mg/kg). <b>(SML to be set by COM)</b>	3 Setting an SML for varnishes and coatings
Article 2(2)	By derogation from paragraph 1, no migration of BPA shall be permitted from varnishes or coatings applied to materials and articles specifically intended to come into contact with infant formula, follow-on formula, processed cereal-based food, baby food, food for special medical purposes developed to satisfy the nutritional requirements of infants and young children or milk-based drinks and similar products specifically intended for young children, as referred to in Regulation (EU) No 609/2013.	By derogation from paragraph 1, no migration of BPA shall be permitted from varnishes or coatings applied to materials and articles specifically intended to come into contact with food.	2 Remove age limit for varnishes and coatings
Annex II Substance 151, Column 8	0,05	_____ <b>(SML to be set by COM)</b>	3 Setting an SML for plastics
Annex II Substance 151, Column 10	Not to be used for the manufacture of polycarbonate infant feeding bottles.  Not to be used for the manufacture of polycarbonate drinking cups or bottles which,	Not to be used for the manufacture of polycarbonate food and beverage packaging containers less than 20 liters.	2 Remove age limit for plastics

	due to their spill proof characteristics, are intended for infants and young children.		
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