



Note for Guidance on the implementation of Commission Regulation (EU) 2024/3190 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

(C/2025/6721)

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1. SCOPE OF COMMISSION REGULATION (EU) 2024/3190

Q1. Is paper and board within the scope of the ban?

No, Article 1(2) of Commission Regulation (EU) 2024/3190 ⁽¹⁾ contains a list of materials that are within its scope, which does not include paper and board. The Regulation concerns the prohibition of the use of bisphenol A (BPA) in the manufacture of food contact materials (FCMs) and therefore includes materials for which BPA may be used in their manufacture, e.g. as a monomer to make plastic or epoxy coatings but also printing inks or adhesives. These materials may however be combined with paper and board and the Regulation would in such case apply to the resulting food contact article, for example the need for a Declaration of Compliance (DoC).

Q2. Are recycled FCMs within the scope of Regulation (EU) 2024/3190?

Recycled FCMs may contain minute amounts of BPA and other bisphenols adventitiously. This is because they may be present as an incidental contaminant in the input used to produce recycled materials including plastic, such as PET, as well as paper and board. Such contamination can persist in the recycled plastic or paper in minute amounts despite the application of cleaning and decontamination processes and may eventually be present in the final food contact article. As BPA is not used intentionally in such manufacturing processes and such contamination cannot be fully controlled, recycled FCMs are not within the scope of Regulation (EU) 2024/3190.

Q3. Is enamel to be regarded as a coating and therefore as falling under the scope of Regulation (EU) 2024/3190?

The word 'coating' may be used not only to indicate the type of material, but also the function of the material, in the same way plastic can be used to coat other materials but still falls within the scope of Commission Regulation (EU) No 10/2011 ⁽²⁾. Although enamels serve as a form of coating or covering of other materials, insofar as it concerns glass-based materials that are melted onto clay, metal, or glass objects, enamel does not fall under the scope of Regulation (EU) 2024/3190 and a DoC according to Annex III of that Regulation is therefore not necessary.

Q4. Are external parts of FCMs within the scope of Regulation (EU) 2024/3190?

Regulation (EU) 2024/3190 is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004 ⁽³⁾. In light of the scope of the latter Regulation ⁽⁴⁾, if the FCM is manufactured with one of the material groups listed in Article 1(2) of Regulation (EU) 2024/3190 and "*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*", Regulation (EU) 2024/3190 applies.

This may be the case, for example, for the exterior of metal coated packaging, under certain production settings, as explained in Recital 19 of Regulation (EU) 2024/3190, where transfer may occur indirectly regardless of whether a layer in addition to the metal is present between the coating and the food, e.g. a plastic.

⁽¹⁾ Commission Regulation (EU) 2024/3190 of 19 December 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, OJ L, 2024/3190, 31.12.2024, ELI: <http://data.europa.eu/eli/reg/2024/3190/oj>.

⁽²⁾ Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, OJ L 12, 15.1.2011, p. 1, ELI: <http://data.europa.eu/eli/reg/2011/10/oj>.

⁽³⁾ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ L 338, 13.11.2004, p. 4, ELI: <http://data.europa.eu/eli/reg/2004/1935/oj>.

⁽⁴⁾ See Article 1(2), in particular point (c), of Regulation (EC) No 1935/2004.

Q5. Why does Regulation (EU) 2024/3190 sometimes refer to food contact materials and articles, but also to ‘intermediate food contact materials and ‘final food contact articles’? What is the difference?

The requirements laid down in Regulation (EU) 2024/3190 apply to food contact materials and articles as per the scope and meaning in Article 1(2) of Regulation (EC) No 1935/2004, which means that they do not have to be in their finished state. Starting materials, intermediate materials and finished food contact materials and articles, which are manufactured from the materials specified in Article 1(2) of Regulation (EU) 2024/3190 are therefore subject to that Regulation. Often, the products at different stages of manufacture or sale are referred to generically as ‘food contact materials and articles’, abbreviated to ‘food contact materials’ or simply the acronym ‘FCMs’.

A distinction is made only for the purpose of the transitional periods laid down in Articles 11 and 12, since placing on the market may take place at different production stages due to the nature of the FCM supply chain. In order to clarify which stage of production and placing on the market the specific transitional dates apply to, Regulation (EU) 2024/3190 refers specifically to ‘final food contact articles’ as opposed to ‘intermediate food contact materials’, that can be placed on the market at various points earlier in the supply chain (see also the section ‘transitional provisions’).

Q6. Are there any examples of ‘intermediate food contact materials’ as opposed to ‘final food contact articles’?

Both terms are defined in Article 2(2) of Regulation (EU) 2024/3190. Examples of intermediate food contact materials include plastic pellets which need to be transformed into bottles, or printing inks and varnishes in liquid form that need to be applied and cured onto another self-standing material. An example of a final food contact material is a reusable plastic drinks bottle put on sale to consumers.

Q7. Does Regulation (EU) 2024/3190 cover materials and articles in contact with pet food?

No, FCMs relate only to food as defined in Article 2 of Regulation (EC) No 178/2002 ⁽⁵⁾. Pet food is considered as ‘feed’, which is defined in Article 3, point 4, of the same Regulation.

Q8. Are pipes belonging to or connected with self-supporting materials covered by the derogation related to self-supporting materials laid down in Annex II to Regulation (EU) 2024/3190?

If the pipes are permanently affixed to vats and tanks, and the resulting self-supporting material or article in its entirety, has a capacity exceeding 1 000 litres, they are considered to fall under the scope of the derogation. However, as Regulation (EU) 2024/3190 reasons in Recital 7, the possible BPA migration to food is limited in large vessels because of their small surface to volume ratio, which is a major reason why the use of BPA can be continued to be allowed in large vessels. It is therefore important to consider the surface area to volume ratio of pipes, as pipes typically have a high surface area relative to their volume, even though the food may only come into brief contact with the material. Furthermore, pipes or other vessels with a high surface to volume ratio are not to be used in accordance with that reasoning in order to store food products, but only to transfer them in a short time. Finally, the derogation related to self-supporting materials laid down in Annex II does not apply to small pipes, which can be detached and replaced without dismantling the entire installation.

2. OTHER BISPHENOLS AND BISPHENOL DERIVATIVES

Q9. Are BPA derivatives banned in Regulation (EU) 2024/3190?

Salts of BPA are banned by virtue of the fact that they fall within the definition of ‘bisphenol’ laid down in Article 2(2)(c) of Regulation (EU) 2024/3190. Otherwise, BPA derivatives are not specifically banned, unless they fall within the scope of Article 5 of the Regulation (‘hazardous bisphenols other than BPA or hazardous bisphenol derivatives’).

⁽⁵⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>.

In particular, at this time, BPA derivatives such as bisphenol-A diglycidyl ether ('BADGE') (CAS No 1675-54-3) can be used in the manufacture of FCMs, but compliance must be ensured with Article 4 of the Regulation. Business operators who wish to manufacture or use bisphenols other than BPA or bisphenol derivatives for FCMs should pay close attention to the manufacturing process and, in particular, exclude the possibility that residual BPA is present in the FCMs, including as an impurity. This is particularly important in the case of BADGE, for which BPA is needed as a precursor for its chemical synthesis.

Q10. In that case, why is there a need for the derogations in Annex II of Regulation (EU) 2024/3190?

For the specific food contact applications laid down in Annex II of Regulation (EU) 2024/3190, BPA itself may be required as a monomer or starting substance in the manufacturing process, as well as to further react with BADGE to produce epoxy resins. For these specific FCMs, that Regulation authorises the use of BPA in the manufacture of those specific FCMs but provides that *migration* of BPA into food must not be detectable.

Q11. What about other bisphenols that may be used as substitutes for BPA, which may have similar hazardous properties?

Certain other bisphenols or bisphenol derivatives, that are used in the manufacture of FCMs, may also present risks similar to BPA. Regulation (EU) 2024/3190 prohibits the use of other bisphenols or bisphenol derivatives listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008 ⁽⁶⁾ due to their harmonised classification as category 1A or 1B 'mutagenic', 'carcinogenic', 'toxic to reproduction' ('CMR') or category 1 'endocrine disrupting ('ED') for human health'. For most bisphenols and their derivatives, toxic to reproduction and endocrine disrupting are normally the most relevant hazardous properties.

Nevertheless, Article 6 of Regulation (EU) 2024/3190 allows the authorisation of the use of such hazardous bisphenols or hazardous bisphenol derivatives in view of the fact that a specific food contact application might be unavoidable, due to a lack of alternatives, and provided that business operators demonstrate that there is no risk to consumers from that specific application.

Q12. If business operators need to use other hazardous bisphenols, including bisphenol S (BPS), in the manufacture of their FCMs, how can they demonstrate that there is no risk?

Article 6 of Regulation (EU) 2024/3190 allows authorisation of hazardous bisphenols or hazardous bisphenol derivatives for specific food contact applications, following the authorisation procedure laid down in Regulation (EC) No 1935/2004. According to Article 6(4) of Regulation (EU) 2024/3190, the European Food Safety Authority (EFSA) is required to publish guidance concerning the information necessary for the risk assessment of other hazardous bisphenols and derivatives in FCMs that applicants are to submit. Such information may include, for example, considerations specifically relevant to the risk assessment of bisphenols or, in the case of BPS, considerations relevant to new scientific information that has become available since the previous risk assessment, whilst respecting the existing EFSA Scientific Guidance ⁽⁷⁾ for applications on substances to be used in plastic FCMs.

Q13. What happens until EFSA publishes the guidance concerning the information necessary for the assessment of hazardous bisphenols or hazardous bisphenol derivatives?

An application for the use of a hazardous bisphenol or hazardous bisphenol derivative cannot be submitted before the publication of the scientific output referred to Article 6(4) of Regulation (EU) 2024/3190. In the meantime, business operators can continue to place FCMs manufactured using hazardous bisphenols or hazardous bisphenol derivatives (see table in Q17) on the market. Therefore, in the case of BPS, its use in plastic FCMs remains permitted until publication of EFSA's scientific output, subject to the current specific migration limit (SML) of 0.05 mg/kg. Its use to manufacture varnishes and coatings, for example as a polymeric binder, remains subject to the general rules of Regulation (EC) No 1935/2004 and to any specific national rules that may exist in Member States.

⁽⁶⁾ 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>.

⁽⁷⁾ <https://www.efsa.europa.eu/en/applications/foodcontactmaterials/regulationsandguidance>.

However, whilst EFSA considers what information is necessary for the risk assessment of the use of hazardous bisphenols and bisphenol derivatives, business operators using or manufacturing and placing on the market FCMs manufactured using BPS or other hazardous bisphenols may themselves wish to consider the relevance of any new scientific information. Concerning BPS, this includes information that has been published since its evaluation by the Scientific Committee on Food (SCF) from 22 June 2000 ⁽⁸⁾, which was not considered by EFSA in its technical report on BPS ⁽⁹⁾ published in 2020.

Q14. What happens after EFSA has published the guidance concerning the information necessary for risk assessing hazardous bisphenols?

In accordance with Article 5(3)(b)(i) of Regulation (EU) 2024/3190, business operators wishing to continue to place on the market FCMs that are manufactured with a hazardous bisphenol or derivative, for which a relevant harmonised classification applies at the time of EFSA's publication, will have 9 months to apply for a derogation from the prohibition. In line with Article 5(3)(a)(i) of that Regulation, business operators must also be able to demonstrate that the FCM in which the hazardous bisphenol or derivative is used for manufacture, was already on the market at the time EFSA publishes the information. If so, that FCM may continue to be placed on the market thereafter until the Commission has taken a decision as to whether it can continue to be placed on the market or not.

If an application for authorisation has not been submitted within 9 months of EFSA's publication, the FCM may no longer be placed on the market (see also Q39). FCMs which are not already on the market at the time EFSA publishes the guidance concerning the information necessary for risk assessing hazardous bisphenols or derivatives may not be introduced on the market thereafter. In both cases however, an application for authorisation could be submitted later in time.

Q15. What happens if a relevant harmonised classification applies to a bisphenol or a bisphenol derivative in the future, after EFSA publishes its guidance?

For hazardous bisphenols or derivatives that are classified with the relevant harmonised classification only after the date on which EFSA makes the information available, business operators will have 9 months after the classification applies to submit an application for a derogation from the prohibition of the hazardous bisphenol or derivative if they want their FCMs to remain on the market. Otherwise, the use of the hazardous bisphenol or derivative in the manufacture of FCMs and placing on the market of FCMs will not be allowed as of 9 months after the date on which the relevant classification applies. However, as explained above, an application for authorisation could be submitted later in time and, if granted, FCMs in the manufacture of which the hazardous bisphenol or derivative is used would be allowed on the market.

In case a bisphenol or bisphenol derivative currently authorised for use in the manufacture of plastic FCM ⁽¹⁰⁾ is later included in table 3 of Annex VI to Regulation (EC) No 1272/2008 and therefore qualifies as a hazardous bisphenol or a hazardous bisphenol derivative, Article 6(6) of Regulation (EU) No 10/2011 would apply from the date on which this harmonised classification becomes applicable, which means it would thus fall only within the scope of Regulation (EU) 2024/3190 and its entry in annex I to Regulation (EU) No 10/2011 would be deleted.

Q16. From when is a hazardous bisphenol classified as such?

A bisphenol or bisphenol derivative is considered as a 'hazardous bisphenol' or a 'hazardous bisphenol derivative' from the date on which the harmonised classification applies in accordance with the amending Regulation to Regulation (EC) No 1272/2008 which adopts the classification of the substance, taking into account any relevant transitional periods laid down in that amendment.

⁽⁸⁾ https://food.ec.europa.eu/document/download/e426f49e-3566-4cd8-93af-5118c7a1560c_en.

⁽⁹⁾ <https://doi.org/10.2903/sp.efsa.2020.EN-1844>.

⁽¹⁰⁾ See Annex I to Commission Regulation (EU) No 10/2011.

Q17. What are the other bisphenols and bisphenol derivatives currently considered as hazardous and falling within the scope of Article 5?

At the time of the entry into force of Regulation (EU) 2024/3190, the decision on the classification of five bisphenols or bisphenol derivatives, in addition to BPA, as CMR 1A, 1B or ED 1 for human health has already been taken (see table below).

Substance name	CAS number	Relevant classification in table 3, Annex VI to Regulation (EC) No 1272/2008
Bisphenol S (BPS)	80-09-1	Repr. 1B
4,4'-Isobutylethylidenediphenol	6807-17-6	Repr. 1B
Phenolphthalein	77-09-8	Carc. 1B
Bisphenol AF (BPAF)	1478-61-1	Repr. 1B
Tetrabromobisphenol-A (TBBPA)	79-94-7	Carc. 1B

For practical purposes, the European Chemicals Agency (ECHA) has prepared a series of excel tables ⁽¹⁾ containing all updates to the harmonised classification and labelling of hazardous substances, which are listed in Table 3 of Annex VI to the Regulation (EC) No 1272/2008. In addition, a registry of classification and labelling (CLH) 'intentions until outcome', listing the intentions and proposals received by ECHA for a new or revised harmonised classification and labelling of a substance is available on its website ⁽²⁾.

It can also be noted that, at the time of the adoption of this guidance, an ECHA RAC opinion ⁽³⁾ was published on 17 September 2024 concerning a proposed harmonised classification (Repro. 1B) for bisphenol F (4,4'-methylene-diphenol) (CAS no. 620-92-8).

Although Regulation (EU) 2024/3190 defines 'hazardous bisphenols' and 'hazardous bisphenol derivatives' in relation to the harmonised classification under Regulation (EC) No 1272/2008, in determining the safety and suitability of alternatives, business operators may wish to take into account ongoing developments as regards new scientific information and steps taken in the classification process, including proposals under Regulation (EC) No 1272/2008 and self-classification.

Q18. Which bisphenols and bisphenol derivatives must be listed in a Declaration of Compliance (DoC) pursuant to Article 8 and in Annex III, point 5 of Regulation (EU) 2024/3190?

All bisphenols and bisphenol derivatives that are used in the manufacture of an FCM, and not only those that are defined as hazardous, need to be listed in the DoC so as to determine compliance with Article 4 of Regulation (EU) 2024/3190.

Q19. What information concerning the status of alternative substances referred to in Article 7(1) of Regulation (EU) 2024/3190 should business operators submit?

At present, only two limited derogations exist for the use of BPA, as specified in Annex II to Regulation (EU) 2024/3190. The relevant Commission services will remain in contact with business operators who produce the relevant food contact articles and/ or their representative organisations concerning the information that will be expected to address the status of alternatives. Such information will likely include the availability of alternatives, their technical viability as well as their economic feasibility. If alternative substances or systems manufactured with substances not in the scope of the Regulation are found viable, Annex II may be amended taking into account the time needed for replacement of the present systems. In the future, this may also concern other hazardous bisphenols or hazardous bisphenol derivatives for which a specific authorisation is given.

⁽¹⁾ <https://echa.europa.eu/information-on-chemicals/annex-vi-to-clp>.

⁽²⁾ <https://echa.europa.eu/registry-of-clh-intentions-until-outcome>.

⁽³⁾ <https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e187fe3e10>.

The Commission will also take account of other available information concerning the availability and practicality of alternatives, which may include information submitted by parties other than those under the reporting obligation.

3. COMPLIANCE AND TESTING

Q20. How can compliance with Regulation (EU) 2024/3190 be demonstrated?

Article 3 of Regulation (EU) 2024/3190 prohibits the *use* of BPA in the manufacture of FCMs. In the first instance, supporting documentation that accompanies the DoC can demonstrate that BPA has not been used in the manufacture of the FCM, including, for example, a list of monomers or starting substances that have been used. In such situations, further verification of compliance by testing is at the discretion of the business operator.

Concerning the FCM articles in which BPA may be used in accordance with Annex II of the Regulation, it will be necessary to demonstrate that migration of BPA does not occur above the detection limit, which can be achieved, for example, by migration testing or mathematical modelling. Documentation must also confirm that other restrictions have been met, e.g. proof of the cleaning and flushing processes.

In case another bisphenol or derivative has been used in the manufacture of the FCM, compliance with Article 4 can be achieved by analytical testing for residual BPA in the FCM or data on the presence of BPA as an impurity, which is particularly relevant for certain derivatives of BPA, such as BADGE.

When testing is carried out on materials for which BPA or another bisphenol has been used in the manufacture, as for all FCMs, it is up to the business operator or competent person(s) to determine certain parameters of the test, for example selection of the worst case to avoid testing every product. Once a representative sample(s) has been tested, it should not ordinarily be necessary to continue to test each and every time the materials are passed on in the supply chain and, for example, combined into multi-later articles with other materials for which BPA or other bisphenols have not been used in their manufacture. Ultimately, however, it is the choice of business operators as to how to verify compliance.

Q21. Is it obligatory to prove the absence of BPA with laboratory analysis?

Regulation (EU) 2024/3190 does not make it obligatory to undertake analytical testing. However, Article 9 lays down the rules for verification of compliance where such testing is used. This is particularly relevant in cases where BPA may be used in accordance with the restrictions laid down in Annex II but where its migration into food must not be detectable, or where another bisphenol or bisphenol derivative such as BADGE has been used but where the presence of residual BPA is not permitted in accordance with Article 4.

Q22. Is the detection limit of 1 µg/kg (1ppb or 0,001 mg/kg) feasible and practical for compliance and enforcement purposes?

During the discussions preceding the adoption of Regulation (EU) 2024/3190, a limit of detection (LoD) of 0,001 mg/kg (1 µg/kg) was supported and considered feasible by Member States to detect BPA. In order to contribute to a uniform application and enforcement of that Regulation, Article 9 gives a role to the European Union Reference Laboratory (EU-RL) in the development of possible methods, in collaboration with National Reference Laboratories (NRLs).

The development of the parameters for verification of compliance, including a LoD different from 1 µg/kg, and other approaches will depend on the methods that will be eventually selected in accordance with Article 9(1) of the Regulation. The information will be made publicly available in due course.

Q23. Does this detection limit apply for migration or for residual content?

Article 9 of Regulation (EU) 2024/3190 may apply for either testing migration of BPA from the food contact articles laid down in Annex II, for which migration is not to be detected; or for verifying compliance with the requirement stemming from Article 4 of that Regulation, that FCMs manufactured using other bisphenols or bisphenol derivatives are not to contain any residual BPA. The detection limit of 1 µg/kg set in that Regulation applies for verification of compliance in both cases, unless the work of the EU-RL leads to a different conclusion.

Q24. Does the limit of detection apply to BPA as a ‘non-intentionally added substance’ (‘NIAS’) or as a contaminant?

The emphasis of Regulation (EU) 2024/3190 is on the *use* of BPA in the manufacture of certain FCMs, rather than on its presence. This is because the main source of BPA from FCMs is due to its intentional use in the manufacture of FCMs, normally as a monomer in materials such as plastics and coatings. In order to comply with Article 4 of the Regulation, if other bisphenols or bisphenol derivatives such as BADGE are used in the manufacture of FCMs, the absence of BPA as a NIAS should be ensured. This can be achieved by ensuring purity of the starting substance and through good manufacturing practices throughout production to avoid undesirable reaction and degradation products. If such control cannot be achieved and the use of other bisphenols or derivatives would lead to the presence of BPA, alternative starting substances would need to be used.

However, Regulation (EU) 2024/3190 does not simply ban the presence of BPA in FCMs, as this presence can arise from adventitious sources, most notably as contamination from recycling streams where levels of BPA or other hazardous bisphenols cannot be reduced to zero.

Q25. Is there an obligation to issue a Declaration of Compliance (DoC) for all FCMs within the scope of Regulation (EU) 2024/3190, even if no BPA has been used?

Yes, all materials specified in Article 1(2) of Regulation (EU) 2024/3190, and including multi-material articles, must be accompanied by a DoC, even if no BPA has been used in the manufacturing process. This means, for example, that printing inks and other materials covered by the scope of the Regulation, and which are intended as food contact materials and/ or to form part of a final food contact article, require a DoC. The resulting multi-material or multi-layer final food contact articles must also be accompanied by a DoC fulfilling the information requirements set out in Annex III.

Q26. Whose responsibility is it to issue the DoC?

The DoC should be issued by business operators at all stages, including for intermediate food contact materials and for final food contact articles, except at the retail stage; for example, business operators selling kitchenware to consumers do not need to provide the DoC to consumers but must have a DoC available in their compliance documentation, which may be requested by a Member State Competent Authority along with supporting documentation.

Q27. Is more than one DoC needed if the FCM falls within the scope of other specific Union rules?

There is no specific format for the DoC and as such, any information required by the DoC under Regulation (EU) No 10/2011 does not need to be duplicated and can be incorporated into the same single document together with the additional information required by Regulation (EU) 2024/3190.

Q28. Is there an obligation to issue a DoC during the transitional periods, i.e. from the date Regulation (EU) 2024/3190 enters into force?

Yes, because compliance with the restrictions, including the SML (0,05 mg/kg) for plastic materials and varnishes and coatings, still need to be ensured. The transfer of information indicating the use of BPA or other bisphenols or derivatives will also help businesses in the production and supply chain to manage the production and placing on the market of final articles, if necessary, before the end of the transitional periods.

As some FCMs, in particular starting and intermediate materials will have been placed on the market before the entry into force of Regulation (EU) 2024/3190, part of the information required by Annex III for the DoC, such as a list of any bisphenols or bisphenol derivatives that have been used, may not be available in practice, to business operators receiving these FCMs and subsequently placing them on the market e.g. as final food contact articles. It is therefore pertinent to take such scenarios into account during compliance work and for enforcement purposes, during the transitional phase.

4. PLACING ON THE MARKET

Q29. Can FCMs manufactured with BPA be exported to third countries?

The purpose of the Union FCM legislation is to ensure the safety of FCMs, which in their 'finished state' are placed on the Union market and come into contact with food intended for the Union market (see, however, also Article 12 of Regulation (EC) No 178/2002⁵ which renders Union food law applicable to exports in certain circumstances). In principle, articles to be brought into contact with food intended for the market of a third country are not considered as falling within the scope of the FCM Regulation. However, it is the responsibility of business operators, under the control of Member States, to ensure that FCMs, either as intermediate materials or final articles, placed on the Union market but intended for export to a third country are accompanied by appropriate documentation to ensure traceability, including a clear demonstration of the destination and which allow Member States to check that they are not diverted and placed on the Union market.

Q30. What about imported FCMs from third countries?

All FCMs, including those not yet in contact with food as well as articles already in contact with food e.g. food packaging, are subject to the same rules concerning the placing on the Union market. If such articles have been manufactured using BPA outside of the Union, they will no longer be allowed on the Union market after the end of the relevant transitional period, unless one of the derogations laid down in Annex II of the Regulation applies. Similarly, FCMs manufactured using bisphenol or bisphenol derivatives will need to comply with Article 4 of Regulation (EU), and the absence of residual BPA in these FCMs will need to be demonstrated, if placed on the Union market, with the same methods as for FCMs manufactured in the Union (see also the section below on 'transitional provisions').

Business operators importing FCMs from third countries must also comply with Article 5 of the Regulation concerning the prohibition of the use of hazardous bisphenols other than BPA or hazardous bisphenol derivatives and, if necessary, make an application for authorisation of the use of a hazardous bisphenol other than BPA or hazardous bisphenol derivative in accordance with Article 6 and comply with the reporting requirements laid down in Article 7.

Q31. What about BPA which may be present in food which does not originate from FCMs placed on the Union market, like food production equipment used in a third country? Or BPA that may already be in the food, for example as a result of environmental contaminant?

It is possible that BPA may be detected in the food itself, either because of the use of FCMs as food production equipment in a third country from which BPA has migrated, because of migration from recycled FCMs or as a result of environmental contamination of the food. However, Union rules on FCMs allow the possibility to take into account that BPA has originated from a source other than FCMs placed on the Union market, including the production and processing of foods from third countries as well as environmental contamination. In this case, the business operator should be able to explain or demonstrate how the presence of BPA has occurred.

Information that may become available in the future as regards the unintended presence of BPA in foodstuffs, including those from third countries, will help the Commission and the Member States to consider what future steps – if any – might be needed to further protect consumers.

5. TRANSITIONAL PROVISIONS

Q32. From the perspective of a business operator, which is the relevant transitional period for placing a food contact article on the Union market?

Food contact materials and articles at any stage of manufacture and including final food contact articles, can be first placed on the market up to 18 months after the entry into force of Regulation (EU) 2024/3190 (until 20 July 2026) in line with Article 11(1) for single-use articles and 12(1) for repeat-use articles.

Furthermore, some specific food contact materials and articles can be first placed on the market up to 36 months after the entry into force (until 20 January 2028). This includes single-use FCM (packaging) for fruits and vegetables ⁽¹⁴⁾, as well as fishery products ⁽¹⁵⁾, and packaging on which a BPA-based coating has been used on the exterior surface in accordance with Article 11(2). Repeat-use final food contact materials and articles that are used as professional food production equipment, excluding those in Annex II to Regulation (EU) 2024/3190, such as plastic food moulds, machinery parts as well as coated containers with a capacity below 1 000 litres, may also be first placed on the market in their final finished state until 20 January 2028, in accordance with Article 12(2).

In all cases, first placing on the market of the final food contact article can only occur once the manufacturing steps are complete, or the final food contact article has been imported, and the final articles are being held for sale or transfer.

Q33. Do the transitional provisions apply also for “intermediate materials” such as varnishes and coatings or plastic resins?

FCMs can be placed on the market at different stages of manufacture or at various points along the supply chain and at different times. For example, pre-polymers for the production of food contact coatings can be placed on the market and made available to a food contact coatings manufacturer. This is a stage before the coating formula is completed and applied to a metal substrate, to form the final food contact article, which is subsequently placed on the market.

However, for legal clarity, and in particular to help compliance and enforcement, the dates at the end of the transitional periods apply specifically to placing on the market of the final food contact articles. This includes most food packaging, such as coated cans, as well as repeat-use food contact materials and articles, in particular those used by consumers such as kitchenware and tableware. The definition of ‘placing on the market’ provided in Article 2(1)(b) of Regulation (EC) No 1935/2004 applies.

Logically, and in order to continue to manufacture final food contact articles, intermediate materials such as pre-polymers and coatings can continue to be made available to the next business in the production chain. In theory, intermediate materials can also be placed on the market until the end of the relevant transitional period(s), although in practice sufficient time will be needed before the end of the transitional periods in order to allow converters and final article producers time to complete and place the final articles on the market before the end of the transitional periods.

Unlike for final food contact articles, there are no provisions concerning continuation of placing on the market or the exhaustion of stocks for intermediate food contact materials. After the end of the relevant transitional periods, the intermediate materials can no longer be used for producing final food contact articles to be placed on the Union market.

Q34. Can the final food contact article then remain on the Union market, or do they need to be removed from sale?

In line with Article 11(3) of Regulation (EU) 2024/3190, **single-use final food contact articles** – principally packaging – which have been first placed on the market (e.g. by their manufacturer) within the 18 or 36-month transitional period, whichever is applicable, and which still need to be filled with food, may then remain on the market for up to one year, in order to allow time for them to be filled with food. Thereafter, provided the articles have been filled, the packaged food can be sold through to retail outlets and thereafter to consumers, until exhaustion of stocks (or expiry of minimum durability or use by dates). Single-use final food contact articles already filled with food and first placed on the market within the 18 or 36-month transitional period, including those imported, may also remain on the market until exhaustion of stocks. Single-use final food contact articles that have not yet been first placed on the market by the end of the 18th or 36th month, whichever is applicable, can no longer be first placed on the market.

⁽¹⁴⁾ Fruits and vegetables excluding products defined in Annex I of Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption. OJ L 10, 12.1.2002, p. 58. ELI: <http://data.europa.eu/eli/dir/2001/112/oj>.

⁽¹⁵⁾ Fishery products as defined by Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin. OJ L 139, 30.4.2004, p. 55. ELI: <http://data.europa.eu/eli/reg/2004/853/oj>.

Article 12(3) of the Regulation allows **repeat-use final food contact articles**, which have been first placed on the market (e.g. by their manufacturer or importer) within the 18- or 36-month period, whichever is applicable, to remain on the market for one year for the purpose of transfer and sale, including to consumers (e.g. kitchenware) or to a businesses that will use the equipment in order to produce, process or distribute food. Thereafter, repeat-use final food contact articles may no longer be placed on the market in accordance with the definition of 'placing on the market' in Article 2(1)(b) of Regulation (EC) No 1935/2004. This includes the transfer or intended transfer to consumers (such as the sale of kitchenware) or to another business operator (such as the sale of professional food production equipment).

Repeat-use final food contact articles may remain under the ownership of a business operator at the end of the one-year period i.e. after 20 July 2027 or 20 July 2029, whichever is applicable. That business operator may not resell the articles or otherwise distribute or transfer them in any way, in accordance with the definition in Article 2(1)(b) of Regulation (EC) No 1935/2004 and with respect to the European Commission's Blue Guide⁽¹⁶⁾, which includes leasing or hire of a product from one business to another. However, the business operator who had legal ownership of the food contact article at the end of the one-year period may continue to use it until it ceases to be functional or until such time that the food business operator choses to replace it, provided that they remain within their legal ownership. This applies for example to professional food production equipment being used by food businesses like confectionary moulds as well as repeat-use articles such as cookware, containers and other articles for distribution of food, used by caterers, restaurants and other businesses in the course of their normal activities.

Q35. What is considered as 'professional food production equipment'?

Professional food production equipment is understood to include food contact articles used by a food business in a food production or processing setting, to produce foodstuffs for placing on the market. This includes for example confectionary moulds, seals, pumps, flanges, gauges and sight glasses as mentioned in Recital 21 of the Regulation, although this is not an exhaustive list. Whether a food contact article qualifies as 'professional food production' for the purposes of Article 12(2) of Regulation (EU) 2024/3190 should be determined on a case-by-case basis, taking account of the justification for the longer transitional period provided in Recitals 21 of that Regulation. That justification includes the use of an article as a component that functions as part of a larger installation, and for which an extended period of time is needed to replace it with a component that has been manufactured without using BPA, in particular to avoid the need to replace the entire food production system.

Q36. What about single-use food contact articles for which a 36-month period is allowed but are also filled with other foodstuffs, e.g. cans containing both fish and pasta?

Single-use final food contact articles intended for the preservation of one of the foodstuffs listed in Article 11(2)(a) of Regulation (EU) 2024/3190 may benefit from the 36-month transitional period in accordance with the Regulation, regardless of whether such foodstuffs are mixed with other ingredients. However, business operators, including food business operators, should take note of the basis on which an extended transitional period has been granted for those specific foodstuffs and the principal ingredients of the foodstuffs for which they intend to use the single-use final food contact articles.

Q37. What about the transitional periods for imported FCMs?

The same rules apply to imported FCMs as they do for those produced within the EU, insofar as they are placed on the Union market.

Thus, single-use final food contact materials (typically packaging) must be placed on the market before the end of the 18- or 36-month periods, depending on the type of food which they are to be filled with, regardless of whether they are imported or not. Thereafter, Article 11(3) of Regulation (EU) 2024/3190 allows a period of one year for empty single-use final food contact articles to be filled with foodstuffs. Single-use final food contact articles that are not placed on the Union market before the end of the relevant transitional periods and are not yet filled with food can no longer be placed on the market after that time.

⁽¹⁶⁾ Commission notice The 'Blue Guide' on the implementation of EU product rules 2022. OJ C 247, 29.6.2022, p. 1. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=oj:JOC_2022_247_R_0001.

Repeat-use final food contact materials, including kitchenware, tableware and professional food production equipment must be first placed on the market, i.e. by an importer, before the end of the 18- or 36-month periods respectively in accordance with the Regulation. After the end of the respective period, a further period of one year is provided for all businesses, including Union importers or businesses to sell the imported repeat-use final food contact materials to consumers and food business operators.

Q38. Are there any transitional measures provided for Article 4 on the presence of residual BPA?

There are no specific transitional measures provided for Article 4. However, the intention of that Article is to ensure that, once BPA is banned in the manufacture of FCM, it should also not be present either as a residue resulting from the use of BPA derivatives, such as BADGE, or other bisphenols or their derivatives. Since Regulation (EU) 2024/3190 provides for transitional measures as regards the use of BPA, it is to be understood that the same transitional periods apply as regards BPA's residual presence as a consequence of the use of other bisphenols or of bisphenol derivatives. Therefore, verification of compliance with Article 4 would only need to start after the end of the relevant transitional periods.

Q39. Will there be any transitional periods applicable for other hazardous bisphenols and derivatives?

Other hazardous bisphenols and derivatives may continue to be used, subject to the provisions of Articles 5 and 6 of the Regulation (see above section on other bisphenols and bisphenol derivatives). In case an application is made and an authorisation given for a specific food contact application, Annex II to Regulation (EU) 2024/3190 will be amended. In case the authorisation is not granted, a transitional period for the use of the hazardous bisphenol or derivative could be laid down when the decision not to grant the authorisation is taken.

Q40. Would it be possible to include a timeline as a visual presentation on the different transitional periods/application dates?

See below. The diagram is for illustrative purposes only and does not necessarily cover every scenario for each and every business operator.

Overview of transitional periods for FCMs within the scope of Commission Regulation (EU) 2024/3190. The table is for illustrative purposes only and does not cover every scenario. It should be read in conjunction with the answers given to the preceding questions and with the Regulation

	FCMs that comply with the rules applicable on the date from which the Regulation applies (20 January 2025)	+ 18 months By 20 July 2026	+ further 12 months By 20 July 2027	+ 36 months By 20 January 2028	+ further 12 months By 20 January 2029	No specified date
A	Single-use final food contact articles (e.g. metal packaging such as a can) except B	Can no longer be first placed on EU market. Unfilled packaging may remain on the market for 1 year for filling with food	Any unfilled packaging must have been filled with foodstuffs and sealed			Filled food packaging may remain on the EU market until exhaustion of stocks
B	Single-use final food contact articles for preservation of fruits, vegetables and fishery products or where a varnish or coating manufactured using BPA has only been applied to the exterior metal surface			Can no longer be first placed on EU market. Unfilled packaging can remain on the market for 1 year for filling with food	Any unfilled packaging must have been filled with foodstuffs and sealed	Filled food packaging may remain on the EU market until exhaustion of stocks
C	Repeat-use final food contact articles (e.g. kitchenware such as drinks bottles) except D	Can no longer be first placed on EU market (i.e. by the manufacturer of the final article or importer)	Can no longer be placed on EU market (e.g. kitchenware for sale to consumers)			Business operators may continue to use articles until replacement
D	Repeat-use final food contact articles used as professional food production equipment			Can no longer be first placed on EU market (i.e. by the manufacturer of the final article or importer)	Can no longer be placed on the EU market (e.g. cannot be passed from one business to another)	Business operators may continue to use articles until replacement