



DISCLAIMER

This note provides answers to common questions which the Commission has received in the context of the development of a measure regarding bisphenol A (BPA) in food contact materials (FCMs). The Commission has not currently made any formal proposals on this matter but is presently determining how to best approach it. The following is to be taken into account when using the information provided in this note:

- The note is intended to supplement a presentation on the topic given by the Commission services during a live webinar on 18 July 2023 ⁽¹⁾. Its purpose is to provide more clarity on some points raised by stakeholders during the webinar and reflects the Commission services' intention at the time of publication. The answers may be subject to change depending on further discussions with Member States and information received from stakeholders.
- It is intended to facilitate discussion and understanding of the matters presented and has not been adopted or endorsed by the Commission. It does not represent a final position and does not commit the Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this note. Only the court of justice of the European Union is competent to authoritatively interpret Union law.

4 August 2023

Questions and answers (Q&A) concerning the risk management approach for bisphenol A (BPA) and other bisphenols in food contact materials (FCMs)

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⁽¹⁾ https://food.ec.europa.eu/system/files/2023-07/cs_fcm_wg_20230718_pres.pdf

BACKGROUND

In the context of food contact materials (FCMs), bisphenol A (BPA) (FCM 151) is primarily used to manufacture varnishes and coatings [hereafter referred to as ‘coatings’] to line metal packaging, including cans and lids as well as large-scale food production, storage and transport equipment. It is used to a lesser extent to manufacture polycarbonate plastic-based articles for the food industry such as water dispensers and confectionary moulding equipment. It may also have limited use in other FCMs such as rubbers, inks and adhesives.

BPA is currently authorised for use as a monomer at EU level in plastic FCM ⁽²⁾ with restrictions including a specific migration limit (SML) of 0.05 mg/kg, which also applies to coated FCMs ⁽³⁾. A prohibition of BPA in FCMs specifically for infants and young children also applies based on the precautionary principle. The SML and prohibitions have applied since 6 September 2018, except in the case of the ban on BPA in polycarbonate infant feeding bottles, which has applied since 2011 ⁽⁴⁾.

The European Food Safety Authority (EFSA) established in a recent opinion a new tolerable daily intake (TDI) of 0.2 ng/kg bodyweight for BPA ⁽⁵⁾ and concluded that there is a health concern from dietary exposure to BPA. As the TDI is considered too low to continue the use of BPA subject to an SML, the Commission is proposing to ban the intentional use of BPA in FCMs ⁽⁶⁾.

The proposed ban concerns the intentional use of BPA as a substance to manufacture an FCM, such as a plastic or coating. The draft measure will therefore include the removal of BPA from Annex I to Commission Regulation (EU) No 10/2011 as an authorised monomer and propose to ban its use in the manufacture of all other synthetic organic materials for which it may be used.

As explained during the webinar ⁽¹⁾ on 18 July 2023, FCMs manufactured using BPA and compliant with the current rules before the introduction of the proposed EU measure would benefit from an 18-month transition period, during which time they may continue to be first placed on the market. A longer transition period may be applied to FCMs for which business operators are able to demonstrate that the application of that longer period is justified, and provided this is accepted by the Commission and the Member States. The information to justify this should be sent to the Commission preferably by 15 September 2023, but at the latest by the end of the four-week feedback period, which is foreseen to take place later in the autumn (see Q23).

At the webinar and also on other occasions, a number of questions have been raised by stakeholders in relation to the envisaged measure. The most frequent questions and answers thereto are set out in this document.

⁽²⁾ <http://data.europa.eu/eli/reg/2011/10/2020-09-23> (consolidated version)

⁽³⁾ <http://data.europa.eu/eli/reg/2018/213/oj>

⁽⁴⁾ http://data.europa.eu/eli/reg_impl/2011/321/oj

⁽⁵⁾ <https://doi.org/10.2903/j.efsa.2023.6857>

⁽⁶⁾ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13832-Food-safety-restrictions-on-bisphenol-A-BPA-and-other-bisphenols-in-food-contact-materials_en

SCOPE

Q1. Which materials would be included in the scope of the measure?

The ban would apply to all food contact materials and articles (FCMs) placed on the market in the EU, which can be or may be manufactured using BPA. This includes plastics, coatings, adhesives, printing inks and rubbers. The ban would not include materials which inherently do not use BPA, such as wood or glass.

Q2. Is it the intention to apply the ban to food production equipment?

Yes, it is the intention to include all materials and articles intended to come into contact with food, including kitchenware and tableware as well as production, storage and transport equipment used in the food industry. FCMs are all materials and articles in the scope of Regulation (EC) No 1935/2004.

Q3. Would the measure also apply to FCMs imported into the EU?

Yes, as is the case for all FCMs, the measure would apply equally to the placing on the EU market of imported FCM. This includes FCMs already in contact with food such as filled food and beverage cans as well as any unfilled food packaging, kitchenware, tableware or food processing equipment.

Q4. What about drinking water materials?

Drinking water materials do not fall within the scope of Regulation (EC) No 1935/2004. They are regulated separately within the EU by Directive (EU) 2020/2184 ⁽⁷⁾, specifically Article 11, which concerns materials used before the point of compliance, namely the tap.

Q5. Would materials used in contact with pet food be included?

No. Regulation (EC) No 1935/2004 concerns only food contact materials and does not extend to materials brought into contact with animal feed.

Q6. Would the measure apply to agricultural and fishing equipment?

In some cases. Note that it only applies to materials and articles within the scope of Regulation (EC) No 1935/2004 insofar as they relate to contact with or transfer of constituents to *food*. The general food law (Regulation (EC) No 178/2002 ⁽⁸⁾) defines when something is a food. For instance, vegetables would only be considered a food post-harvest, and therefore agricultural equipment used up to and including harvest would not be an FCM.

Q7. What about marine vessels and containers coming to the EU from third countries that transport food?

Marine vessels and containers that transport food to the EU will not be within the scope of the measure where they are not imported and are not placed on the EU market. Containers that are imported for onward transport and therefore placed on the market would be subject to the measure.

⁽⁷⁾ Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast) <http://data.europa.eu/eli/dir/2020/2184/oj>.

⁽⁸⁾ <http://data.europa.eu/eli/reg/2002/178/2022-07-01> (current consolidated version)

INCIDENTAL PRESENCE OF BPA IN FCMS

Q8. What rules would apply to the incidental presence of BPA in FCM?

Even though the measure would no longer allow the intentional use of BPA in FCMS, it is known that residual traces of BPA may still be present in an FCM adventitiously. Examples include recycled FCMS, such as plastic or paper and board due to contamination of recycling streams, the input for which may contain materials not previously used as FCM. Other examples include its presence as a non-intentionally added substance (NIAS) in other plastics, such as polystyrene or where it is already present in the food, particularly as a consequence of environmental contamination.

Such incidental presence of BPA would not be subject to the ban but instead, levels will need to be monitored in order to generate data on occurrence, understand the relevance of any occurrence and to promote investigations in order to determine the source and where actions to control the contamination can be taken or foreseen.

Q9. Is the intention to apply the ban to the non-food contact side of the material e.g. the exterior coating of metal packaging?

The scope of Regulation (EC) No 1935/2004 on which the measure will be based includes “materials and articles which in their finished state can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use” (Article 1(2)(c)).

Whereas the primary intention of the measure would be to prevent its use and migration from materials in contact with food, in certain cases, during production processes of metal cans, which can be considered as an absolute barrier through which BPA cannot pass, vapour-phase transfer may still occur whereby substances from the exterior coating may transfer to the interior of the can in small amounts and consequently migrate into food. Similar transfer may result from physical contact between the interior and exterior sides of FCMS, for instance if the use of the FCM involves its intermediate storage on a reel. In such a case the outer layer could on the basis of Article 1(2)(c) be interpreted to be an FCM.

Deployment of good manufacturing practices (GMP) and eventual replacement of BPA altogether in the production of metal food packaging are therefore expected.

Q10. What about BADGE?

The ban is intended to apply to the intentional use of BPA as a substance in the manufacture of FCMS, to limit its presence and potential migration into food. Bisphenol A diglycidyl ether (BADGE) (CAS No. 1675-54-3) has been subject to separate risk assessment and risk management considerations in the past and is regulated by Commission Regulation (EC) No 1895/2005⁽⁹⁾. As part of recent work under the REACH Regulation, BADGE has also been under assessment⁽¹⁰⁾ though it is not currently classified with any properties of concern relevant to consumers from oral exposure via food.

The use of BPA to make BADGE and subsequent production of coatings, including heavy duty coatings used on large tanks, containers and vessels in the food production, storage and transport industries will be the subject of further discussion with Member States and stakeholders. Business operators should in any case already take steps to

⁽⁹⁾ <http://data.europa.eu/eli/reg/2005/1895/oj>

⁽¹⁰⁾ <https://echa.europa.eu/ed-assessment/-/dislist/details/0b0236e180765dd0>

ensure good manufacturing practices (GMP) that minimise the presence of unreacted BPA monomer as an impurity. In light of the high volume to surface area ratios, contact with foods often at ambient or low temperatures and the repeated use over long periods of time, migration into and exposure via food is presently expected to be extremely small.

Q11. How can I demonstrate compliance? How can a distinction be made between intentional use and incidental contamination?

As with all EU specific measures on FCMs, a Declaration of Compliance (DoC) would be required for those FCMs affected which would need to be made available by FCM business operators from one to another in the supply chain. The DoC acts as a legal statement to confirm compliance with the applicable measure, i.e. in this case it would be the absence of BPA as a substance in the manufacture of the FCM(s). Further supporting documentation can also be requested by Member State competent authorities when carrying out controls.

Where physical sampling and analysis is undertaken that indicates the presence of BPA despite the DoC stating that BPA has not been used, further investigations should be undertaken by the business operator in cooperation with the Member State competent authorities to determine the source and whether actions to control the incidental contamination can be taken or foreseen.

Q12. Would an FCM be taken off the market if a Member State competent authority detects that it contains BPA?

The precise approach will be discussed in detail with the Member States in due course. The approach will depend on whether the competent authority is able to verify that the FCM was not manufactured with intentional use of BPA, based on compliance and supporting documentation provided by its manufacturer(s) and depending on the level found. Instead, the enforcement actions would firstly focus at identifying and removing the source of the BPA contamination if the competent authority considers further action justified. See also the next question.

Q13. Might there be a level of allowed incidental contamination of BPA in FCMs or in food? What action are Member States likely to take when BPA is found?

The Commission services will discuss with Member States a possible level(s) above which it may be prudent to take further action and what that further action will entail, with a view to ensuring a coherent approach. This may include foodstuffs as well as FCMs.

Q14. At what level can current analytical techniques reliably detect the presence of BPA? Will a test method be developed?

As part of the ongoing discussions, the Commission services will consider the current analytical capabilities and what is feasible and practicable from the point of view of ensuring consistent and reliable data across the EU in all Member States.

Q15. What about food processing equipment used in third countries?

Contamination of food may occur due to the continued use of BPA in food production, storage and transport systems outside the EU in the future. If such foods are found to contain significant levels of BPA, follow-up action should be considered with the

supplier from the third country, depending on the level and frequency of contamination. Further EU risk management may also eventually be considered if justified.

Q16. Specifically, which rules would apply to recycled plastic FCM?

Commission Regulation (EU) 2022/1616 applies to recycled plastic materials and articles intended to come into contact with foods. It only allows the recycling of plastics that are compliant with Commission Regulation (EU) No 10/2011. Therefore, plastic materials and articles manufactured with BPA such as polycarbonate can no longer be recycled under FCM legislation after BPA is removed from Annex I to Regulation (EU) No 10/2011. With regards its possible presence as a contaminant, the same rules will apply as to all other contaminants that may occur in recycled plastics, i.e. decontamination should be adequate in view of the contamination level of the input.

REPLACEMENT OF BPA AND OTHER BISPHENOLS

Q17. Is the ban likely to apply to other bisphenols?

The Commission has committed as part of the Chemicals Strategy for Sustainability (CSS) ⁽¹¹⁾ to ban the use of the most harmful chemicals i.e. those with specific hazardous properties from FCMs, except in cases where the use of such a chemical substance is deemed essential and the risk can be controlled. For bisphenols and their derivatives, the main human health hazards are their reproductive toxicity and potential endocrine disrupting (ED) properties. The foreseen measure would therefore also concern other bisphenols for which it is known that they have such specific hazardous properties.

Q18. Will the Commission request EFSA to complete an assessment of other bisphenols?

At present, no further requests to EFSA for risk assessment of bisphenols are foreseen (see also answer below).

Q19. Why is the Commission considering other bisphenols when the EFSA opinion only relates to BPA?

Although the recent EFSA opinion does not address other bisphenols, a prohibition on BPA prompts the need to identify substances to replace it, particularly for FCM coatings, in order to continue to ensure food safety and security. However, replacement of BPA with bisphenols that have similar or other specific hazardous properties of concern should be avoided unless their use is considered essential and is supported by an up-to-date risk assessment demonstrating their restricted use is nevertheless safe. Such an approach will ensure maximum consumer protection whilst enhancing consistency, transparency and predictability of EU risk management of substances with similar hazard and use profiles and therefore provide a more predictable regulatory environment.

Recently, the European Chemicals Agency (ECHA) and Member States have assessed a group of 148 bisphenols and recommended that more than 30 bisphenols need to be restricted due to their potential hormonal or reprotoxic effects ⁽¹²⁾ for human health as well as the environment. Data is also being generated for a further 22 bisphenols. The CSS emphasises the need for coherence and consistency in the assessment work of substances amongst the different legislation on chemicals and the extent to which this

⁽¹¹⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN>

⁽¹²⁾ <https://echa.europa.eu/en/-/group-assessment-of-bisphenols-identifies-need-for-restriction>

work is relevant and can be integrated into future EU legislation on FCM will be considered as part of the foreseen general revision of EU FCM rules ⁽¹³⁾.

At present, monitoring of ongoing developments in this area will also help to direct businesses in their research and development of alternatives with the aim to avoid so-called 'regrettable substitution'.

Q20. How will the replacement materials be tested [for safety]?

A range of different new technologies are being developed and used which are proprietary to the various coating manufacturers. Business operators should ensure that they undertake appropriate risk assessments in line with industry standard practice and in accordance with internationally recognised methods on all new food contact coatings, including substances used in their manufacture, to ensure compliance with Regulation (EC) No 1935/2004 and in particular, Article 3.

Business operators may also wish to make use of Member States' risk assessment bodies within the context of any authorisation of substances at national level. As part of the revision of EU FCM rules, the Commission is assessing ways to improve efficiency of risk assessment and risk management procedures to support safe FCMs on the EU market.

Q21. Do you anticipate supply chain issues?

Currently no major problems are anticipated, taking into account the envisaged 18-month transition period and possibly longer for certain food contact articles.

TRANSITIONAL MEASURES AND APPLICATION OF THE MEASURE

Q22. Will there be an impact assessment?

A full impact assessment will not be undertaken. However, the Commission services will continue to engage with all relevant stakeholders during the process for preparing the measure and will publish the draft measure in the autumn for a four-week feedback period to give all stakeholders the opportunity to comment on the draft.

Q23. How can I apply for a longer transitional period?

In its webinar on the intended measure, the Commission services indicated a number of points that should be addressed, in case business operators consider that they will encounter significant problems with the envisaged 18-month transition time and will require a longer transitional period. These include the following:

- impact on food safety (e.g. microbiological & chemical contamination);
- impact on food security, food waste and supply chain;
- additional resources including costs;
- the absence of directly available alternatives, including alternative packaging or food production systems;
- status of development of alternatives and reasonable additional time required, for further development and certification activities;
- current typical migration levels of BPA from the material concerned.

⁽¹³⁾ https://food.ec.europa.eu/safety/chemical-safety/food-contact-materials/revision-eu-rules_en

Business operators are encouraged to provide data, where possible through relevant EU professional associations and Member States' competent authorities. There is no format or template for the submission of this information, however, any information or claims should be substantiated with verifiable and quantifiable scientific data.

Information should eventually be sent to SANTE-FCM-CONSULTATIONS@ec.europa.eu by Friday 15 September 2023 in order to be taken into account for the preparation of the draft measure that will become subject to the feedback period. Further information can be submitted during the four-week feedback period and no later than by the end of it.

Q24. What about canned foods that are currently on the market or placed on the market before the date of application and have a shelf life of several years?

The date from which the new rules would apply concern FCMs insofar as they fall within the definition of 'placing on the market', laid down in Article 2 of Regulation (EC) No 1935/2004. FCMs that fall under this definition before the date from which the ban would apply, taking account of the envisaged 18-month transitional period (or possibly longer) will be allowed to remain on the market, until the exhaustion of stocks, following the normal practice set out in regular changes to Commission Regulation (EU) No 10/2011. This would include coatings that have been manufactured using BPA held for the purpose of transfer or sale in the FCM production chain (e.g. to metal packaging producers) and by extension, coated metal packaging not yet brought into contact with food as well as those that have been filled and are already sold through to food businesses and consumers.

FCMs that are not on the market before the application of the ban would be subject to it and may not be [first] placed on the market after that date, taking account of any relevant transitional period(s).

Q25. What about food processing equipment with a long service life that use heavy duty coatings? What about repairs and maintenance?

Food contact articles with a long service life that are on the market before the ban would apply, taking account of any relevant transitional period(s), would be able to remain on the market and be used until the end of their service life. This may include for example, polycarbonate equipment as well as food processing, storage and transport tanks and their coatings.

Further, the measure should allow the continuation of repairs and maintenance that require the reapplication of BPA-based coatings, using coatings that were on the market before the date from which the ban applies, as well as the use of replacement parts manufactured with BPA, if they were placed on the market before that date. Business operators should inform the Commission with the requested information as regards the need for a transitional period beyond 18 months for such FCMs (see Q23).

Q26. What happens to the current applicable EU rules? Will the current SML still apply?

Once in force, the foreseen measure would repeal and replace the existing EU rules, including the authorisation of BPA in Annex I to Commission Regulation (EU) No 10/2011; the current SML of 0.05 mg/kg laid down in Commission Regulation (EU) 2018/213 would also no longer apply, taking into account any transitional period(s).

Q27. There are some national requirements for BPA and sometimes also other bisphenols relevant for FCM: could there be a harmonised approach to avoid national ones?

The EU measure would be a Regulation, that is directly applicable in all EU Member States. Taking into account the provisions in Regulation (EC) No 1935/2004, national measures may not be in contradiction with EU rules.

TIMEFRAME FOR INTRODUCTION OF AN EU MEASURE

Q28. When will we be able to comment on a draft measure?

It is the intention to launch a 4-week feedback period in the autumn this year, which will allow all stakeholders to comment on a draft version of a legislative text.

Q29. When is a measure likely to be in force? More importantly, from when would the ban apply?

Taking into account the need for further discussions with Member States, the public feedback period and agreement in the Standing Committee on Standing Committee on Plants, Animals, Food and Feed (Novel Foods and Toxicological Safety of the Food Chain), a measure can be adopted, published and in force by spring of next year (2024).

Thereafter, a default 18-month transitional measure would apply except in case of specific FCM articles for which a longer transitional period may be established. It is estimated that the prohibition for FCM articles subject to an 18-month transitional period would apply as from the end 2025/ beginning 2026.